Data Analysis and Assessment Criteria Handbook

RCPAQAP

The Royal College of Pathologists of Australasia
Quality Assurance Programs

Version 7.0 - February 2021

Contents

Welcome

The RCPAQAP Pty Ltd is a Proficiency Testing Provider for pathology laboratories, made up of discipline programs that have been developed independently over many years. We provide laboratories with External Quality Assurance programs which facilitate the assessment of performance by peer group comparison and provide educational activities to monitor and assist in their service to the community.

The RCPAQAP is undergoing major changes to the software platform used to host the programs that collect survey data and issue reports. The software system that has been used in the past will be referred to as the "**Legacy"** software and the new software platform will be referred to as the "**eQuality**" software, for the remainder of this booklet.

This booklet provides our customers with direction to the data analysis systems used to assess performance in all RCPAQAP disciplines. There is some commonality between disciplines on how performance is assessed, and this continues to be harmonised even further as we develop the eQuality software. The data analysis systems used by disciplines providing surveys for qualitative analysis may vary in some aspects, and this may be dependant on the clinical scenario or the nature of the sample being sent. Customers should be directed to the required section to fully understand the assessment criteria for their pathology discipline.

All Serology, Molecular Infectious Disease and Microbiology programs are hosted on the eQuality platform and these disciplines have now adopted the harmonised approach to analyse survey data and assess performance. The new improved reporting system illustrates peer group comparison based on all survey results or from the main variable in a test method (measurement system, kit method etc).

Customers enrolled in Chemical Pathology, Immunology, Haematology, Transfusion or Molecular Genetics will have their programs hosted on both the Legacy software and on the eQuality platform. The report examples in this booklet will represent reports produced from the Legacy software. As reports are released from eQuality, a guide to interpret the reports will be available on the ***myQAP help page*****.** Customers will be notified as programs transition to the eQuality platform.

As we move forward we will endeavour to provide you with the highest quality service to further enhance your quality management system.

Yours sincerely,

John Sioufi

Manager User Experience

Accessing myQAP

For information and instructions on how to access the myQAP login page, please click here.

RCPAQAP Result Entry

For information and instructions on how to access the myQAP Result Entry, please click here. For instructions on customising these result entry pages, please click here.

Viewing RCPAQAP Reports

For information and instructions on how to view RCPAQAP Reports in myQAP, please click here. For instructions on using the in-built RCPAQAP myQAP Report Quality Review System, please click here.

RCPAQAP Report Types

The use of report types has been standardised across the RCPAQAP, with the aim of simplifying the nomenclature for our Participants.

The table below outlines the types of reports offered by RCPAQAP.

Report Type	Description
Survey Report	This is an individual participant report issued at the end of a survey.
Generic Report	This is a general discussion report issued to all participants at the end of a survey. It includes general survey data, not individual participant data.
End of Cycle Report	This is an individual participant report issued at the end of a cycle (where a cycle is comprised of a number of surveys). These are offered by the Chemical Pathology, Haematology, Immunology and Transfusion disciplines.
Preliminary Report	This is an individual participant report issued after the close of a survey. A subsequent Final Report is issued, replacing the Preliminary Report, at the end of the survey. These are offered by the Anatomical Pathology, Cytopathology, Molecular Genetics, Molecular Infectious Diseases and Biosecurity disciplines.
Final Report	This is an individual participant report issued at the end of a survey, replacing the corresponding Preliminary Report previously issued for the participant.
Yearly Report	This is a summary performance report issued at the end of a year. These are offered by the Cytopathology and Microbiology disciplines.
Supervisor Report	The supervisor report is designed for a nominated person of a group of laboratories, to have all the group results in the one report. These are offered by the Chemical Pathology, Immunology and Haematology disciplines. The Chemical Pathology and Immunology disciplines also offer Supervisor reports that are composed of participants who wish to form a collaborative group with a common interest. This may be regional, organisational, special interest, instrument or reagent groups. Inclusion in any group is subject to an approval process from the participating laboratories.
KPI Report	The Key Performance Indicator (KPI) Report is a report that summarises the performance of all programs for one participant over a six month period. Two reports are generated per calendar year and are issued in February and August. This is offered by the Chemical Pathology discipline.

Analytical Performance Specifications – Quantitative Analysis

In laboratory medicine the quality of tests performed must allow our clinicians to practice good medicine. This raises the questions of exactly what level of quality is required to ensure clinical decision making and how can an external quality assurance program objectively assess the quality of results obtained by laboratories.

The RCPAQAP has been using analytical performance goals to assess the quality of results. These goals, called Analytical Performance Specifications (APS) are quality standards to allow participating laboratories to assess their performance and respond accordingly. They have been total error goals based on clinical need and were initially established and maintained by advisory expert groups based on expert opinion and peer based capability.

There now exists an internationally agreed hierarchy of preferred methods for establishing performance goals. These were developed at a conference organised by World Health Organisation (WHO), International Federation of Clinical Chemistry (IFCC) and International Union of Pure and Applied Chemistry (IUPAC) in Stockholm in 1999. The consensus statement *Strategies to Set Global Analytical Quality Specifications in Laboratory Medicine* provided a series of approaches arranged in a hierarchy with the aim to apply models higher in the hierarchy in preference to those at lower levels. In summary these models are:

1. Goals based on clinical outcome
2. Goals based on clinical decision making
    a. Clinician survey
    b. Biological inter and intra individual variability
3. Goals based on Expert Opinion
4. Goals based on peer capability (e.g. from external quality assurance)
5. Goals otherwise based on state of the art

The RCPAQAP Chemical Pathology and RCPAQAP Immunology began the process of reviewing the APS's based on the Stockholm Hierarchy for all quantitative measurands. Whilst goals based on clinical outcome are rare and clinician surveys uncommon, intra-individual and inter-individual biological variability estimates are available for all common measurands.

The Australasian Association of Clinical Biochemists (AACB) established a Working Party on Analytical Performance Specifications which has assisted the RCPAQAP in understanding the use of APSs within the RCPAQAP and developed some principles to allow the review of the APSs based on the Stockholm Hierarchy. They have presented QC Updates during the AACB Scientific Conference, as well as at the RCPA Pathology Update and AACB Scientific Education Seminars. At these meetings, the feasibility of applying biological variability as the basis for all APSs has been presented.

Analytical Performance Specifications Based on Biological Variability

Biological variability is the variability in a parameter due to physiological differences within individuals (CV_i) and between individuals (CV_g). Each individual has random fluctuations around a homeostatic set point, but these homeostatic set points will vary between individuals.

Similarly, analytical goals may relate to monitoring a single patient or making a diagnosis based on the likelihood of belonging to a healthy or diseased group of patients. It is logical that the more difficult task is to perceive a change within an individual compared to being able to tell the difference between individuals. The analytical goal for monitoring a patient is that noise added by analytical uncertainty (CV_a) should be less than half the daily biological variability of the patient ($CV_a < ½\ CV_i$). The performance goals for diagnosis are wider and typically expressed as

Total Error (TE) = $0.25\ (CV_i^2 + CV_g^2)^{½} + 1.65 \times ½\ CV_i$.

Callum Fraser also described a fine tuning of imprecision and total error goals from minimal, desirable and optimal. External Quality Assurance (EQA) experts have also considered that when stating total error goals for EQA programs, we should be 99% sure when we say that a laboratory has exceeded the performance goals (rather than 95% sure) so 2.33 is used as the multiple for imprecision rather than 1.65.

	Monitoring (APS = 2 x CV_a)	**Diagnosis (APS = TE)**
Optimal	CV_a = ¼ CV_i	TE = **0.125** $(CV_i^2 + CV_g^2)^{½}$ + 2.33 x ¼ CV_i
Desirable	CV_a = ½ CV_i	TE = **0.250** $(CV_i^2 + CV_g^2)^{½}$ + 2.33 x ½ CV_i
Minimal	CV_a = ¾ CV_i	TE = **0.375** $(CV_i^2 + CV_g^2)^{½}$ + 2.33 x ¾ CV_i

Therefore, the new APS are all defined using biological variability principles but only adopted when the majority of participants can achieve the goals. As a general rule, a goal is adopted if over 80% of laboratories can achieve the performance as we also seek to encourage further refinement of methods particularly to achieve the tighter monitoring goals.

Analytical Performance Specification Review Process

The aim is for the APS of all measurands to be reviewed based on the principles outlined above. Revised APSs have been introduced for most of the Chemical Pathology, Haematology and Immunology programs. The review is ongoing, and conducted by the specialist parties, the RCPAQAP and other experts when required.

References

- Badrick T, *Biological Variations: Understanding why it is so important*. Practical Laboratory Medicine 2021;23, e00199, ISSN 2352-5517.

  https://doi.org/10.1016/j.plabm.2020.e00199

  (https://www.sciencedirect.com/science/article/pii/S2352551720301621)

Click on the links below to access Analytical Performance Specifications for RCPAQAP disciplines

Chemical Pathology Analytical Performance Specifications

Haematology Analytical Performance Specifications

Immunology Analytical Performance Specifications

Transfusion Analytical Performance Specifications

Analysing results with less than (<) or greater than (>)values

RCPAQAP encourages the submission of survey results as you would for patients. This includes < and > results. Previously, these results were excluded from the statistical analysis for some programs and not assessed or displayed on histograms, youden or linearity plots. Likewise, where programs had two samples per survey, the result of the accompanying sample would not plot on the Youden. Our customers have asked if there were any options to still display these results on their reports.

As we transition quantitative programs to eQuality, results above or below the nominated measuring range will be included in the statistical analysis and display on the reports. RCPAQAP software will strip the < / >, and the resulting numerical values used to obtain the target median. The results will still show as submitted (e.g. <4.0 mmol/l) on the report, and will not be assessed against the related APS.

We will continue to assess if this change adds value to your reports and welcome your feedback.

RCPAQAP Method Classifications – Quantitative modules

The method classification system is designed to comprehensively describe your analytical system for each measurand. The methods are broken down into categories that will describe the variables of the test method, such as the analytical principle, instrument, reagent manufacturer and calibrator. This breakdown facilitates a high level of peer review, where your data is able to be shown in relation to your immediate peers using the same analytical systems.

An example of the categories used are:

Category 1 - Analytical Principle

Category 2 - Measurement System

Category 3 - Reagent Source

Category 4 - Calibrator or Additional Information

Note: *In 2020 the RCPAQAP commenced transitioning over to a new software platform (eQuality). The new platform continues to use method categories to analyse survey data, however, is not coded as currently performed in the legacy software. RCPAQAP programs that are delivered via the new platform are all Serology, Molecular Infectious Disease and Microbiology programs as well as some programs administered by the Chemical Pathology, Haematology, Transfusion and Immunology discipline. Method category values, such as the 'Measurement system used" will be listed on the result entry page to select when entering survey results, submitting method codes will no longer be necessary.*

Legacy software: The following instructions to allocate the method used provides guidance to participants

Categories 1 and 4 use one letter (A – Z) which are different for each measurand. Consult *Method Codes by Program and Measurands* or the individual separate *Method Booklets* supplied for larger programs under the '*Documents'* tab in the myQAP participant portal.

Category 2 - Measurement System

Select from the *Measurement System Master List* under the *Docs* tab in the myQAP participant portal. The code will consist of two digits followed by a letter (A-Z). The digits (01-99) refer to a particular manufacturer or instrument type and the letter specifies the instrument model.

e.g.	Beckman AU 600/640	**28G**
	Beckman AU 400	**28H**

For chromatography instruments e.g. HPLC, GC, LC, ICPMS, the measurement Code 22 is used to describe the sample preparation.

Category 3 - Reagent Source

Select from the *Reagent Source Master List* under the *Docs* tab in the myQAP participant portal. Three digits (001-200) are used to specify individual reagent suppliers.

Method Codes by Program and Measurands

The "Chemical Pathology Method Codes by Program and Measurands" can by located in the myQAP portal under the "Documents" tab.

Measurement System and Reagent Source Master Lists

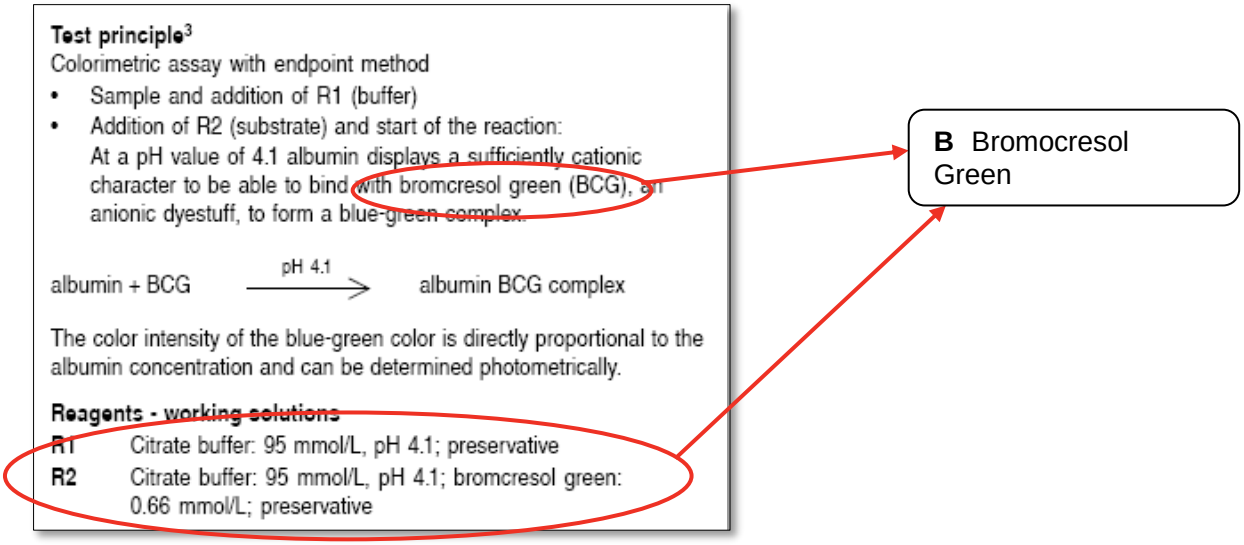
The “Chemical Pathology Measurement System & Reagent Source Master Lists” can be located in the myQAP portal under the “Documents” tab.

Example of Method Classification

Albumin - B 21L 069 A

Category 1 – Analytical Principle

The analytical principle for a specific measurand can be found in the manufacturers package insert. This can then be selected from the options for Analytical Principle



Category 2 – Measurement System

Choose the category from the Measurement System Master list that describes the type of Instrument your laboratory is using for albumin.

21L	**Roche Diagnostics Hitachi Modular**

Category 3

Select from the Reagent Master List the manufacturer of the reagent being used for the measurand, for example, albumin.

069	**Roche Diagnostics**

Category 4

Choose the calibrator type from the options provided for the measurand (in this example a Roche CFAS calibrator is being used).

A	**Analyser Specific Calibrator Supplied by your Manufacturer**

Enter your Method Classification

- Download the program specific Method Classification Sheet from the *Forms* tab in the myQAP portal and fax to the +61 2 9356 2003.

MEASURAND	CATEGORY			
	1	2	3	4
ALBUMIN	B	21L	069	A

Note: If any of your classifications are "@ OTHER", please provide additional information.

Changing Method Classification (Legacy software)

Method Classification forms can be downloaded from the myQAP website under the '*Forms'* tab. Remember to enter the program name, your participant number and the sample numbers from which the changes will apply.

Reporting and Deleting Measurands (Legacy software)

Measurands will be reported if results are entered or a Method Classification has been provided. If you wish to delete a measurand you may delete the method code for that measurand by using a Method Classification sheet, which can be found under the *Forms* tab in the myQAP participant portal.

Haematology / Immunology / Transfusion (Legacy Software)

The Haematology, Immunology and Transfusion disciplines allow participants to enter their method classification system on-line while entering survey results, using the 'Result Entry' tab in myQAP. Instructions can be found on the myQAP portal under the Documents tab.

Your test methods will transfer from one year to the next so you do not need to resubmit methods unless they have changed.

All methods must be coded according to the Method Classification System for the individual discipline. **The Method Classification Systems used are located on the myQAP portal, under the Documents tab and selecting the respective discipline, Haematology or Immunology.**

The RCPAQAP will be monitoring the method classification changes made to the database each survey to ensure the correct methodology has been selected by participants.

If you are having difficulty coding your method or unable to find a method code in the Method Classification system, then please contact the relevant RCPAQAP department via lodging a request online (myQAP) or directly via phone or email.

TRANSFUSION: Please complete the Method Classification sheets available through the Forms tab in the myQAP portal (RCPAQAP Transfusion Method Classification System) and email to our office.

Email:Transfusion@rcpaqap.com.au

Chemical Pathology

Survey Reports

Survey Reports summarise every pair of specimens for each measurand and provide summary data on your performance throughout the cycle. Reports provide a graphical comparison of individual results with all results received and with participants using the same analytical principle, analyser and reagent source.

Quantitative results are usually compared with the target value or “overall median”. Acceptable limits are set either side of the expected value. Non-numerical results (descriptive results) are compared with a target value or overall method group consensus.

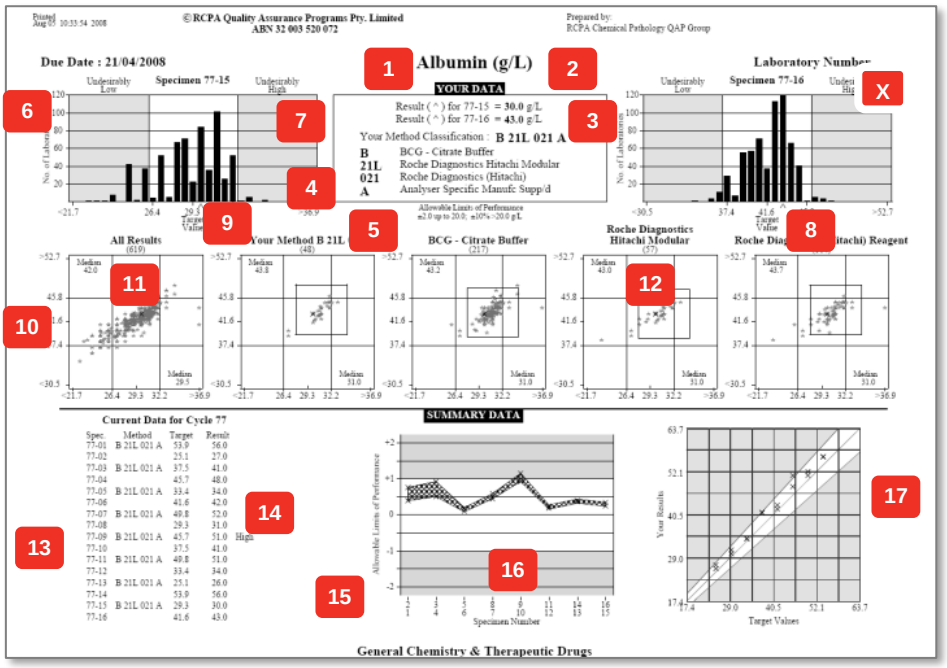
The Analytical Performance Specifications (APS) are unique for each measurand, and the acceptable range for each specimen is calculated from the central value (target, median or weighed-in value). These ranges are displayed in the report histograms and Youden Plots. The comment “Low” or “High” is added if the result is outside the APS.

Report Interpretation (Legacy Software)

The Survey Report examples below will be for programs that are still hosted on the **legacy platform**.

Report examples and the interpretation, produced from the eQuality platform (new reporting system) can be found on the myQAP help page.

The Survey Reports provide a simple, direct comparison of your results with all results received and with participants using the same method, instrument, reagent and combination of method, instrument and reagent (your method classification).



1 Measurand

The full name of the measurand. In some cases an measurand may be processed in 2 or more subgroups using different target values. The name will identify such occurrences, e.g.:

- Lactate Dehydrogenase (Lactate to Pyruvate)

- Lactate Dehydrogenase (Pyruvate to Lactate)

2 **Units**

The units of the report. For some measurands there is a choice of SI or mass units. The report will default to the units submitted by the laboratory.

3 **Results**

If both results were received by the closing date then they will be listed. If results were not received then an appropriate message is returned.

4 **Method Classification**

The method classification the laboratory has submitted. Stored with each pair of results for the complete cycle. If an alteration is submitted it is stored from the date advised to the end of the cycle. In this way it is possible to monitor method changes throughout the cycle.
Please ensure that your method classification is correct. If the method classification information provided by us does not allow for adequate definition of your method then please contact us.
Note: Measurands with no method classification and no results will not be printed. Consequently, if you wish to receive a report for an measurand for which you do not submit results then provide a method classification.

5 **Analytical Performance Specifications (APS)**

Unique for each measurand. The acceptable range for each specimen is calculated from the central value (target, median or weighed-in value). These ranges are used in the histograms and Youden Plots.

6 **Histograms**

Histograms showing distribution of all results compared to the target value and APS.

7 **Undesirably Low, High**

Results more than the APS from the target value.

8 **Result**

Relative position (**^**) of the reported result.

9 **Target Value**

The central value can be a target, median or weighed-in value

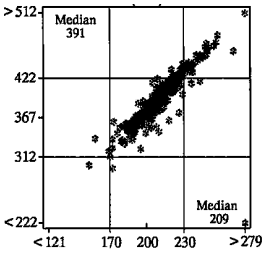
10 **Youden Plots**

Plots of the low concentration specimen (abscissa) against the high concentration specimen (ordinate). The laboratory's pair of results are highlighted (**x**). If both results are acceptable the point will be in the central square.

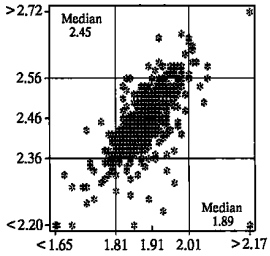
Plots are of all results and subgroups using the same method, analytical principle, instrument and reagent as the laboratory. The number of results in each group is shown in brackets.

Examples of Youden Plots:

Inter-laboratory bias



With-in laboratory Bias



11 **Medians**

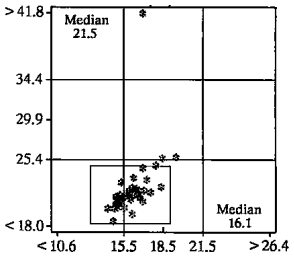
Median values for the pair of specimens for “All Results” and each subgroup.

12 **Peer Review Box**

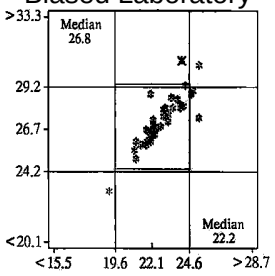
Youden plots of each subgroup include a box that is centred around the median values for the pair of specimens. The box encompasses the APS based on subgroup median values rather than the target values assigned by program organisers. Considering results in relationship to this box provides a comparison with other participants using the same analytical systems.

Examples of Peer Review Boxes:

Biased Results



Biased Laboratory



13 **Current Data**

A complete record of data held by program organisers for the cycle.

- Method – will show any method changes for your laboratory.
- Target, median or weighed-in value depending on measurand.
- Results returned by participant.

14 **Low or High Comments**

The comment “Low” or “High” is added if the result is outside the Analytical Performance Specification.

15 **Late and Amended**

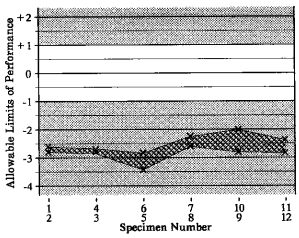
The comments “Late” and “Amended” are added if applicable.

16 **Levey Jennings Style Reports**

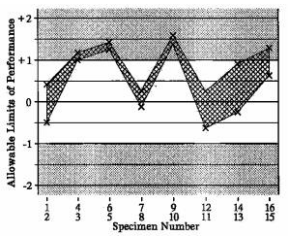
A plot of each pair of results showing deviations from the target value in the APS. The relative position of each pair is shown by the position of the specimen numbers on the abscissa. Acceptable results are within ±1 Analytical Performance Specifications of the central value (and this is highlighted by the shading on the graph). The scale of APS is adjusted to accommodate your results up to a maximum range of ± 9 limits.

Examples of Levey Jennings Plots

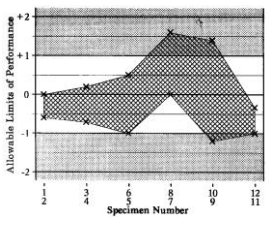
Biased Results



Poor Precision – Between Run



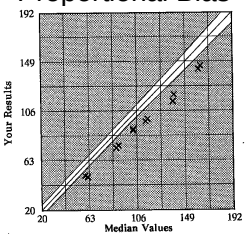
Poor Precision – Within Run



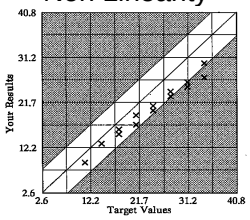
17 **Linearity Graph**

Specimens are linearly related. This graph shows non-linearity, imprecision & inaccuracy. Results in the shaded area are outside the APS.

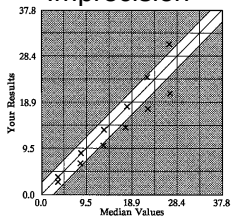
Proportional Bias



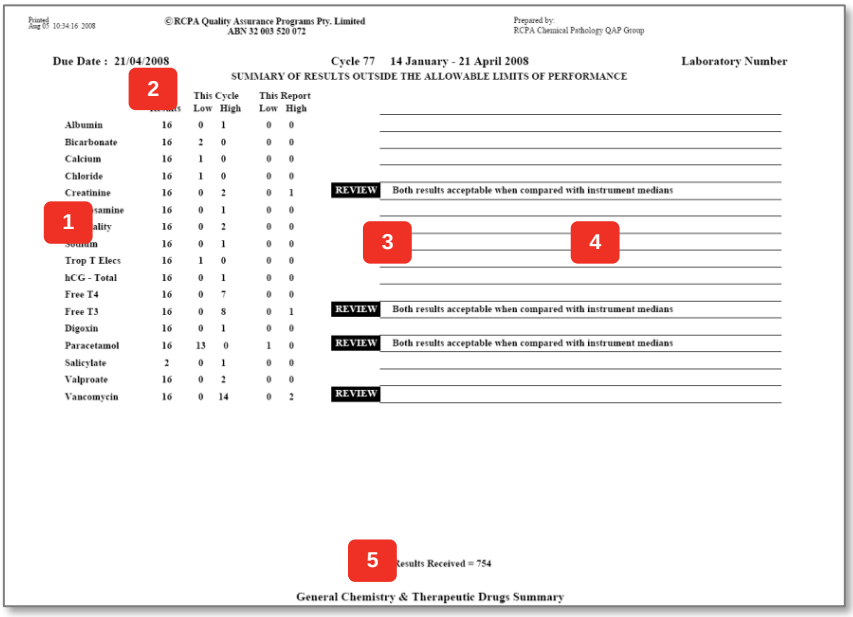
Non Linearity



Imprecision



Summary Of Results Outside The Analytical Performance Specifications
The last page of each report summarises all measurands outside the APS.



1 **Measurand**
Measurands with results outside the APS.

2 **Number of Results**
Total results returned and the number of low and high results to date and in this report.

3 **Review**
REVIEW is added to measurands with low or high results in this report. The comment “Both results acceptable when compared to instrument medians” is added if the pair of results are encompassed within the peer review box for the laboratory’s analyser when five or more results are reported.

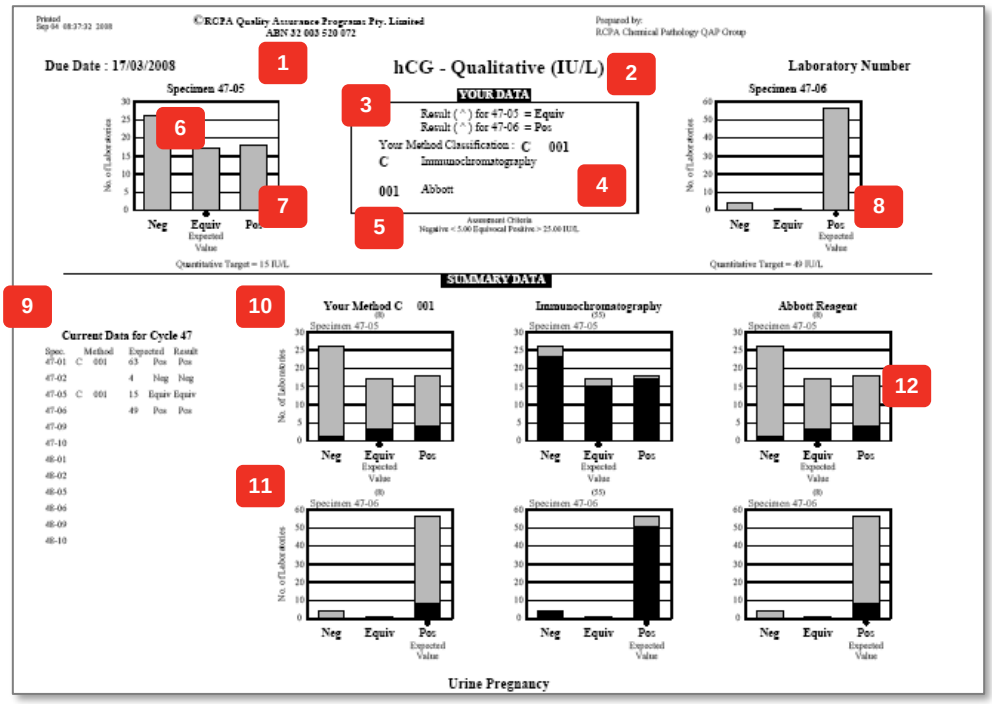
4 **Comments Area**
Space for comments to be written by laboratory personnel.

5 **Summary Statistics**
The total number of results to date.

The Quantitative Survey Report Interpretation Flowchart can be found by clicking on this link.

Notes on the Qualitative Survey Report

The Qualitative Survey Reports provide a simple, direct comparison of your qualitative results with all results received and with participants using the same method, reagent and combination of method and reagent (your method classification).



1 **Measurand**

The full name of the measurand.

2 **Units**

The units of the report. For some measurands there is a choice of SI or mass units. The report will default to the units submitted by the laboratory.

3 **Results**

If both results were received by the closing date then they will be listed. If results were not received then an appropriate message is returned.

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4 **Method Classification**

The method classification the laboratory has submitted. Stored with each pair of results for the complete cycle. If an alteration is submitted it is stored from the date advised to the end of the cycle. In this way it is possible to monitor method changes throughout the cycle.

Ensure that your method classification is correct. If the method classification information provided by us does not allow for adequate definition of your method then contact the RCPAQAP.

Note: Measurands with no method classification and no results will not be printed. Consequently, if you wish to receive a report for an measurand for which you do not submit results then provide a method classification.

5 **Assessment Criteria**

This is unique for each measurand and reflects the qualitative assessments commonly used in laboratories at various quantitative levels for the measurand. These ranges are used in the histograms.

6 **All Results Histograms**

Histograms showing distribution of all results, grouped on the basis of the qualitative assessments and compared to the Expected Value.

7 **Result**

Relative position (♦) of the result reported by your laboratory.

8 **Expected Value**

The Expected Value is based on a qualitative interpretation of the overall program median achieved from the quantitative analysis of the measurand on the program.

9 **Current Data**

A complete record of data held by program organisers for the cycle.

- Method – will show any method changes for your laboratory.
- The expected value.
- Results returned by participant.

10 **Histograms for Method Breakdowns – sample 1**

These Histograms show the distribution of results for your method, your analytical principle and your reagent group across the assessment criteria groupings for the first sample analysed in this assessment.

11 **Histograms for Method Breakdowns – sample 2**

These Histograms show the distribution of results for your method, your analytical principle and your reagent group across the assessment criteria groupings for the second sample analysed in this assessment.

12 **Shading**

The distribution for the sub-group denoted in the histogram heading is shown in black shading and the remainder of the participant results are shown in the gray shading.

End of Cycle Reports

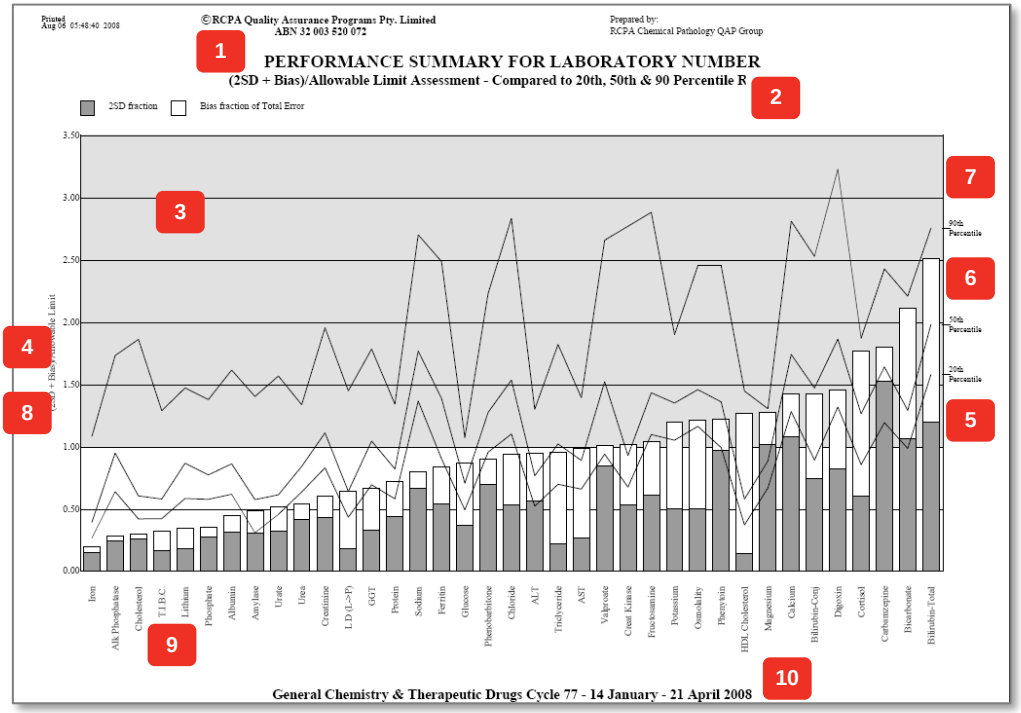
Cumulative result data for the current cycle are summarised for each laboratory. There are 3 parts to the report:

- A one page Performance Summary report summarising and ranking the performance of all measurands within the program;
- An End of cycle Error Analysis Report providing a critical assessment of those measurands with results outside the Analytical Performance Specifications set by program organisers.
- A report summarising your performance for each measurand, comparing your performance to all participants and those participants using the same analytical principle, analyser and reagent source.

Note: *The survey reports produced from the eQuality platform now incorporate components of the legacy "end of cycle" reports to measure accuracy and precision. The survey reports display how accurate and precise survey results are over consecutive survey runs in every report. Report examples and the interpretation, produced from the eQuality platform can be found on the myQAP help page.*

Performance Summary Report

The Performance Summary Report is a single-page summary showing analytical performance of all measurands submitted by your laboratory. Measurands are ranked from best to worse on the basis of a new parameter defined as "Measurand Performance". The 20th, 50th and 90th percentile performance of all participants is also provided for peer review.



1 Title

Name of the report and your laboratory number.

2 Assessment Criteria

The assessment criteria is defined as measurand performance. As analytical error is due to both imprecision and bias, program organisers have defined Total Error as follows:

$$Total\ Error = 2SD + Bias$$

The quality of your laboratory's performance is then determined by comparing the Total Error to the Analytical Performance Specification at the mid-point of the range of measurand concentrations for the cycle as follows:

$$Measurand\ Performance = \frac{2SD + Bias}{Analytical\ Performance\ Specification}$$

These examples of bicarbonate analyses may assist in understanding this method of assessment.

- QA specimens are as follows:
  Low Level 15.0 mmol/L
  High Level 35.0 mmol/L
  The mid-point concentration is therefore 25.0 mmol/L

- The Analytical Performance Specification for bicarbonate is:
  ± 2.0 mmol/L up to 20.0 mmol/L
  ± 10% when greater than 20.0 mmol/L.
  The Analytical Performance Specification at the mid-point (25.0 mmol/L) is therefore 2.5 mmol/L.

Example - Laboratory 1
SD = 0.8 mmol/L Bias = 0.5 mmol/L
Total Error = (2 × 0.8) + 0.5 = 2.1 mmol/L

$$\textit{Measurand Performance} = \frac{2.1}{2.5} = 0.84$$

Note: When the Total Error is less than the Analytical Performance Specification then the Measurand Performance will be less than 1.0. This is the desired level of performance.

Example – Laboratory 2
SD = 1.5 mmol/L Bias = 0.1 mmol/L
Total Error = (2 × 1.5) + 0.1 = 3.1 mmol/L

$$\textit{Measurand Performance} = \frac{3.1}{2.5} = 1.24$$

An undesirable result – due predominantly to imprecision.
Example – Laboratory 3
SD = 0.5 mmol/L Bias = 2.0 mmol/L.
Total Error = (2 × 0.5) + 2.0 = 3.0 mmol/L

$$\textit{Measurand Performance} = \frac{3.0}{2.5} = 1.20$$

An undesirable result – due predominantly to bias.

3 **Graphical Presentation**
Each individual Measurand Performance is plotted as a column where the relative contribution of imprecision (2SD) appears as a shaded grey area and that of bias appears as a clear area.

4 **Level of Performance**
A scale using the Measurand Performance is on the left y axis (numerical scale). The right y axis shows the 20th, 50th and 90th percentile values. This is performed by determining the Measurand Performance for all participants and then the 20th, 50th and 90th percentile values are plotted for comparative purposes and peer review. The percentile performances are displayed by use of a line graph for each measurand as follows:

- 5 20th percentile
- 6 50th percentile
- 7 90th percentile

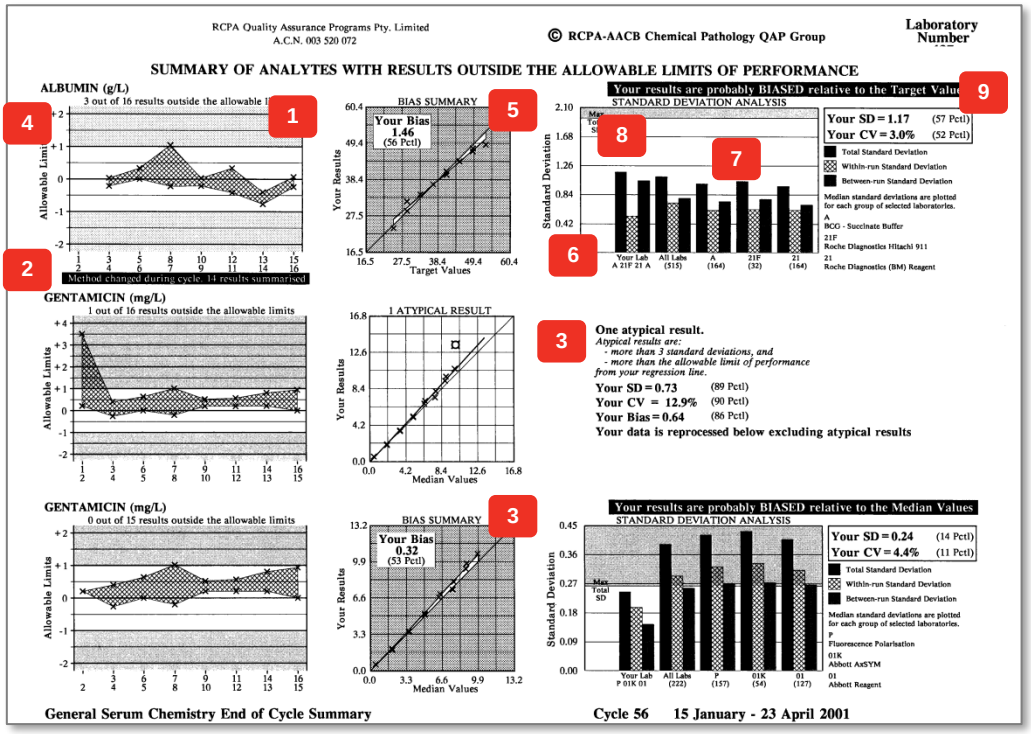
8 **Desirable Level of Performance**
The desirable Measurand Performance is less than 1.00. The shading when Measurand Performance is above 1.00 highlights the measurands that may require attention.

9 **Measurands**
The measurands are plotted in ascending order of your Analytical Performance. Best measurand on the left, worst measurand on the right.

10 **Program Name**
Name of the program and cycle number being summarised (including the start and end dates of the cycle).

End of cycle Error Analysis Report

This report provides a brief summary of measurands having one or more results greater than the Analytical Performance Specifications (APS) from their expected values. The graphical summaries and statistics should assist in identifying problem areas.



1 Number of Outliers and Results

The number of outliers and results returned.

2 Method Change

If your method code is changed during the cycle, only results with the most recent classification are considered. The comment *"*Method changed during cycle. # Results summarised*"* is printed.

3 Atypical Results

All results are tested to determine whether atypical results have been reported. These are results not consistent with your usual analytical performance and consequently affect end of cycle summary statistics. It is inappropriate to comment on such end of cycle statistics.

A result is defined as atypical when it is:

- More than 3 standard deviations and
- More than the APS from your regression line.

The atypical data is summarised using:

- A Levey-Jennings style plot
- An atypical result graph highlighting each atypical result
- A list of your affected Standard Deviation, Coefficient of Variation and Bias.

Atypical results are excluded, the End of cycle statistics recalculated and the measurand reported again in the usual manner.

4 Levey-Jennings Plot

The Levey-Jennings style plot summarises reported results.

5 Bias Summary

Your biases at the low value, high value and mid value are determined. These are the differences between the line of expectation and your line of best fit. The average bias is then calculated as indicated by the formula:

$$Bias = \frac{[low\ bias] + [mid\ bias] + [high\ bias]}{3}$$

The bias summary plots your results against the expected values showing:

- Each result
- Your line of best fit
- Your bias
- The percentile ranking (Pctl) of your bias relative to the biases of all participants

6 Standard Deviation Analysis Plot

The linear regression Standard Deviation (SD), which is calculated using each of the results returned, is the standard error of the estimate (Sy.x). This value can be regarded as the average SD over the range of values analysed and is the total SD.

7 Standard deviation column graphs

The first set of 3 columns shows:

- Your total SD (black)
- Your within-run SD (hatched)
- Your between-run SD (grey)

The median standard deviations and the number of participants in each group are plotted for:

- All participants
- Participants using the same analytical principle as your laboratory
- Participants using the same analyser as your laboratory
- Participants using the same reagent as your laboratory

8 Maximum Total Standard Deviation

The SD's are compared to the Maximum Total SD. This SD is derived from the APS for the measurand being reviewed.

9 Comments on Performance

Computer generated comments are made on most measurands reviewed. The basis for these comments is as follows:

- Total SD greater than the Maximum Allowable SD.
- Bias with a percentile ranking greater than 50.

Failure to meet these criteria will result in these comments:

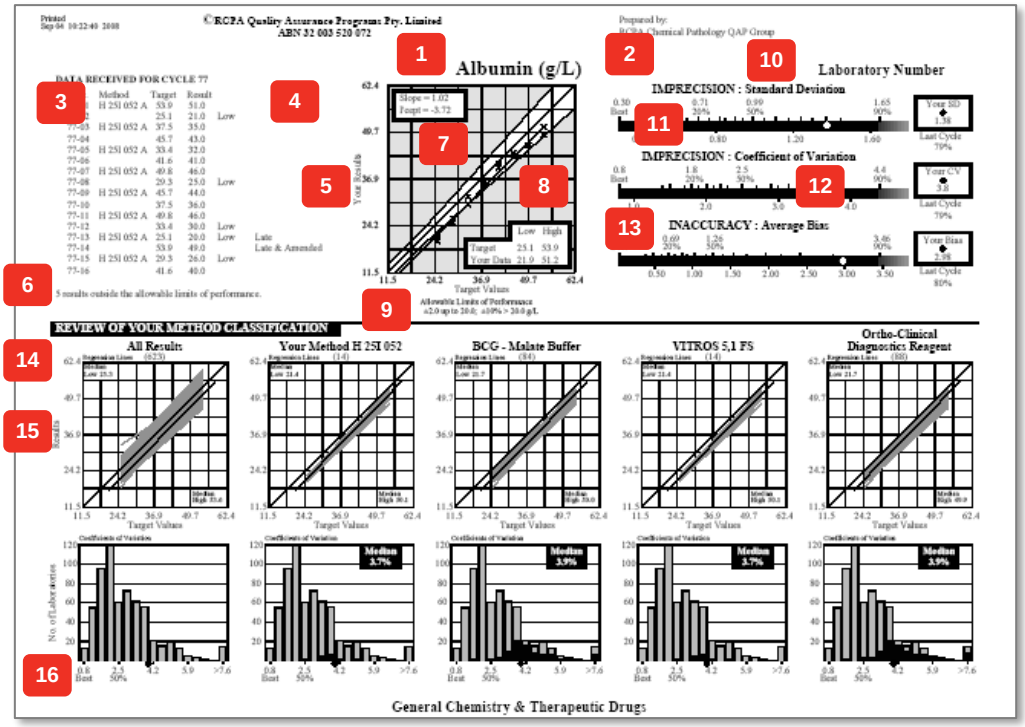
- "Probably IMPRECISE" and
- "Probably BIASED" compared to the relevant central values.

Being computer generated these comments are only a suggestion and you are advised to review your data.

End of cycle Report

Each measurand is summarised on a single A4 sheet of paper. The report is divided into two sections printed on opposite sides of the sheet. Data from your laboratory and comparing your laboratory performance to other laboratories is printed on one side of the paper. Summary data for the measurand being considered is printed on the reverse side.

A Certificate of Participation is printed at the end of the measurand reports.



Note: The key to obtaining maximum information from this report format is to ensure that you have accurately provided your method classification. The information you provide is used to select subgroups of data including participants using the same analytical systems.

1 **Measurand**

The full name of the measurand. In some cases an measurand may be processed in two or more subgroups using different target values. The name will identify such occurrences, e.g.:

- Lactate Dehydrogenase (Lactate to Pyruvate)
- Lactate Dehydrogenase (Pyruvate to Lactate)

2 **Units**

The units of the report. Fixed to the same units used by the laboratory for the last pair of specimens.

3 **Data Received for the Cycle**

A complete record of data submitted for the cycle and held by program organisers. Any method code changes will be shown. Only data with exactly the same method code as the last pair of specimens is included in the end of cycle calculations. Method code changes will not be accepted for the last pair of specimens in any cycle.

4 **Low or High Comments**

The comment “Low” or “High” is added if the result is outside the Analytical Performance Specification.

5 **Late and Amended**

The comments “Late” and “Amended” are added only if applicable.

6 **Additional Comments**

A commentary on the number of results outside the APS. Additional comments will be added

- If all results are not used in the calculations:
- When the method code has been altered
- When a result is reported < or > than a particular value
- If any results are reported in alternative units

7 **Linearity Graph**

Simple least squares linear regression analysis compared to the target value is used for End of cycle calculations. Westgard and Hunt (Clinical Chemistry 1973; 19:49-57) have presented data showing the effect various errors have on the linear regression calculation. The slope and intercept are recorded and your laboratory’s line of best fit values at the lowest and highest values analysed are shown. Individual data points and the line of best fit for your laboratory are shown in comparison to the line of agreement. Results outside the APS fall in the shaded area.

8 **Low and High Values**

Using the slope and intercept the values of your line of best fit are determined compared to the lowest and highest target values for the cycle.

9 **Analytical Performance Specification**

Unique for each measurand.

10 **Bar Graphs**

The Standard Deviation, Coefficient of Variation (CV) and Average Bias are summarised in bar graphs. Two scales appear on each bar graph. The lower scale is linear in the units of the statistic. The upper scale shows the percentile scale, highlights the best, 20th, 50th and 90th percentiles and indicates the value of the statistic at these percentiles. Your laboratory’s statistic, (◊), is plotted within the bar and is recorded in the box with the percentile ranking for the last cycle recorded beneath the box.

11 **Standard Deviation**

The SD is the standard error of the estimate (Sy.x) and can be regarded as the average SD across the range of concentrations analysed. SD provides a value in the units of the test. SD will tend to be high if you report high results and low if you report low results.

12 **Coefficient of Variation**

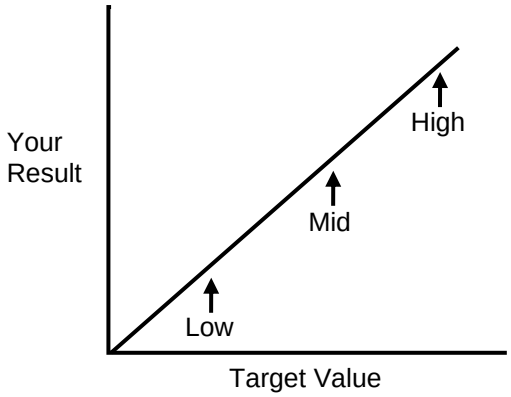
The SD divided by the mid-point of your laboratory’s range of concentrations, expressed as a percentage:

$$CV\% = \frac{SD}{(\text{low value} + \text{high value})/2} x100$$

CV “corrects” for differences in concentration and so may be a better assessment of imprecision.

13 **Average Bias**

Your biases at the low value, high value and mid value are determined. These are the differences between the line of expectation (45° line) and your line of best fit.



The average bias is calculated as:

$$Bias = \frac{[low\ bias] + [mid\ bias] + [high\ bias]}{3}$$

14 **Review of Method Classification**

The accuracy and precision of the laboratory are compared to all other participants and subgroups using the same method, instrument and reagent as the laboratory.

15 **Regression Lines Review**

Plots of the lines of best fit of selected laboratories highlighting your laboratory's line of best fit and showing the line of agreement. The number of participants in each group is shown in brackets. The low and high median for each subgroup is shown in the top left and bottom right corner. The graphs provide a summary of the accuracy of your laboratory and the laboratories selected in each subgroup.

16 **Coefficients of Variation**

A histogram showing the distribution of CV's for all participants and highlighting the participant's CV (♦). Histograms showing subgroups of data are superimposed in black on the columns and the median value for is subgroup is provided. The graphs provide a summary of the precision of the laboratory and the laboratories selected in each subgroup.

Summary Data

The End of cycle calculations provide a valuable database for reviewing methods, instruments, reagents and calibrators. In addition these summaries are useful in showing the number of participants using particular systems. This data is printed on the back of the laboratory report for each measurand.

Method Category Identity

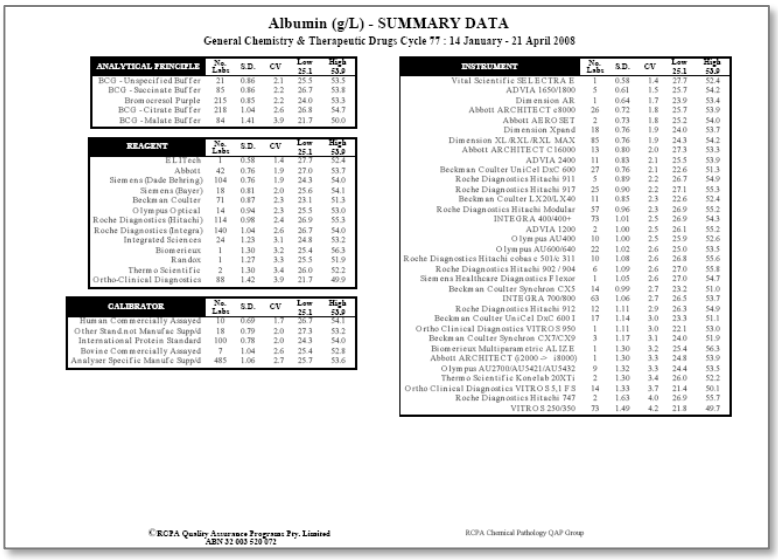
Data is summarised in up to 4 categories depending on the measurand.

- Analytical principle
- Measurement System
- Reagent source
- Calibrator

The information provided is:

- The number of participants in each group
- The median standard deviation of the group
- The median CV of the group
- The median Low and High values compared to the appropriate target value

Groups are printed in ascending %CV.



Albumin (g/L) - SUMMARY DATA

General Chemistry & Therapeutic Drugs Cycle 77 : 14 January - 21 April 2008

ANALYTICAL PRINCIPLE	No. Labs	S.D.	CV	Low 25.1	High 53.9
BCG - Unspecified Buffer	21	0.86	2.1	25.5	53.5
BCG - Succinate Buffer	85	0.86	2.2	26.7	53.8
Bromocresol Purple	215	0.85	2.2	24.0	53.3
BCG - Citrate Buffer	218	1.04	2.6	26.8	54.7
BCG - Malate Buffer	84	1.41	3.9	21.7	50.0

REAGENT	No. Labs	S.D.	CV	Low 25.1	High 53.9
ELITech	1	0.58	1.4	27.7	52.4
Abbott	42	0.76	1.9	27.0	53.7
Siemens (Dade Behring)	104	0.76	1.9	24.3	54.0
Siemens (Bayer)	18	0.81	2.0	25.6	54.1
Beckman Coulter	71	0.87	2.3	23.1	51.3
Olympus Optical	14	0.94	2.3	25.5	53.0
Roche Diagnostics (Hitachi)	114	0.98	2.4	26.9	55.3
Roche Diagnostics (Integra)	140	1.04	2.6	26.7	54.0
Integrated Sciences	24	1.23	3.1	24.8	53.2
Biomerieux	1	1.30	3.2	25.4	56.3
Randox	1	1.27	3.3	25.5	51.9
Thermo Scientific	2	1.30	3.4	26.0	52.2
Ortho-Clinical Diagnostics	88	1.42	3.9	21.7	49.9

CALIBRATOR	No. Labs	S.D.	CV	Low 25.1	High 53.9
Human Commercially Assayed	10	0.69	1.7	26.7	54.1
Other Stand.not Manufac Suppld	18	0.79	2.0	27.3	53.2
International Protein Standard	100	0.78	2.0	24.3	54.0
Bovine Commercially Assayed	7	1.04	2.6	25.4	52.8
Analyser Specific Manufc Suppld	485	1.06	2.7	25.7	53.6

INSTRUMENT	No. Labs	S.D.	CV	Low 25.1	High 53.9
Vital Scientific SELECTRA E	1	0.58	1.4	27.7	52.4
ADVIA 1650/1800	5	0.61	1.5	25.7	54.2
Dimension AR	1	0.64	1.7	23.9	53.4
Abbott ARCHITECT c8000	26	0.72	1.8	25.7	53.9
Abbott AERO SET	2	0.73	1.8	25.2	54.0
Dimension Xpand	18	0.76	1.9	24.0	53.7
Dimension XL/RXL/RXL MAX	85	0.76	1.9	24.3	54.2
Abbott ARCHITECT C16000	13	0.80	2.0	27.3	53.3
ADVIA 2400	11	0.83	2.1	25.5	53.9
Beckman Coulter UniCel DxC 600	27	0.76	2.1	22.6	51.3
Roche Diagnostics Hitachi 911	5	0.89	2.2	26.7	54.9
Roche Diagnostics Hitachi 917	25	0.90	2.2	27.1	55.3
Beckman Coulter LX20/LX40	11	0.85	2.3	22.6	52.4
Roche Diagnostics Hitachi Modular	57	0.96	2.3	26.9	55.2
INTEGRA 400/400+	73	1.01	2.5	26.9	54.3
ADVIA 1200	2	1.00	2.5	26.1	55.2
Olympus AU400	10	1.00	2.5	25.9	52.6
Olympus AU600/640	22	1.02	2.6	25.0	53.5
Roche Diagnostics Hitachi cobas c 501/c 311	10	1.08	2.6	26.8	55.6
Roche Diagnostics Hitachi 902 / 904	6	1.09	2.6	27.0	55.8
Siemens Healthcare Diagnostics Flexor	1	1.05	2.6	27.0	54.7
Beckman Coulter Synchron CX5	14	0.99	2.7	23.2	51.0
INTEGRA 700/800	63	1.06	2.7	26.5	53.7
Roche Diagnostics Hitachi 912	12	1.11	2.9	26.3	54.9
Beckman Coulter UniCel DxC 600 I	17	1.14	3.0	23.3	51.1
Ortho Clinical Diagnostics VITROS 950	1	1.11	3.0	22.1	53.0
Beckman Coulter Synchron CX7/CX9	3	1.17	3.1	24.0	51.9
Biomerieux Multiparametric ALIZE	1	1.30	3.2	25.4	56.3
Abbott ARCHITECT (2000 -> i8000)	1	1.30	3.3	24.8	53.9
Olympus AU2700/AU5421/AU5432	9	1.32	3.3	24.4	53.5
Thermo Scientific Konelab 20XTi	2	1.30	3.4	26.0	52.2
Ortho Clinical Diagnostics VITROS 5,1 FS	14	1.33	3.7	21.4	50.1
Roche Diagnostics Hitachi 747	2	1.63	4.0	26.9	55.7
VITROS 250/350	73	1.49	4.2	21.8	49.7

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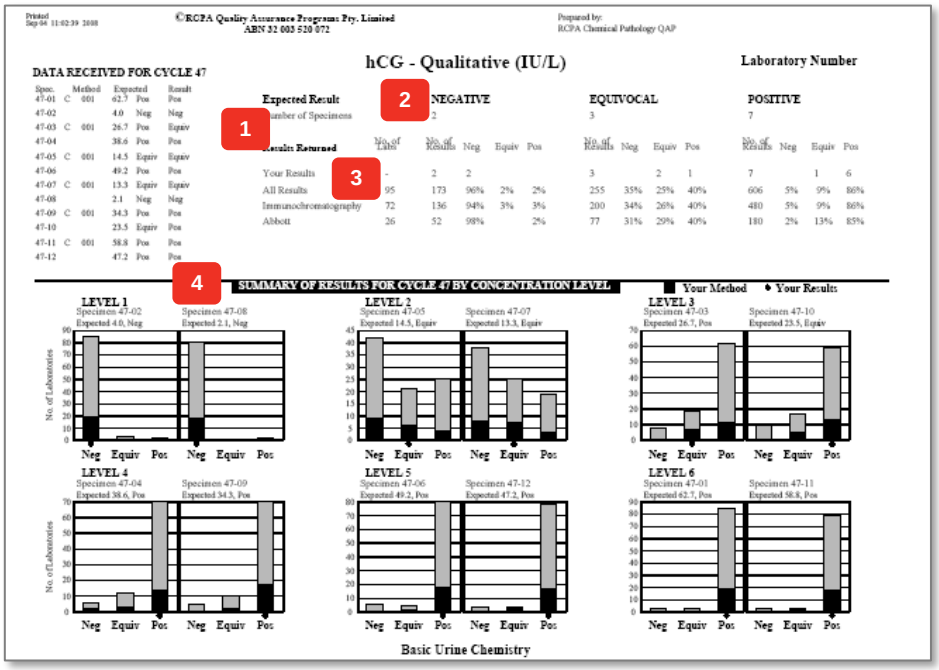
RCPA Chemical Pathology QAP Group

Notes on the Qualitative End of cycle Report



Printed Sep 04 11:02:39 2008

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Prepared by: RCPA Chemical Pathology QAP

hCG - Qualitative (IU/L)

Laboratory Number

DATA RECEIVED FOR CYCLE 47

Spec.		Method	Expected	Result
47-01	C	001	62.7 Pos	Pos
47-02			4.0 Neg	Neg
47-03	C	001	26.7 Pos	Equiv
47-04			38.6 Pos	Pos
47-05	C	001	14.5 Equiv	Equiv
47-06			49.2 Pos	Pos
47-07	C	001	13.3 Equiv	Equiv
47-08			2.1 Neg	Neg
47-09	C	001	34.3 Pos	Pos
47-10			23.5 Equiv	Pos
47-11	C	001	58.8 Pos	Pos
47-12			47.2 Pos	Pos

1

Expected Result — Number of Specimens

2

	NEGATIVE	EQUIVOCAL	POSITIVE
	2	3	7

Results Returned

3

	No. of Labs	No. of Results	Neg	Equiv	Pos	No. of Results	Neg	Equiv	Pos	No. of Results	Neg	Equiv	Pos
Your Results	-	2	2			3		2	1	7		1	6
All Results	95	173	96%	2%	2%	255	35%	25%	40%	606	5%	9%	86%
Immunochromatography	72	136	94%	3%	3%	200	34%	26%	40%	480	5%	9%	86%
Abbott	26	52	98%		2%	77	31%	29%	40%	180	2%	13%	85%

4 SUMMARY OF RESULTS FOR CYCLE 47 BY CONCENTRATION LEVEL — Your Method — Your Results

LEVEL 1 — Specimen 47-02 Expected 4.0, Neg — Specimen 47-08 Expected 2.1, Neg

LEVEL 2 — Specimen 47-05 Expected 14.5, Equiv — Specimen 47-07 Expected 13.3, Equiv

LEVEL 3 — Specimen 47-03 Expected 26.7, Pos — Specimen 47-10 Expected 23.5, Equiv

LEVEL 4 — Specimen 47-04 Expected 38.6, Pos — Specimen 47-09 Expected 34.3, Pos

LEVEL 5 — Specimen 47-06 Expected 49.2, Pos — Specimen 47-12 Expected 47.2, Pos

LEVEL 6 — Specimen 47-01 Expected 62.7, Pos — Specimen 47-11 Expected 58.8, Pos

No. of Laboratories

Neg Equiv Pos Neg Equiv Pos

Basic Urine Chemistry

1 Data Received for the Cycle

This is the same table that is printed in the Survey Reports. The specimen number, your method code, the expected result (showing the quantitative value and the qualitative result) and your result. Comments on “Late” or “Amended” results will be added if required.

2 Summary of Expected Results for the Cycle

The number of expected specimens having negative/equivocal/positive answers returned for the cycle.

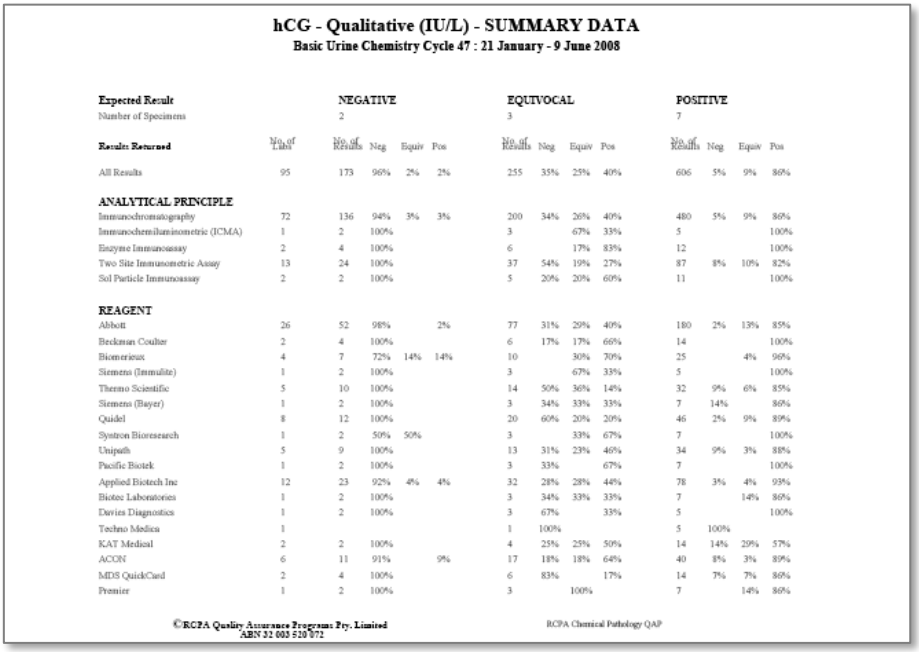
3 Summary of Results Returned

Your laboratory’s results and all laboratory results together with your method breakdown are summarised. The number of participants returning results are listed. For each result category, negative, equivocal or positive, there is a breakdown of the number of results with the percentage of negative/equivocal/positive answers returned.

4 Summary of Results by Concentration Level

Each concentration level of material is run twice during the cycle. Specimens are sorted by concentration level from lowest to highest and the results displayed as histograms. The expected quantitative and qualitative result is at the top of each histogram. Your method is highlighted in black and your result indicated by ◆.

Data is summarised for the results returned for All Results, Analytical Principle and Reagent. There is a breakdown of the number of participants using each method with the total number of results and percentage of results for each category of sample.



hCG - Qualitative (IU/L) - SUMMARY DATA
Basic Urine Chemistry Cycle 47 : 21 January - 9 June 2008

Expected Result		NEGATIVE				EQUIVOCAL				POSITIVE			
Number of Specimens		2				3				7			
Results Returned	No. of Labs	No. of Results	Neg	Equiv	Pos	No. of Results	Neg	Equiv	Pos	No. of Results	Neg	Equiv	Pos
All Results	95	173	96%	2%	2%	255	35%	25%	40%	606	5%	9%	86%
ANALYTICAL PRINCIPLE													
Immunochromatography	72	136	94%	3%	3%	200	34%	26%	40%	480	5%	9%	86%
Immunochemiluminometric (ICMA)	1	2	100%			3		67%	33%	5			100%
Enzyme Immunoassay	2	4	100%			6		17%	83%	12			100%
Two Site Immunometric Assay	13	24	100%			37	54%	19%	27%	87	8%	10%	82%
Sol Particle Immunoassay	2	2	100%			5	20%	20%	60%	11			100%
REAGENT													
Abbott	26	52	98%		2%	77	31%	29%	40%	180	2%	13%	85%
Beckman Coulter	2	4	100%			6	17%	17%	66%	14			100%
Biomerieux	4	7	72%	14%	14%	10		30%	70%	25		4%	96%
Siemens (Immulite)	1	2	100%			3		67%	33%	5			100%
Thermo Scientific	5	10	100%			14	50%	36%	14%	32	9%	6%	85%
Siemens (Bayer)	1	2	100%			3	34%	33%	33%	7	14%		86%
Quidel	8	12	100%			20	60%	20%	20%	46	2%	9%	89%
Syntron Bioresearch	1	2	50%	50%		3		33%	67%	7			100%
Unipath	5	9	100%			13	31%	23%	46%	34	9%	3%	88%
Pacific Biotek	1	2	100%			3	33%		67%	7			100%
Applied Biotech Inc	12	23	92%	4%	4%	32	28%	28%	44%	78	3%	4%	93%
Biotec Laboratories	1	2	100%			3	34%	33%	33%	7		14%	86%
Davies Diagnostics	1	2	100%			3	67%		33%	5			100%
Techno Medica	1					1	100%			5	100%		
KAT Medical	2	2	100%			4	25%	25%	50%	14	14%	29%	57%
ACON	6	11	91%		9%	17	18%	18%	64%	40	8%	3%	89%
MDS QuickCard	2	4	100%			6	83%		17%	14	7%	7%	86%
Premier	1	2	100%			3		100%		7		14%	86%

The Quantitative End of Cycle Report Interpretation Flowchart can be found by clicking on this link.

Patient Report Comments Program

The Patient Report Comments Program is an educational self-assessment tool for individuals who, in the course of their duties, would attach comments to results sent out from their laboratories or provide interpretative advice by telephone (e.g. Duty Biochemists, Chemical Pathologists and Scientists), as well as personnel who are training for such duties.

Cases

One case per month is offered over ten months in a year. Each case report has patient information (age, gender and location of the patient, as well as brief clinical notes), the set of biochemistry results for commenting and additional relevant information or results available to the laboratory.

Comments

Participants are to comment on the results assuming that they have been asked to provide an interpretative comment by the requesting clinician. The comment should follow the pattern of a written report.

1. When commenting, assume you have been approached by a clinician for an interpretative comment on the results.
2. Comment on the “Results for commenting”, not on the “Additional lab results” which are given to aid the interpretation of the “Results for commenting”.
3. Take into account the clinical details rather than listing all possible causes for an abnormal result.
4. State the most likely diagnoses or causes for the set of results given the clinical situation. Do not suggest a big list of follow-up tests.
5. Do not tell the clinician how to do his/ her job (e.g. “Suggest examine patient”), and be cautious in suggesting invasive investigations, e.g. liver biopsy.
6. This is not a case study; the focus is on the ability to offer useful advice to clinicians in a succinct manner.
7. Restating an obvious abnormality (e.g. “hyponatraemia”, “raised potassium”) is generally not a preferred comment; however, quantifying the degree of an abnormality (e.g. “severe hyponatraemia”, “mild increase in potassium”) may be considered to add value.
8. For the comment to add value, it should not restate the clinical question, e.g.: if the clinical notes state “? hypothyroid”, a comment such as “consider hypothyroidism” has really not provided new information to the clinician, while the slightly different comment “results consistent with hypothyroidism” or an even stronger statement “results suggest hypothyroidism” may be considered more useful answers to the clinical question.

Please note that submitted comments which are longer than the allowable space provided for commenting will be truncated at the space limit.

Review of Comments

The participants' comments will be broken down into components and the components summarised into common keywords or phrases. Each key-phrase will be classified as 'Preferred', 'Less Relevant', 'Not Supported’ or ‘Misleading’' by a Review Panel who will generate a summary report with the classification of all key-phrases, a 'suggested' (ideal) comment and case discussion rationale.

Classification of KeyWords

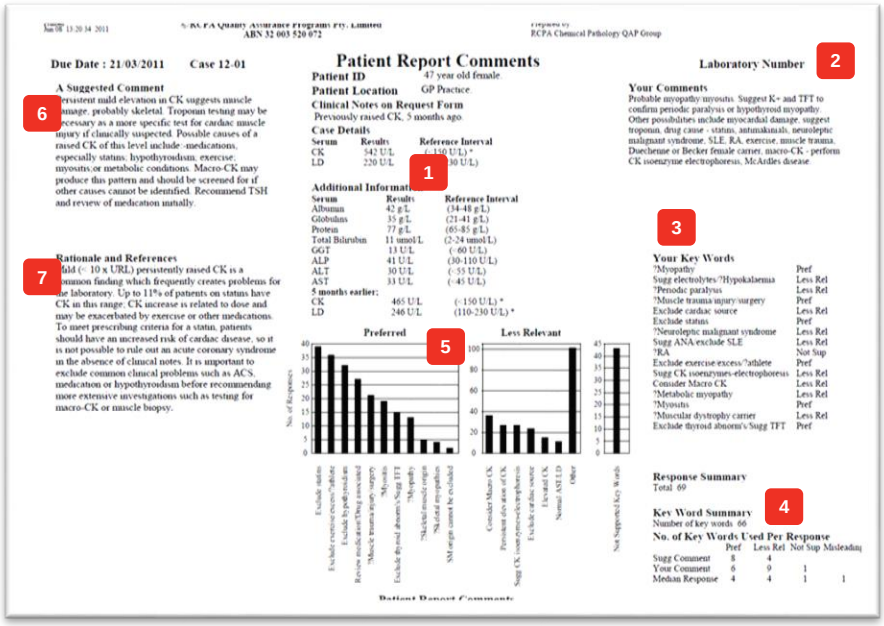
Preferred
Keywords classified 'Preferred' are those considered appropriate, correct and adding value to the results and therefore of utility to the clinician who would receive the report. They may relate to diagnosis or differential diagnosis, possible interferences or suggestions for further testing. They should be addressed in assisting with interpretation of the results for this measurement but may include reference to or input from additional information.

Relevant
Keywords classified 'Relevant' are those considered not to add value to the current results; i.e. not useful to the requesting doctors, although not erroneous or misleading. Comments focussing on the additional information rather than the results for commenting are also likely to fall into this category.

Not Supported
Keywords classified as 'Not Supported' are diagnoses which are possibly correct but not supported by the supplied information, or tests not felt to be indicated given the available information.

Misleading
Keywords classified 'Misleading' are those which may possibly lead to a wrong interpretation, misdiagnosis or mismanagement of the patient

Notes on the Patient Report Comments Report



1 **Case Information**

All information relating to the case is provided. Case number, closing date for return of results, patient identification, patient location, case details, clinical notes on request form and additional information are printed.

2 **Your Comment**

The comment you have submitted for this case.

3 **Your Keywords**

The keywords allocated to your comment and the classification.

4 **Response and Keyword Summary**

The Response Summary is the total number of responses received for this case. The Keyword Summary indicates the number of keywords used to describe the comments for this case. The number of keywords used per response describes the number of ‘Preferred’, ‘Less Relevant’, ‘Not Supported’ and ‘Misleading’ keywords used in the suggested comment, your comment and the median response. This allows you to compare your keywords with ‘best practice’ (suggested comment) and peer review (median response).

5 **Histograms of Responses**

There is a histogram of all responses. Keywords are sorted into 'Preferred Keywords' and 'Less Relevant Keywords'. Not Supported Keywords are placed in a single group.

Preferred Keywords are sorted from most frequent to least frequent. The introduction of ‘Preferred’ keywords in intended to introduce an element of 'best practice’ into the program.

Less Relevant keywords are also ranked. If there are too many key words to fit onto the histograms those are grouped into a group titled 'Other'. These appear in the shaded area of the histogram.

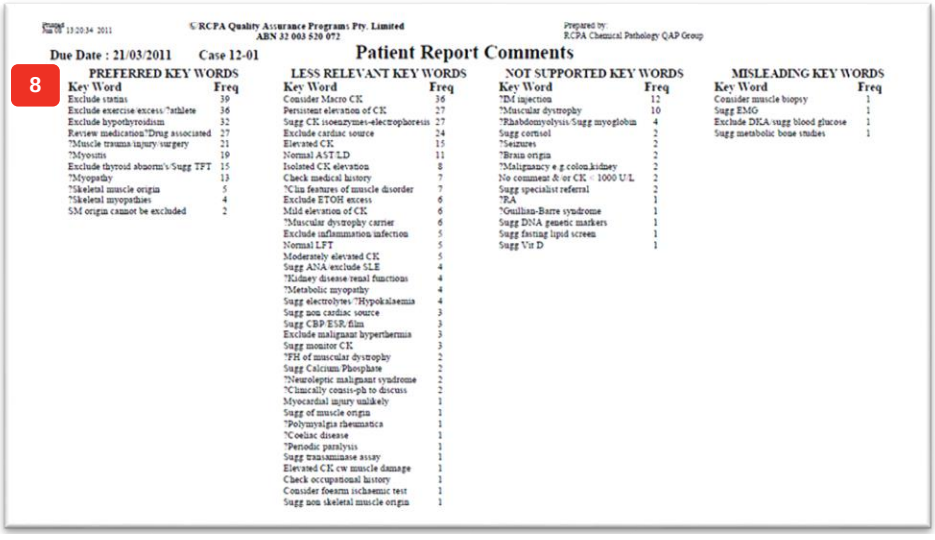
6 **Suggested Comment**

An example comment which is considered by the panel to reflect a reasonable response to the results and information supplied. The suggested comment recognises the need for brevity and therefore will generally address common interpretive possibilities unless specific details are provided. It is recognised that there may be great variability in the formation of acceptable comments.

7 **Rationale and References**

The content of this section reflects current best practice in Australia and New Zealand.

8 **Keyword Summary**



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ABN 32 003 520 072

Prepared by:
RCPA Chemical Pathology QAP Group

Due Date : 21/03/2011 Case 12-01

Patient Report Comments

8

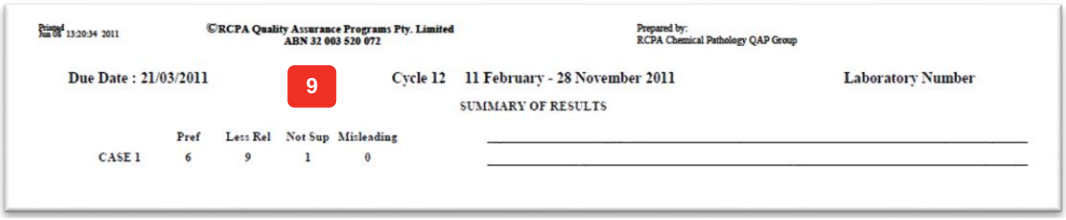
PREFERRED KEY WORDS		LESS RELEVANT KEY WORDS		NOT SUPPORTED KEY WORDS		MISLEADING KEY WORDS	
Key Word	Freq	Key Word	Freq	Key Word	Freq	Key Word	Freq
Exclude statins	39	Consider Macro CK	36	?IM injection	12	Consider muscle biopsy	1
Exclude exercise excess ?athlete	36	Persistent elevation of CK	27	?Muscular dystrophy	10	Sugg EMG	1
Exclude hypothyroidism	32	Sugg CK isoenzymes-electrophoresis	27	?Rhabdomyolysis/Sugg myoglobin	4	Exclude DKA/sugg blood glucose	1
Review medication/?Drug associated	27	Exclude cardiac source	24	Sugg cortisol	2	Sugg metabolic bone studies	1
?Muscle trauma/injury/surgery	21	Elevated CK	15	?Seizures	2		
?Myositis	19	Normal AST/LD	11	?Brain origin	2		
Exclude thyroid abnorm's/Sugg TFT	15	Isolated CK elevation	8	?Malignancy e.g.colon,kidney	2		
?Myopathy	13	Check medical history	7	No comment & or CK < 1000 U/L	2		
?Skeletal muscle origin	5	?Clin features of muscle disorder	7	Sugg specialist referral	2		
?Skeletal myopathies	4	Exclude ETOH excess	6	?RA	1		
SM origin cannot be excluded	2	Mild elevation of CK	6	?Guillian-Barre syndrome	1		
		?Muscular dystrophy carrier	6	Sugg DNA genetic markers	1		
		Exclude inflammation/infection	5	Sugg fasting lipid screen	1		
		Normal LFT	5	Sugg Vit D	1		
		Moderately elevated CK	5				
		Sugg ANA exclude SLE	4				
		?Kidney disease renal function	4				
		?Metabolic myopathy	4				
		Sugg electrolytes ?Hypokalaemia	4				
		Sugg non cardiac source	3				
		Sugg CBP/ESR/film	3				
		Exclude malignant hyperthermia	3				
		Sugg monitor CK	3				
		?FH of muscular dystrophy	2				
		Sugg Calcium/Phosphate	2				
		?Neuroleptic malignant syndrome	2				
		?Clinically consis-ph to discuss	2				
		Myocardial injury unlikely	1				
		Sugg of muscle origin	1				
		?Polymyalgia rheumatica	1				
		?Coeliac disease	1				
		?Periodic paralysis	1				
		Sugg transaminase assay	1				
		Elevated CK cw muscle damage	1				
		Check occupational history	1				
		Consider forearm ischaemic test	1				
		Sugg non skeletal muscle origin	1				

All keywords used are listed on the back of the report. These are grouped into ‘Preferred Keywords’, ‘Less Relevant Keywords’, ‘Not Supported’ and ‘Misleading’.

Review of the Less Relevant Keyword list will provide details of keywords placed in the 'Other' column in the histograms.

Review of the Not Supported Keyword list will provide details of keywords placed in the 'Not Supported Keywords’ column.

9 **Summary of Results**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Prepared by:
RCPA Chemical Pathology QAP Group

Due Date : 21/03/2011 **9** Cycle 12 11 February - 28 November 2011 Laboratory Number

SUMMARY OF RESULTS

	Pref	Less Rel	Not Sup	Misleading
CASE 1	6	9	1	0

A Summary of Results page is included with the report. This summarises the number of Preferred, Less Relevant, Not Supported and Misleading keywords for each case.

At this stage, "acceptable performance" has not been defined. Since there are no criteria for standards in the area of patient comments the program cannot be used as a generic competency assessment. However, individual organisations may choose to use the cases and the responses for this purpose provided they accept responsibility for setting the required standard for any responses.

Supervisor Reports

Supervisor Reports are designed for a nominated person (Coordinator) who has an interest in overseeing a group of participants and/or sites enrolled in the RCPAQAP Chemical Pathology programs. This common interest may be; regional, organisational, special interest, instrument or reagent groups.

A Supervisor Report may be set up by anyone wanting to set up a collaborative group of participants with a common interest. There must be sufficient participants sharing this common interest to make the statistics generated a true representation of the group. A minimum of 5 participants is generally suggested to make the Supervisor Report viable.

Each Supervisor Report has a designated Coordinator who is the recipient of the reports and has the responsibility to disseminate information to members of the group and to maintain confidentially of all results.

Supervisor Reports are provided to the nominated Coordinator of the group after each Survey run and at the end of each cycle following the End of cycle reports. There is an annual enrolment fee for a Supervisor Report.

New Supervisor Reports

The proposer of a new Supervisor Report should write to the RCPAQAP Chemical Pathology organisers by logging a request through the myQAP participant portal to request the set-up of the group and to nominate a Coordinator.

The RCPAQAP Chemical Pathology office will liaise with the proposed Coordinator of the group who will be sent *Supervisor Report Coordinator Agreement* and *Supervisor Report Participant Authorisation* forms to complete and send back to the RCPAQAP Chemical Pathology office.

Existing Supervisor Reports

Existing Supervisor Reports can be ordered through the myQAP website when enrolling or by contacting the RCPAQAP Enrolment Office directly.

Confidentiality

Information on each participant obtained from the RCPAQAP is held in strict confidence by program organisers. The Coordinator of each Supervisor Report undertakes to keep the name of the individual participants confidential and only to release summaries of performance of methods, instruments and coded results.

Available Supervisor Reports

There are a number of Supervisor Reports that are open to all participants to join. Participants who wish to be part of an existing Supervisor Report can fill in the Supervisor Report Participation Form.

The Supervisor Report Participation Form gives the RCPAQAP Chemical Pathology permission to release your results to the nominated Co-ordinator of the chosen Supervisor Report for the program(s) you nominate.

Supervisor Report Participation Form

Please follow the link to view the list of available Supervisor Reports and to access the Supervisor Report Participation Form The Supervisor Report Participation Form can also be found under the *Documents* tab in the myQAP participant portal.

Supervisor Report Interpretation Notes

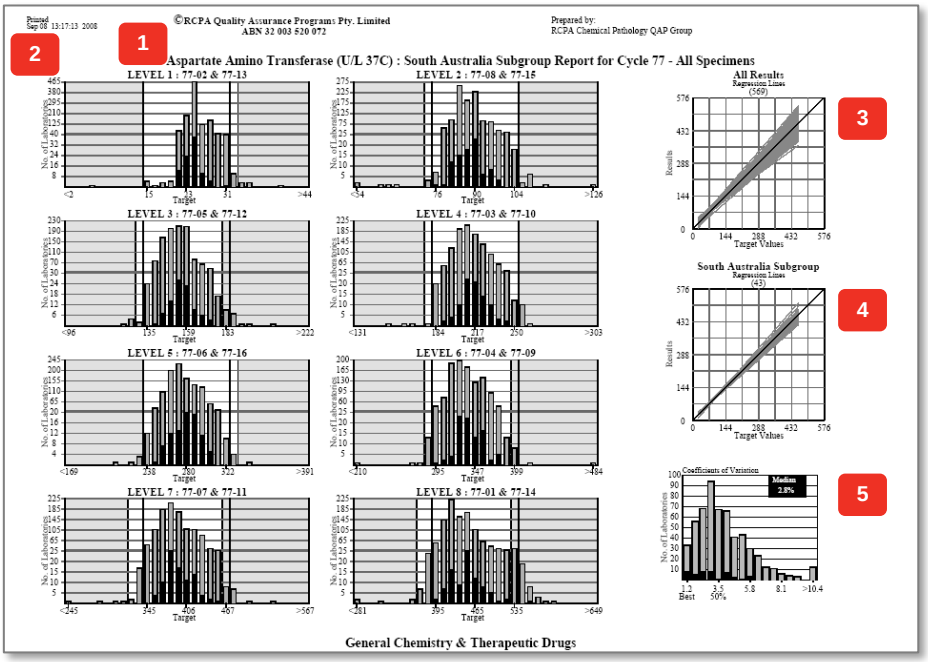
Supervisor Reports are provided to the Supervisor Report Co-ordinator following each survey run and at the end of a cycle. Participant data is included only if they have provided written approval to the RCPAQAP Chemical Pathology.

Supervisor Group List

A list of participant number, contact name, department, participant name, address, phone & fax numbers (this information should be kept confidential).

Individual Concentrations – Graphical Summary (legacy software).

Example of the Supervisor report produced from the eQuality software can be found by clicking on the myQAP help page.



1 **Title**

The measurand, group, cycle and specimens being reported.

2 **Histograms**

A separate histogram is prepared for each concentration level. If more than one specimen exists for the concentration level then specimens are merged. The specimen numbers corresponding to the concentration level are at the top of the graph. Plots of all results submitted compared to the target, median or weighed-in value. The analytical performance specification (APS) range is within the bold central vertical lines. The area not shaded is the acceptable range based on the group median and analytical performance specification. Group results are displayed in black.

3 **Regression Graph – All Results**

If End of cycle data has been calculated the regression lines of all participants are plotted. The number of participants submitting results is in brackets.

4 **Regression Graph – Group Data**

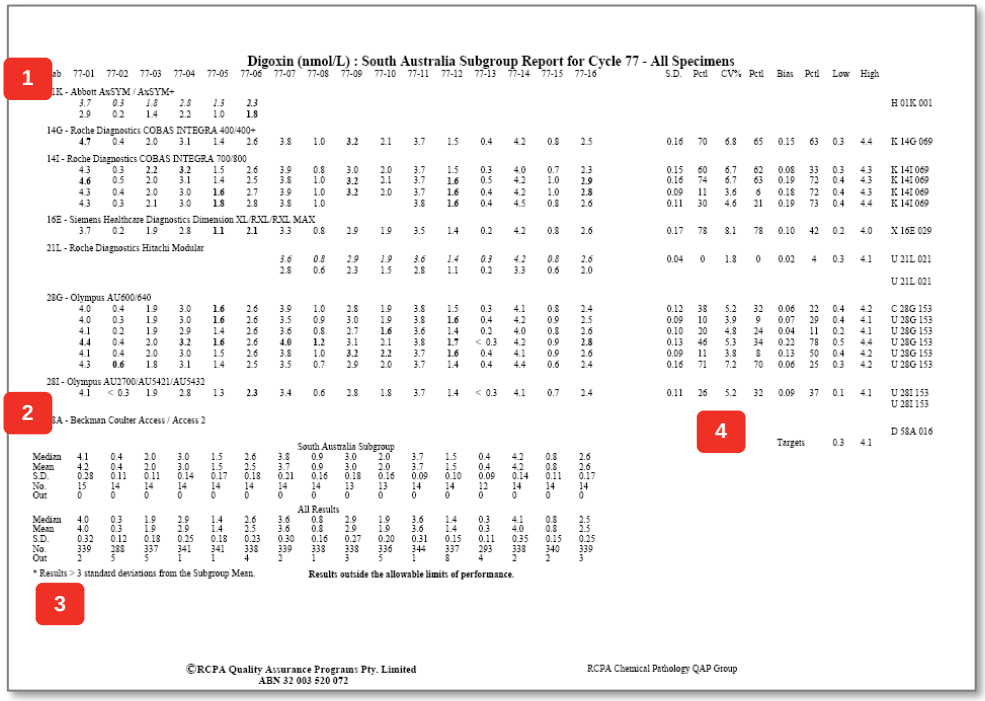
The regression lines of the group.

5 **Coefficients of Variation**

This is only available if End of cycle data has been calculated. The histogram will display the coefficients of variation (CV) from all participants. Group results are printed in black and the median for the group is provided.

Individual Concentrations – Numerical Summary

A table of all data for the group held by the organisers is provided.



Digoxin (nmol/L) : South Australia Subgroup Report for Cycle 77 - All Specimens

Lab	77-01	77-02	77-03	77-04	77-05	77-06	77-07	77-08	77-09	77-10	77-11	77-12	77-13	77-14	77-15	77-16	S.D.	Pctl	CV%	Pctl	Bias	Pctl	Low	High	
01K - Abbott AxSYM / AxSYM+																									
	3.7	*0.3*	*1.8*	*2.8*	*1.3*	*2.3*																			H 01K 001
	2.9	0.2	1.4	2.2	1.0	**1.8**																			
14G - Roche Diagnostics COBAS INTEGRA 400/400+																									
	4.7	0.4	2.0	3.1	1.4	2.6	3.8	1.0	**3.2**	2.1	3.7	1.5	0.4	4.2	0.8	2.5	0.16	70	6.8	65	0.15	63	0.3	4.4	K 14G 069
14I - Roche Diagnostics COBAS INTEGRA 700/800																									
	4.3	0.3	**2.2**	**3.2**	1.5	2.6	3.9	0.8	3.0	2.0	3.7	1.5	0.3	4.0	0.7	2.3	0.15	60	6.7	62	0.08	33	0.3	4.3	K 14I 069
	4.6	0.5	2.0	3.1	1.4	2.5	3.8	1.0	**3.2**	2.1	3.7	**1.6**	0.5	4.2	1.0	**2.9**	0.16	74	6.7	63	0.19	72	0.4	4.3	K 14I 069
	4.3	0.4	2.0	3.0	**1.6**	2.7	3.9	1.0	**3.2**	2.0	3.7	**1.6**	0.4	4.2	1.0	**2.8**	0.09	11	3.6	6	0.18	72	0.4	4.3	K 14I 069
	4.3	0.3	2.1	3.0	**1.8**	2.8	3.8	1.0			3.8	**1.6**	0.4	4.5	0.8	2.6	0.11	30	4.6	21	0.19	73	0.4	4.4	K 14I 069
16E - Siemens Healthcare Diagnostics Dimension XL/RXL/RXL MAX																									
	3.7	0.2	1.9	2.8	**1.1**	**2.1**	3.3	0.8	2.9	1.9	3.5	1.4	0.2	4.2	0.8	2.6	0.17	78	8.1	78	0.10	42	0.2	4.0	X 16E 029
21L - Roche Diagnostics Hitachi Modular																									
							3.6	*0.8*	*2.9*	*1.9*	*3.6*	*1.4*	*0.3*	*4.2*	*0.8*	*2.6*	0.04	0	1.8	0	0.02	4	0.3	4.1	U 21L 021
							2.8	0.6	2.3	1.5	2.8	1.1	0.2	3.3	0.6	2.0									
																									U 21L 021
28G - Olympus AU600/640																									
	4.0	0.4	1.9	3.0	**1.6**	2.6	3.9	1.0	2.8	1.9	3.8	1.5	0.3	4.1	0.8	2.4	0.12	38	5.2	32	0.06	22	0.4	4.2	C 28G 153
	4.0	0.3	1.9	3.0	**1.6**	2.6	3.5	0.9	3.0	1.9	3.8	**1.6**	0.4	4.2	0.9	2.5	0.09	10	3.9	9	0.07	29	0.4	4.1	U 28G 153
	4.1	0.2	1.9	2.9	1.4	2.6	3.6	0.8	2.7	**1.6**	3.6	1.4	0.2	4.0	0.8	2.6	0.10	20	4.8	24	0.04	11	0.2	4.1	U 28G 153
	4.4	0.4	2.0	**3.2**	**1.6**	2.6	**4.0**	**1.2**	3.1	2.1	3.8	**1.7**	< 0.3	4.2	0.9	**2.8**	0.13	46	5.3	34	0.22	78	0.5	4.4	U 28G 153
	4.1	0.4	2.0	3.0	1.5	2.6	3.8	1.0	**3.2**	**2.2**	3.7	**1.6**	0.4	4.1	0.9	2.6	0.09	11	3.8	8	0.13	50	0.4	4.2	U 28G 153
	4.3	**0.6**	1.8	3.1	1.4	2.5	3.5	0.7	2.9	2.0	3.7	1.4	0.4	4.4	0.6	2.4	0.16	71	7.2	70	0.06	25	0.3	4.2	U 28G 153
28I - Olympus AU2700/AU5421/AU5432																									
	4.1	< 0.3	1.9	2.8	1.3	**2.3**	3.4	0.6	2.8	1.8	3.7	1.4	< 0.3	4.1	0.7	2.4	0.11	26	5.2	32	0.09	37	0.1	4.1	U 28I 153
																									U 28I 153
58A - Beckman Coulter Access / Access 2																									D 58A 016
																					Targets		0.3	4.1	
South Australia Subgroup																									
Median	4.1	0.4	2.0	3.0	1.5	2.6	3.8	0.9	3.0	2.0	3.7	1.5	0.4	4.2	0.8	2.6									
Mean	4.2	0.4	2.0	3.0	1.5	2.5	3.7	0.9	3.0	2.0	3.7	1.5	0.4	4.2	0.8	2.6									
S.D.	0.28	0.11	0.11	0.14	0.17	0.18	0.21	0.16	0.18	0.16	0.09	0.10	0.09	0.14	0.11	0.17									
No.	15	14	14	14	14	14	14	14	13	13	14	14	12	14	14	14									
Out	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0									
All Results																									
Median	4.0	0.3	1.9	2.9	1.4	2.6	3.6	0.8	2.9	1.9	3.6	1.4	0.3	4.1	0.8	2.5									
Mean	4.0	0.3	1.9	2.9	1.4	2.5	3.6	0.8	2.9	1.9	3.6	1.4	0.3	4.0	0.8	2.5									
S.D.	0.32	0.12	0.18	0.25	0.18	0.23	0.30	0.16	0.27	0.20	0.31	0.15	0.11	0.35	0.15	0.25									
No.	339	288	337	341	341	338	339	338	338	336	344	337	293	338	340	339									
Out	2	5	5	1	1	4	2	1	3	5	1	8	4	2	2	3									

* Results > 3 standard deviations from the Subgroup Mean. **Results outside the allowable limits of performance.**

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RCPA Chemical Pathology QAP Group

1 **Raw Data Table**

This table displays all data for each specimen number submitted by each laboratory in the group. This data is cumulative. Data is listed by individual analytical systems.

Results greater than the APS from the target value are printed in bold. Results greater than 3 Standard Deviations (SD) from the group mean for the specimen are highlighted with an asterisk (*).

2 **Group Statistics**

The median, mean and SD of the group results. The number of results included in the mean calculation and the number of outliers (results greater than 3 SD's from the mean) are provided.

3 **All Results Statistics**

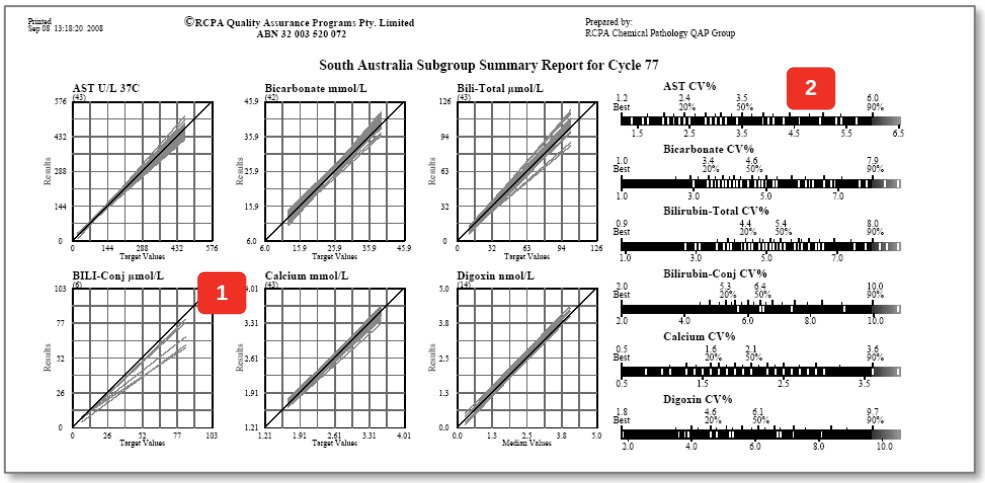
The median, mean and standard deviation of all results. The number of results included in the mean calculation and the number of outliers (results greater than 3 SD's from the mean) are provided.

4 **End of cycle Statistics**

The End of cycle statistics for each participant if available. The Standard Deviation, Standard Deviation percentile ranking, Coefficient of Variation, Coefficient of Variation percentile ranking, bias, bias percentile ranking, the low and high values (compared to the low and high target values) and the method classification are printed.

Group Summary Report

This is only available if the End of cycle data has been calculated.



1 **Regression Lines**

The regression lines of the group for each measurand.

2 **Coefficient of Variations Bar Graph**

A coefficient of variation (%CV) bar graph is provided for each measurand. The top scales indicate the %CV for the best, 20th, 50th and 90th percentile.

The white lines indicate the %CV's for each laboratory within the group.

Haematology

The Survey Report examples below will be for programs that are still hosted on the legacy platform. Report examples produced from the eQuality platform (new reporting system) can be found on the myQAP help page.

Survey Report – General Information

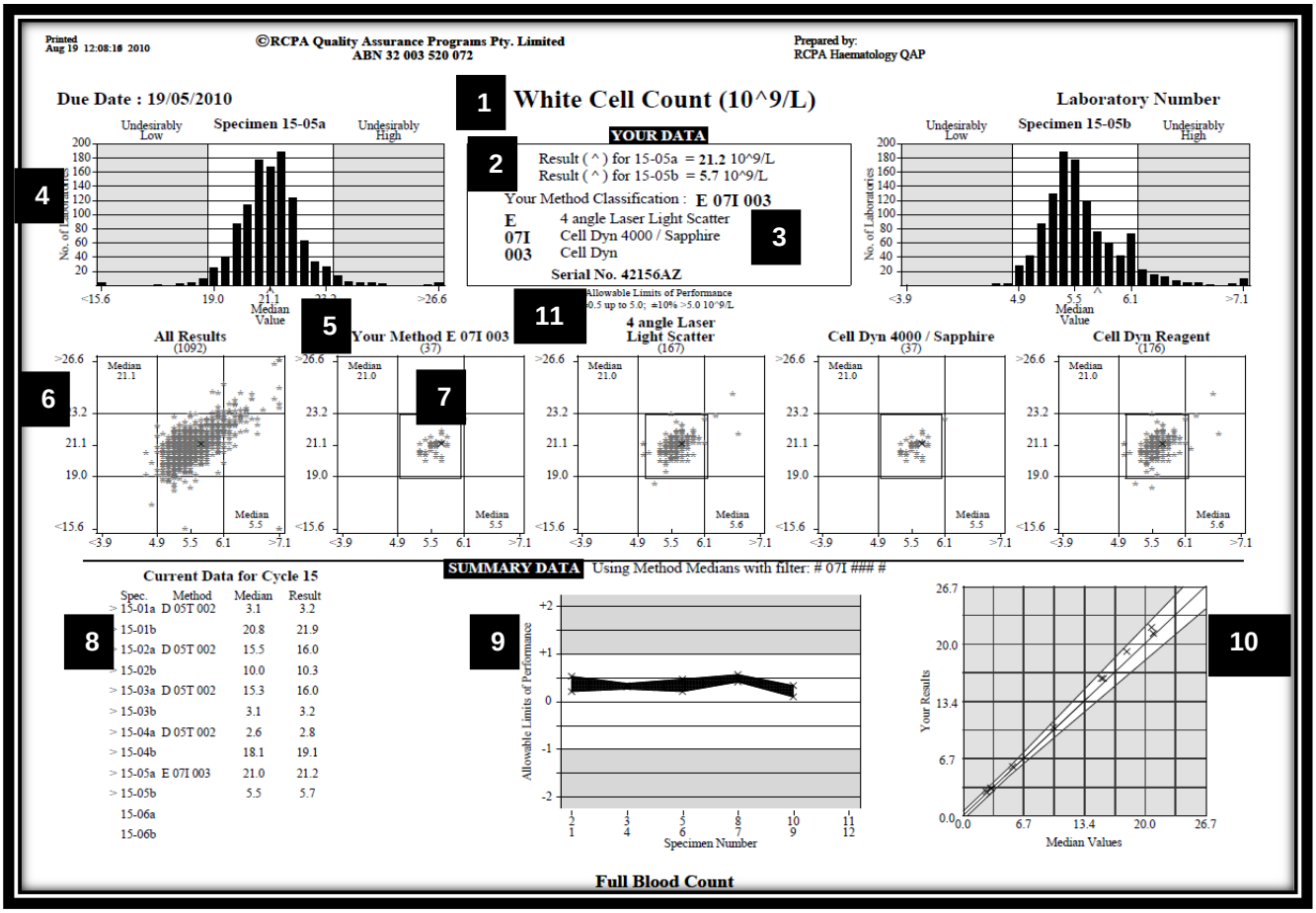
The survey report provides a simple, direct comparison of individual participant results with all results received and graphical representations showing results from the same method, instrument and reagent groups. Participants' results will be compared to a calculated median from all method classifications for a particular test as well as comparing results within an instrument or reagent group. Survey reports are issued for each measurand/test after the scheduled closing date. Analytical Performance Specifications (APS) are unique for each measurand. APSs are calculated from the target overall median value of your instrument or reagent group, whichever is applicable, and are used in the histograms and youden plots. The APSs are based on clinical needs and are set and reviewed by program organisers and expert committee members.

Reports contain:

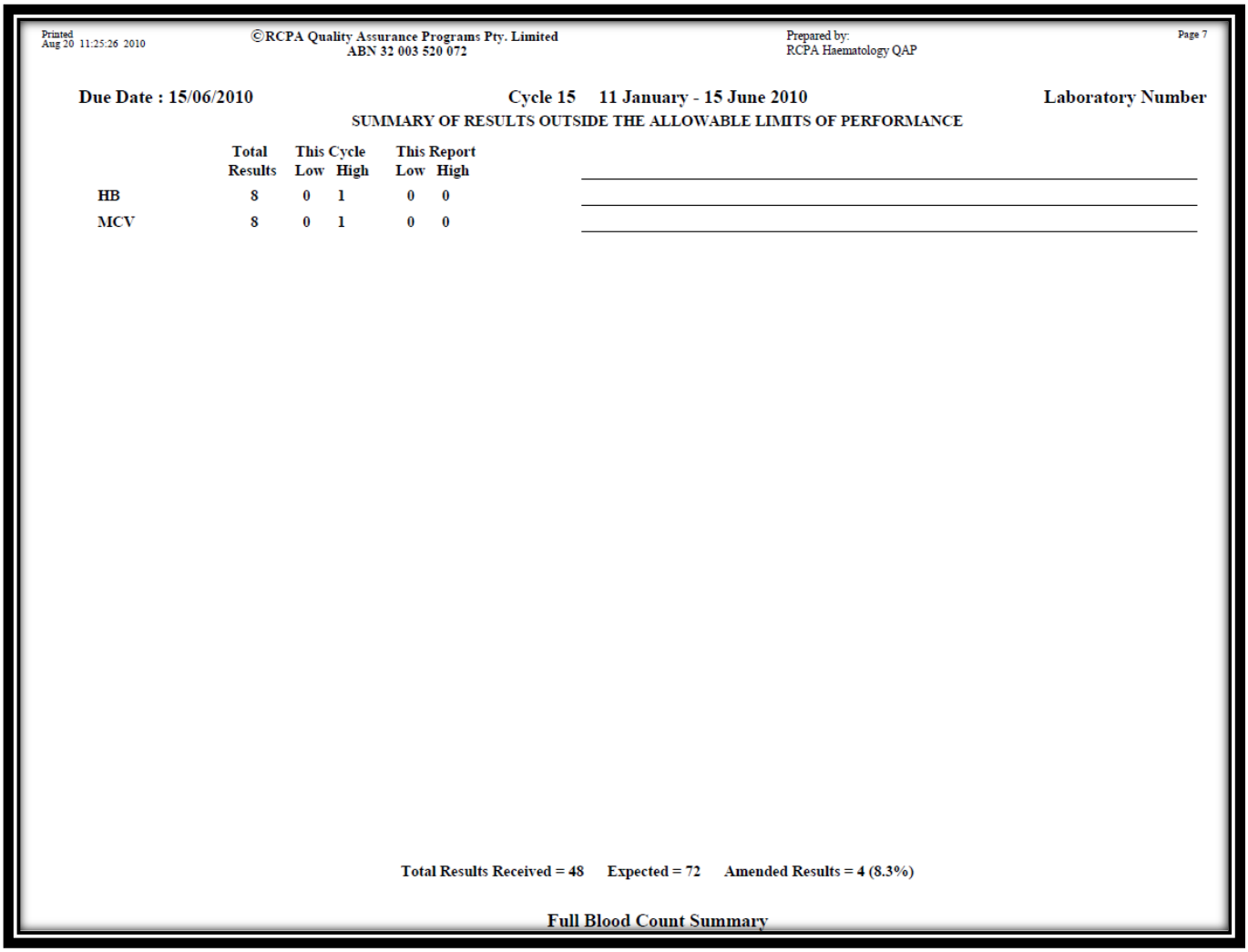
- Data for the current test samples
- Summary Data which includes all results for the current cycle, including cumulative method and target value data
- If results are late, amended or fall outside the APS, then an appropriate flagging message is printed along the sample number in current data table
- Data from each specimen is displayed in histograms, showing the distribution of all results compared to the all method median value using the APS
- Youden plots show results for paired specimens as a plot of the low value specimen (abscissa) against the high value specimen (ordinate)
- Individual participant results are highlighted
- Method groups are displayed in youden plots - each plot includes a central box which encompasses the APS based on the medians
- A Levy-Jennings plot is a plot of each pair of results showing the deviations from the target value in APS. The relative position of each pair of results is shown by the position of the specimen numbers on the abscissa. Acceptable results are within +/-1 APS of the target/median value (shaded)
- A linearity graph plots individual data against each specimen's central value. Shading shows the optimal range for results, calculated from APSs
- The final page of a report includes a table summarising the performance of the laboratory and highlighting those measurands outside the APS

Example – Quantitative Survey Report (legacy software)

Report style – FBC, Haemostasis and Special Haemostasis Programs - quantitative component



1. **TEST**: Full name of test parameter and units
2. **RESULTS:** The results your laboratory reported for these specimens
3. **METHOD CLASSIFICATION:** Method classification information in QAP database
4. **RESULT HISTOGRAM:** Histogram showing distribution of results compared to the median. Undesirably high and low areas shaded - the participant's result within the distribution indicated with a (^)
5. **MEDIAN VALUE:** Calculated all method median
6. **YOUDEN PLOTS:** Plot of the low concentration specimen (abscissa) against the high concentration specimen (ordinate). Individual results highlighted (x). If both results are within the APS the (x) will be within the central square. Youden plots represent exact methodology, analytical principle, instrument and reagent
7. **PEER REVIEW BOX:** Box encompasses the APS for the subgroup calculated median
8. **CURRENT DATA:** Complete record of data for the cycle. Includes methods medians and results for the cycle. Results outside the APS are designated 'High' or 'Low'
9. **LEVY JENNINGS PLOT:** A plot of your result, showing the distance from the calculated median. The relative position of each result is shown by the position of the specimen numbers on the abscissa. Acceptable results are within +/- 1 Analytical Performance Specification of the median
10. **LINEARITY GRAPH:** Specimens are linearly related. This graph shows non-linearity, imprecision and inaccuracy. Results in the shaded area are outside the APS
11. **ANALYTICAL PERFORMANCE SPECIFICATIONS:** Unique for each test. Based on the clinical relevance and statistical evaluation



Printed
Aug 20 11:25:26 2010

Prepared by:
RCPA Haematology QAP

Page 7

Due Date : 15/06/2010 **Cycle 15 11 January - 15 June 2010** **Laboratory Number**

SUMMARY OF RESULTS OUTSIDE THE ALLOWABLE LIMITS OF PERFORMANCE

	Total Results	This Cycle Low	This Cycle High	This Report Low	This Report High
HB	8	0	1	0	0
MCV	8	0	1	0	0

Total Results Received = 48 Expected = 72 Amended Results = 4 (8.3%)

Full Blood Count Summary

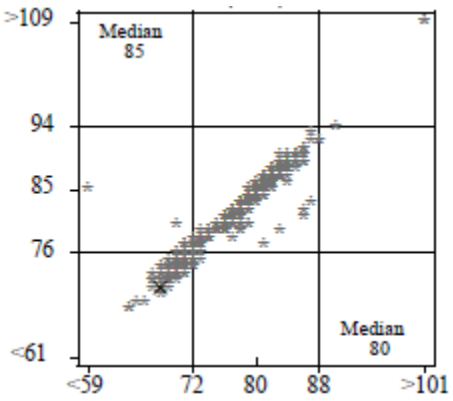
Summary Page

In all Survey Reports a summary page will be included on the last page. This will summarise your performance over the cycle, listing tests that have fallen outside the 'Analytical Performance Specifications'. This page should be used by subscribers to note if any action has been taken if warranted by the results of your report.

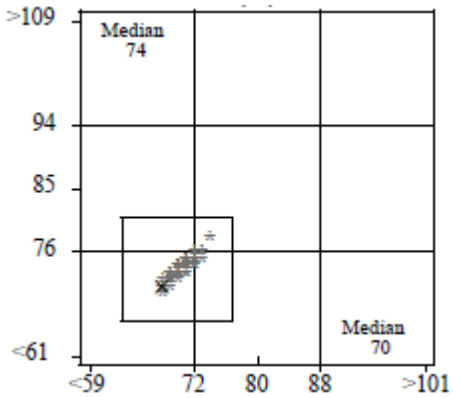
Example of Graphical Representations

Example of biased results

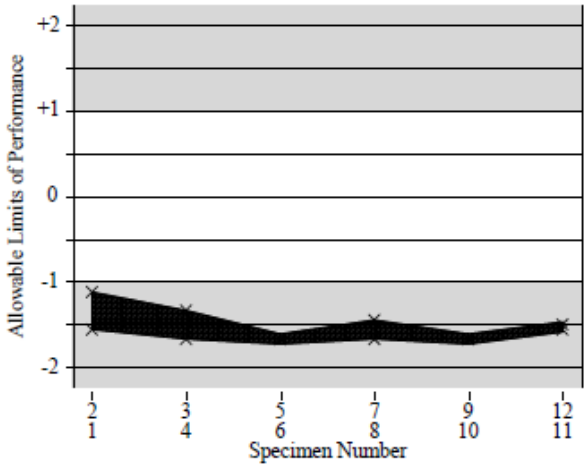
Youden Plots



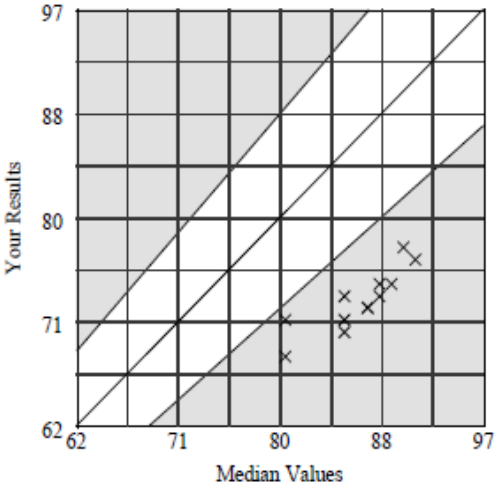
Peer Review Boxes



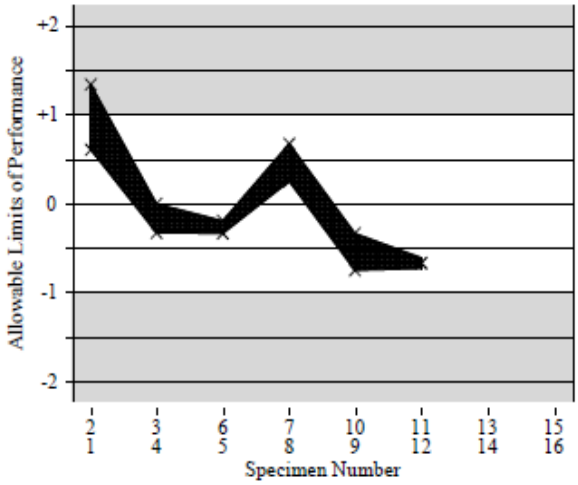
Levey Jennings Plots

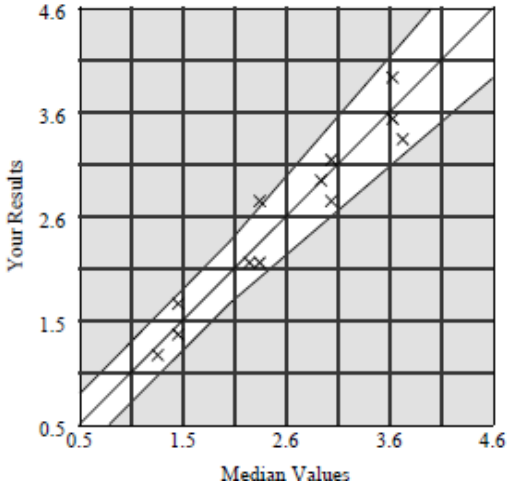


Linearity Graphs



Examples of Imprecision



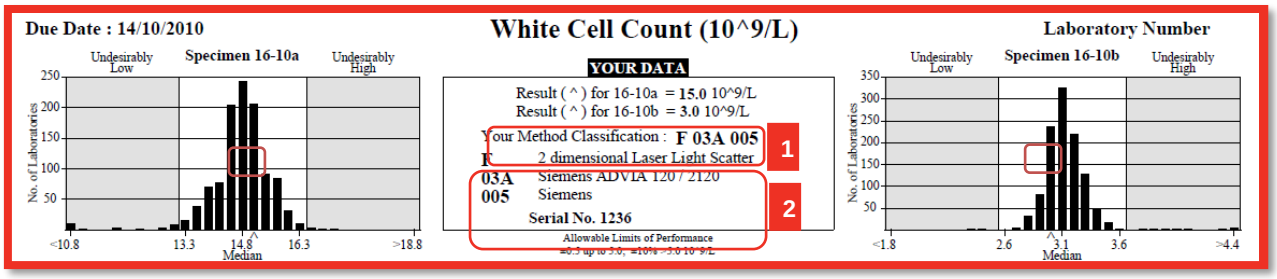


Examples of bias may be seen among test results and this will depend on the type of technology used to count cells. From studies with this system it has been noted that this will be particularly seen in the MCV, HCT/PCV, MCHC, RDW-CV, Platelet Count, and MPV. For this reason a filter is applied so that participants are compared to their peer instrument, or in some programs reagent group. FBC instruments that sphere the red cells before passing through an aperture will yield a lower MCV for stabilised blood. This will also affect the HCT and MCHC, which is a calculated parameter dependent on the RCC and the MCV. Similarly with the platelet count, FBC instruments that have a lower threshold to count platelets will yield a higher platelet count for stabilised blood. Stabilised blood when treated with fixatives will reduce the size of the platelet.

This is a multifaceted report, therefore laboratories will need to look at the whole picture, as what may initially appear to be a result that requires immediate attention may be a result of instrument bias and this will be demonstrated in the report.

Quantitative Survey Report Interpretation Guide

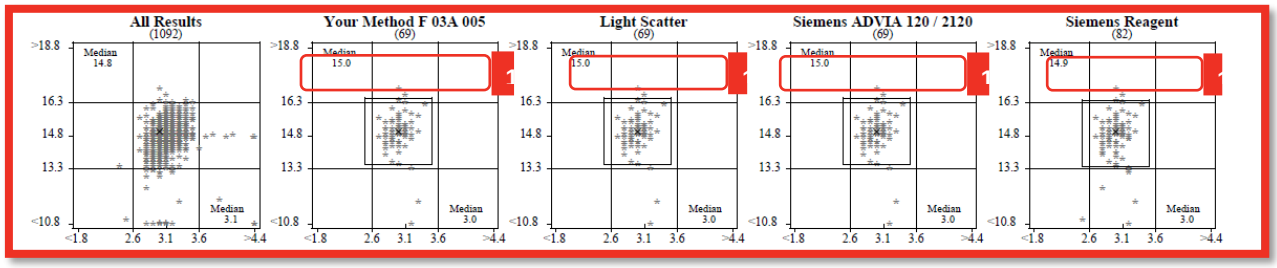
PART A – Histograms



Are your results (^) within the analytical performance specifications (APS)?

If NO check for –
- *Transcription error (1 above)*
- *Unit conversion error (1 above)*
- *Incorrect method code (2 above)*

PART B – Youden plots

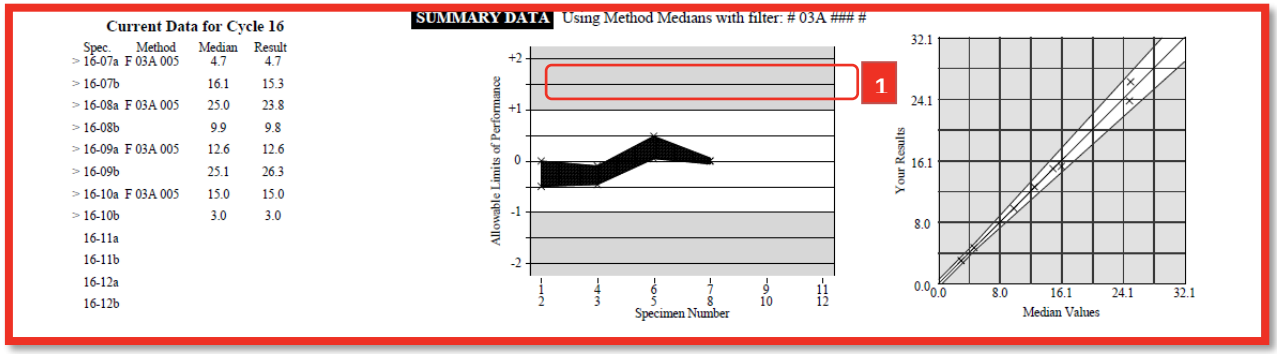


Are your results within your peer group box?

If NO review –
- *QAP Sample reconstitution*
- *Check internal QC in run*
- *Any change in reagent lot or calibrator*

Important: Check the correct Principle/Instrument/Reagent are held by RCPAQAP Haematology (1 above)

PART C – Summary Data



Are any results outside ± 1 APS?

Levey Jennings: If YES –
- *Low / high bias*
- *Poor precision within run or between run*
- *Change in performance due to?*

Linearity: If YES –
- *Proportional bias*
- *Non-linearity*
- *Imprecision*

Important: Your results are compared to the Method Median filter, e.g. # 03A ### (1 above)

The Quantitative Survey Report Interpretation Flowchart can be found by clicking on this link.

Qualitative Evaluation

Interpretive Comments

- Interpretive comments are reviewed by the reference ranges set by the participating laboratories for the test being assayed
- Interpretive comments are not assessed for acceptability. They are for a review of the interpretive component from subscribing laboratories
- Histograms are produced illustrating the distribution of interpretive comments

Scoring - Morphology/Paediatric Morphology/Malarial Parasite/Bone Marrow Program

The RCPAQAP Haematology has introduced a scoring system to assess the performance of subscribers in the Morphology and Malarial Parasite Programs. The scoring system assesses the performance by allocating scores for correct descriptions and diagnoses.

2 types of reports for Morphology / Paediatric Morphology & Malarial Parasite programs:

- Survey Report: Split into 2 parts; Part A (Descriptive Component) and Part B (Diagnostic Component). Both parts use a scoring system to assess performance
- End of cycle/Summary Report: Cumulative data for the cycle

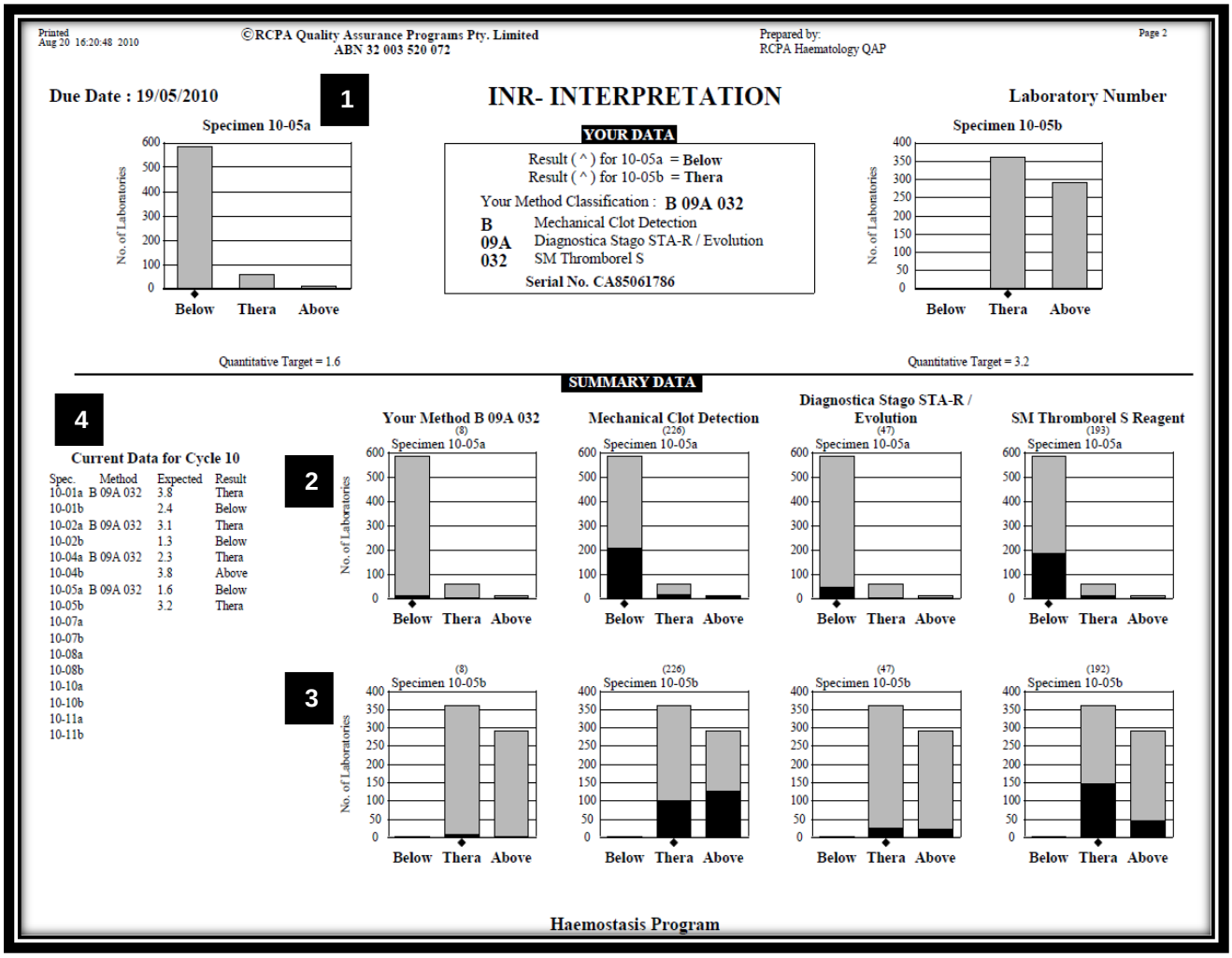
Please Note: For the purposes of performance evaluation for laboratories participating in the Morphology and Paediatric Morphology modules, results from laboratories classified as scientist / medical technologist are assessed for the descriptive component only. From an educational perspective, we actively encourage scientist / medical technologist only laboratories to report a diagnosis where possible.

Specialist haematologist / pathologist reporting laboratories are expected to report both descriptive and diagnostic components.

Diagnosis – Haemoglobinopathy- As *report examples become available from the eQuality platform (new reporting system) they will uploaded to the RCPQAP website's* *myQAP help page.*

For reports generated from legacy software, participants are asked to submit a diagnosis based on results. The Haemoglobinopathy Advisory Committee then reviews submitted Diagnoses and designates each as either "Concordant", Minor Discordant or "Discordant".

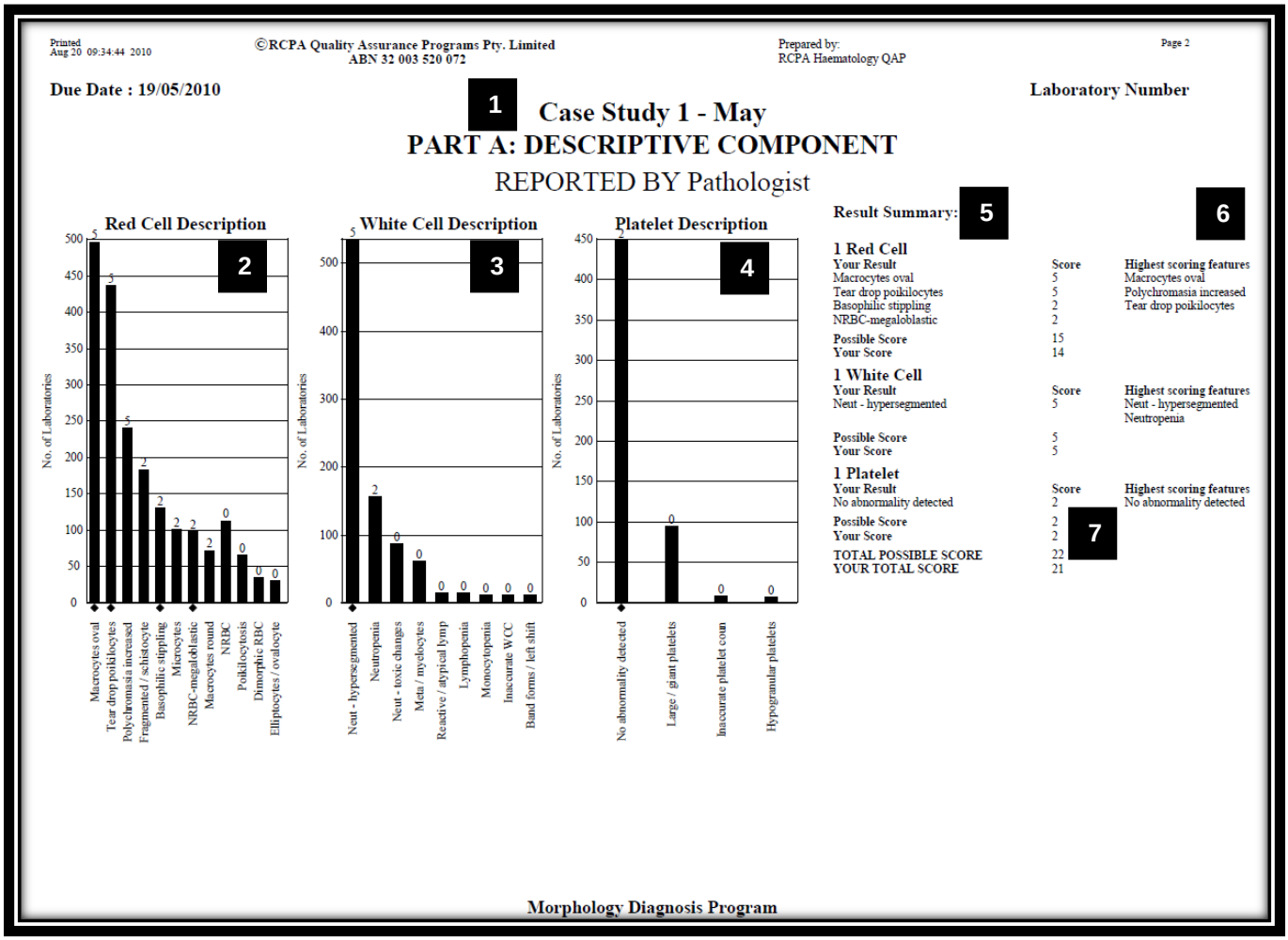
Example – Qualitative Survey Report



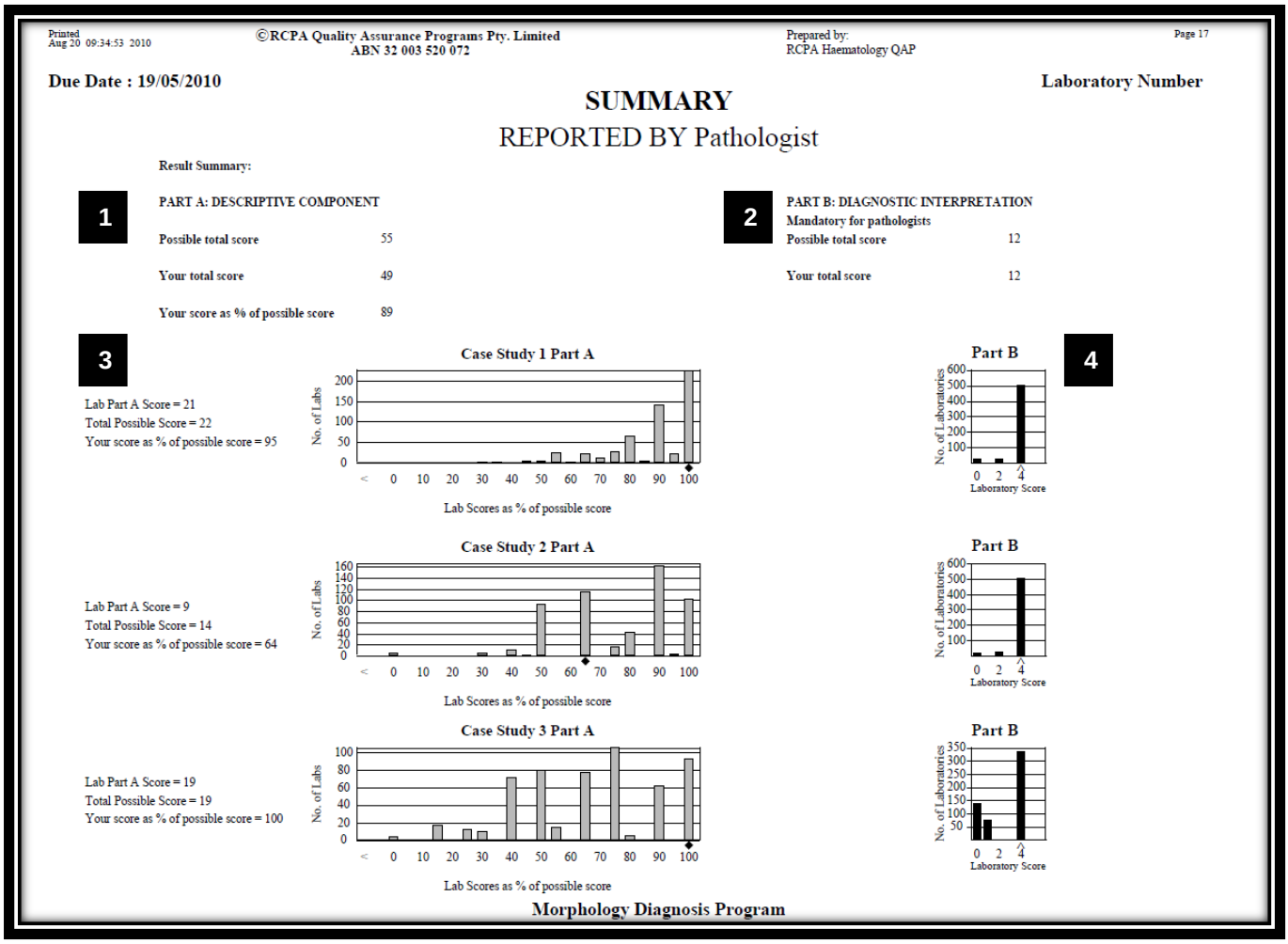
For all programs with an interpretive component the method classification system is also used, where the analytical system is split into four categories, the analytical principle, measurement system (instrument), reagent source and a fourth category (if required).

1. **INTERPRETATION HISTOGRAMS:** The two histograms at the top of the report indicate the responses from all laboratories marking your response with a '♦'.
2. **BREAKDOWN HISTOGRAMS**: Specimen 1: The participant's method followed by a breakdown of the interpretations into analytical principle, instrument and reagent. The dark area is the interpretations from the specific group listed compared to all results in grey.
3. **BREAKDOWN HISTOGRAMS**: Specimen 2: The participant's method and then a breakdown of the interpretations into analytical principle, instrument and reagent. The dark area is the interpretations from the specific group listed compared to all results in grey.
4. **SUMMARY:** There is also a summary of results listing the interpretive results and an All Method Median result obtained for each test. The latter is a cumulative summary of results for the cycle.

Survey Report – Morphology Program



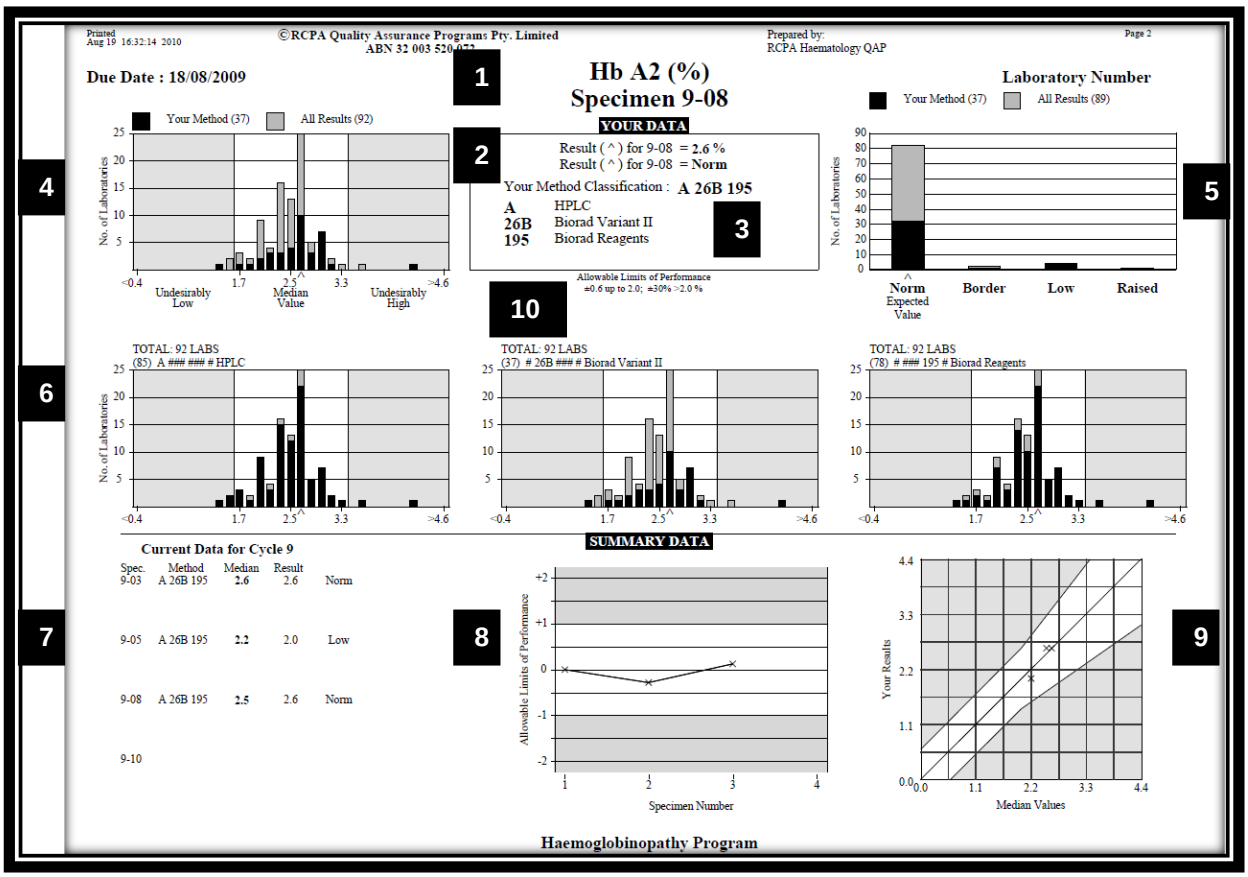
1. **CASE STUDY:** The specimen number used for the case study.
2. **HISTOGRAM for Red Cell Description:** Distribution of all RC descriptions. (♦) indicates the participant's responses. Score allocated recorded above each column.
3. **HISTOGRAM for White Cell Description:** Distribution of all WC descriptions. (♦) indicates the participant's responses. Score allocated recorded above each column.
4. **HISTOGRAM for Platelet Description:** Distribution of all Platelet descriptions. (♦) indicates the participant's responses. Score allocated recorded above each column.
5. **LABORATORY RESULTS:** Participant's responses with allocated score – The 'Possible Score" is a capped maximum possible value, compared to the individuals score
6. **HIGHEST SCORING FEATURES:** Highest scored features as set by the Morphology Selection committee. These features are considered the relevant descriptions for diagnosis.
7. **OVERALL SCORE:** Laboratory's total descriptive score and the total possible score for this case study.



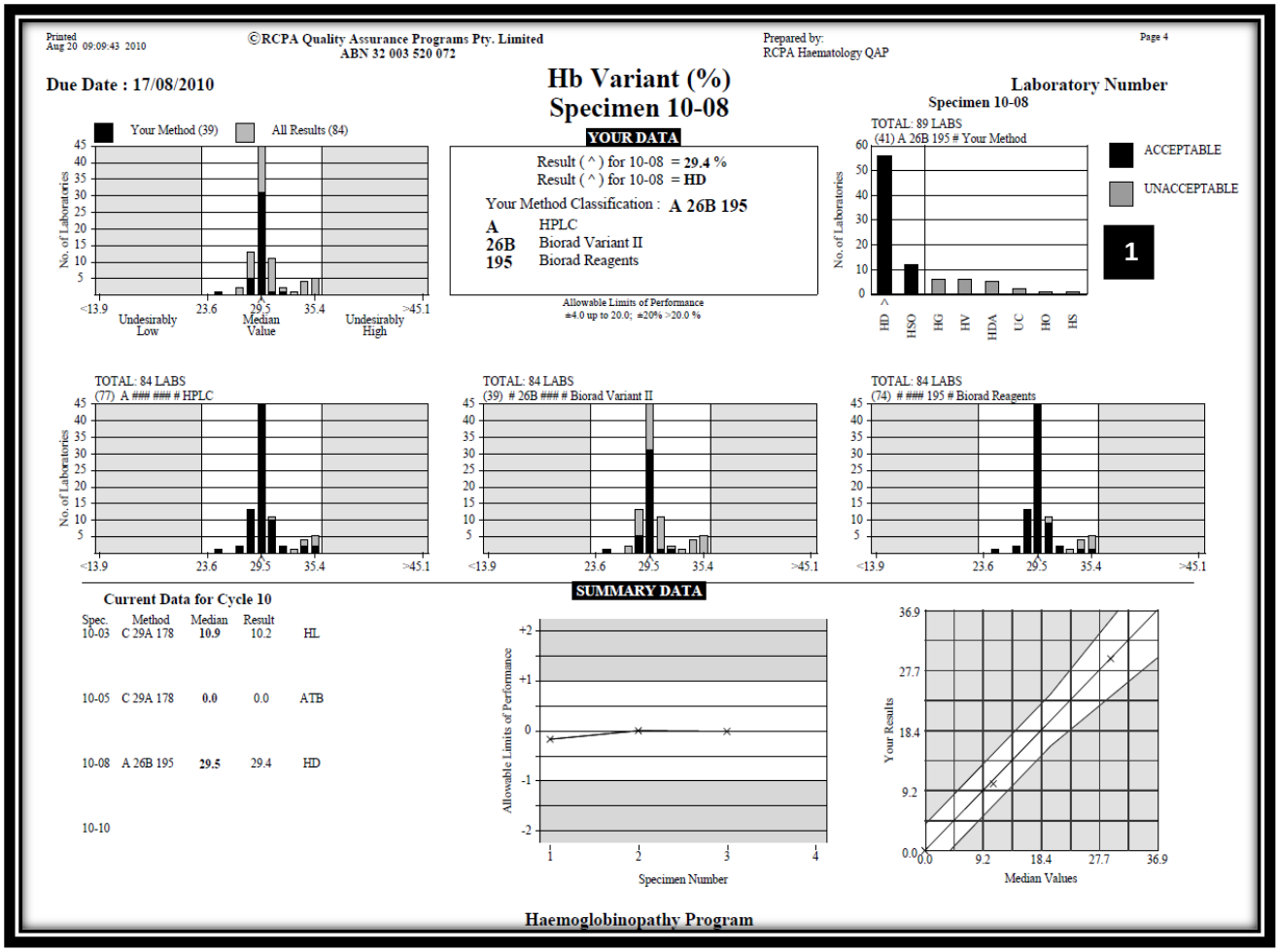
1. **PART A - DESCRIPTIVE COMPONENT:** Lists the 'Possible total score', which is the cumulative score for Part A in all 3 Case studies, and 'Your total score' - the cumulative score for your laboratory (Part A in all 3 Cases). Your total score is also expressed as a percentage (%) of the possible total score.
2. **PART B - DIAGNOSTIC INTERPRETATION:** Lists the 'Possible total score', which is the cumulative score for Part B in all 3 Case studies (will always be 12 as each diagnosis is worth 4), and 'Your total score' - the cumulative score for your laboratory - Part B in all 3 Cases.
3. **HISTOGRAMS FOR DESCRIPTIVE COMPONENT:** A histogram representing the percentage (%) score for Part A of all laboratories for each Case study. This histogram allows participants to compare their descriptive score for each case with all other participants. A participant's score is indicated with (♦).
4. **HISTOGRAMS FOR DIAGNOSTIC INTERPRETATION:** A histogram for the Part B score of all laboratories for each Case study. Scores of 0, 1, 2, 3 or 4 are possible for each case - this histogram allows participants to compare their diagnostic score for each case with all other participants. A participant's score is indicated with (^).

Please note: The survey report for the Malarial Parasite Program uses the same data analysis system to assess laboratory performance.

Survey Report - Haemoglobinopathy Program *(the report example below is produced from the legacy software). In 2021 the program will be hosted on the eQuality platform and the report will take on the standardised format. A full explanation of the report will be available on the myQAP help page, once the first survey report is available.*

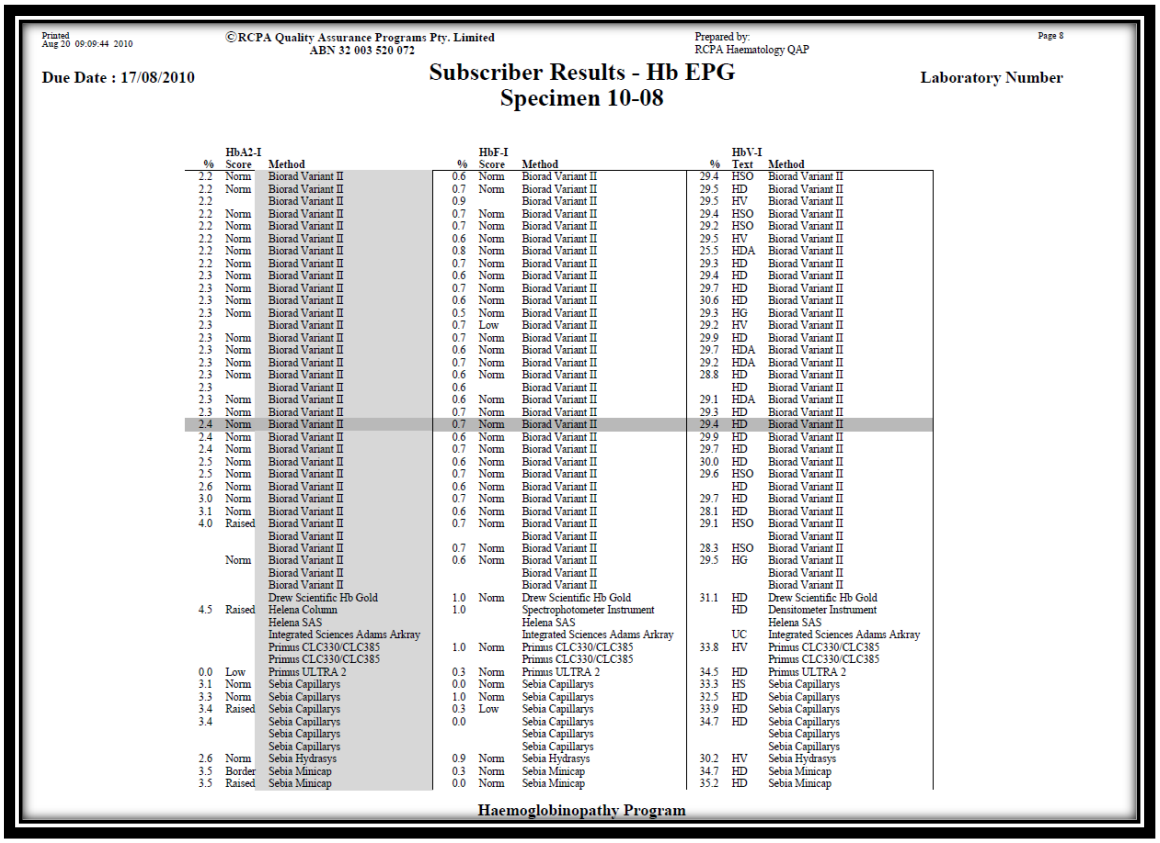


1. **TEST:** The specimen number and test.
2. **RESULTS:** The results your laboratory reported for this specimen.
3. **METHOD CLASSIFICATION:** The method classification stored in the QAP database.
4. **RESULT HISTOGRAM:** Histogram showing the distribution of all results compared to the median. Undesirably high and low areas shaded in grey. The participant's result within the distribution is indicated with a (^). The black coloured bars within the histogram indicate results from the same method classification group.
5. **INTERPRETATION HISTOGRAM:** Illustrates the distribution of all interpretive comments, highlighting in black the interpretation of your method classification group, indicating the participant's result within the distribution (^).
6. **RESULT HISTOGRAM BREAKDOWN:** Three histograms showing the distribution of results compared to the median broken down into results from the same principle, the same instrument and the same reagents. Undesirably high and low areas are shaded - the participant's result indicated with a (^).
7. **CURRENT CYCLE DATA:** A complete record of data for the cycle. Results outside the acceptable range are designated 'HIGH' or 'LOW'
8. **LEVY JENNINGS STYLE PLOT:** A plot of your result, showing the distance from the calculated median. The acceptable results are within +/- 1 Analytical Performance Specification of the median.
9. **LINEARITY GRAPH:** This graph shows non-linearity, imprecision and inaccuracy. Results inside the shaded area are outside the APS.
10. **ANALYTICAL PERFORMANCE SPECIFICATIONS:** Unique for each test. Based on the clinical relevance and statistical evaluation.



DIAGNOSTIC INTERPRETATION (for legacy software reports): The Hb Variant page contains a histogram of the diagnostic interpretations of the specimen issued in the survey. This histogram indicates whether the result interpretations are acceptable or unacceptable. The laboratory's result is highlighted with a (^). A list of codes is presented on the next page with the full description of the shortcut code shown on the histogram.

The following page of the report provides laboratories with the result commentary for the current survey. This information is prepared by the Haemoglobinopathy Advisory committee.



Printed Aug 20 09:09:44 2010

Prepared by: RCPA Haematology QAP

Page 8

Due Date : 17/08/2010

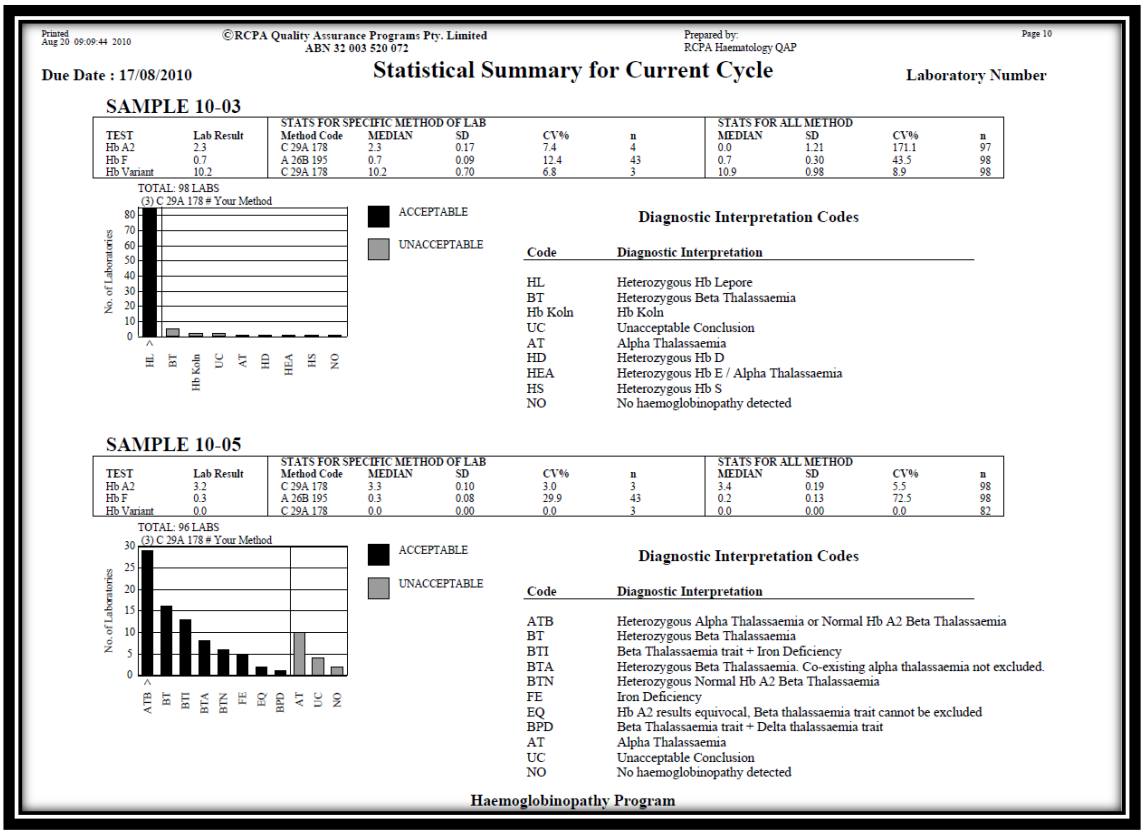
Subscriber Results - Hb EPG
Specimen 10-08

Laboratory Number

HbA2-I %	HbA2-I Score	HbA2-I Method	HbF-I %	HbF-I Score	HbF-I Method	HbV-I %	HbV-I Text	HbV-I Method
2.2	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.4	HSO	Biorad Variant II
2.2	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.5	HD	Biorad Variant II
2.2		Biorad Variant II	0.9		Biorad Variant II	29.5	HV	Biorad Variant II
2.2	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.4	HSO	Biorad Variant II
2.2	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.2	HSO	Biorad Variant II
2.2	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.5	HV	Biorad Variant II
2.2	Norm	Biorad Variant II	0.8	Norm	Biorad Variant II	25.5	HDA	Biorad Variant II
2.2	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.3	HD	Biorad Variant II
2.3	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.4	HD	Biorad Variant II
2.3	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.7	HD	Biorad Variant II
2.3	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	30.6	HD	Biorad Variant II
2.3	Norm	Biorad Variant II	0.5	Norm	Biorad Variant II	29.3	HG	Biorad Variant II
2.3		Biorad Variant II	0.7	Low	Biorad Variant II	29.2	HV	Biorad Variant II
2.3	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.9	HD	Biorad Variant II
2.3	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.7	HDA	Biorad Variant II
2.3	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.2	HDA	Biorad Variant II
2.3	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	28.8	HD	Biorad Variant II
2.3		Biorad Variant II	0.6		Biorad Variant II		HD	Biorad Variant II
2.3	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.1	HDA	Biorad Variant II
2.3	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.3	HD	Biorad Variant II
2.4	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.4	HD	Biorad Variant II
2.4	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.9	HD	Biorad Variant II
2.4	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.7	HD	Biorad Variant II
2.5	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	30.0	HD	Biorad Variant II
2.5	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.6	HSO	Biorad Variant II
2.6	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II		HD	Biorad Variant II
3.0	Norm	Biorad Variant II	0.7	Norm	Biorad Variant II	29.7	HD	Biorad Variant II
3.1	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	28.1	HD	Biorad Variant II
4.0	Raised	Biorad Variant II	0.7	Norm	Biorad Variant II	29.1	HSO	Biorad Variant II
		Biorad Variant II			Biorad Variant II			Biorad Variant II
		Biorad Variant II	0.7	Norm	Biorad Variant II	28.3	HSO	Biorad Variant II
	Norm	Biorad Variant II	0.6	Norm	Biorad Variant II	29.5	HG	Biorad Variant II
		Biorad Variant II			Biorad Variant II			Biorad Variant II
		Biorad Variant II			Biorad Variant II			Biorad Variant II
		Drew Scientific Hb Gold	1.0	Norm	Drew Scientific Hb Gold	31.1	HD	Drew Scientific Hb Gold
4.5	Raised	Helena Column	1.0		Spectrophotometer Instrument		HD	Densitometer Instrument
		Helena SAS			Helena SAS			Helena SAS
		Integrated Sciences Adams Arkray			Integrated Sciences Adams Arkray		UC	Integrated Sciences Adams Arkray
		Primus CLC330/CLC385	1.0	Norm	Primus CLC330/CLC385	33.8	HV	Primus CLC330/CLC385
		Primus CLC330/CLC385			Primus CLC330/CLC385			Primus CLC330/CLC385
0.0	Low	Primus ULTRA 2	0.3	Norm	Primus ULTRA 2	34.5	HD	Primus ULTRA 2
3.1	Norm	Sebia Capillarys	0.0	Norm	Sebia Capillarys	33.3	HS	Sebia Capillarys
3.3	Norm	Sebia Capillarys	1.0	Norm	Sebia Capillarys	32.5	HD	Sebia Capillarys
3.4	Raised	Sebia Capillarys	0.3	Low	Sebia Capillarys	33.9	HD	Sebia Capillarys
3.4		Sebia Capillarys	0.0		Sebia Capillarys	34.7	HD	Sebia Capillarys
		Sebia Capillarys			Sebia Capillarys			Sebia Capillarys
		Sebia Capillarys			Sebia Capillarys			Sebia Capillarys
2.6	Norm	Sebia Hydrasys	0.9	Norm	Sebia Hydrasys	30.2	HV	Sebia Hydrasys
3.5	Border	Sebia Minicap	0.3	Norm	Sebia Minicap	34.7	HD	Sebia Minicap
3.5	Raised	Sebia Minicap	0.0	Norm	Sebia Minicap	35.2	HD	Sebia Minicap

Haemoglobinopathy Program

Subscriber data with individual participants result highlighted



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Prepared by: RCPA Haematology QAP

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Due Date : 17/08/2010

Statistical Summary for Current Cycle

Laboratory Number

SAMPLE 10-03

TEST	Lab Result	STATS FOR SPECIFIC METHOD OF LAB: Method Code	MEDIAN	SD	CV%	n	STATS FOR ALL METHOD: MEDIAN	SD	CV%	n
Hb A2	2.3	C 29A 178	2.3	0.17	7.4	4	0.0	1.21	171.1	97
Hb F	0.7	A 26B 195	0.7	0.09	12.4	43	0.7	0.30	43.5	98
Hb Variant	10.2	C 29A 178	10.2	0.70	6.8	3	10.9	0.98	8.9	98

TOTAL: 98 LABS
(3) C 29A 178 # Your Method

ACCEPTABLE

UNACCEPTABLE

Diagnostic Interpretation Codes

Code	Diagnostic Interpretation
HL	Heterozygous Hb Lepore
BT	Heterozygous Beta Thalassaemia
Hb Koln	Hb Koln
UC	Unacceptable Conclusion
AT	Alpha Thalassaemia
HD	Heterozygous Hb D
HEA	Heterozygous Hb E / Alpha Thalassaemia
HS	Heterozygous Hb S
NO	No haemoglobinopathy detected

SAMPLE 10-05

TEST	Lab Result	STATS FOR SPECIFIC METHOD OF LAB: Method Code	MEDIAN	SD	CV%	n	STATS FOR ALL METHOD: MEDIAN	SD	CV%	n
Hb A2	3.2	C 29A 178	3.3	0.10	3.0	3	3.4	0.19	5.5	98
Hb F	0.3	A 26B 195	0.3	0.08	29.9	43	0.2	0.13	72.5	98
Hb Variant	0.0	C 29A 178	0.0	0.00	0.0	3	0.0	0.00	0.0	82

TOTAL: 96 LABS
(3) C 29A 178 # Your Method

ACCEPTABLE

UNACCEPTABLE

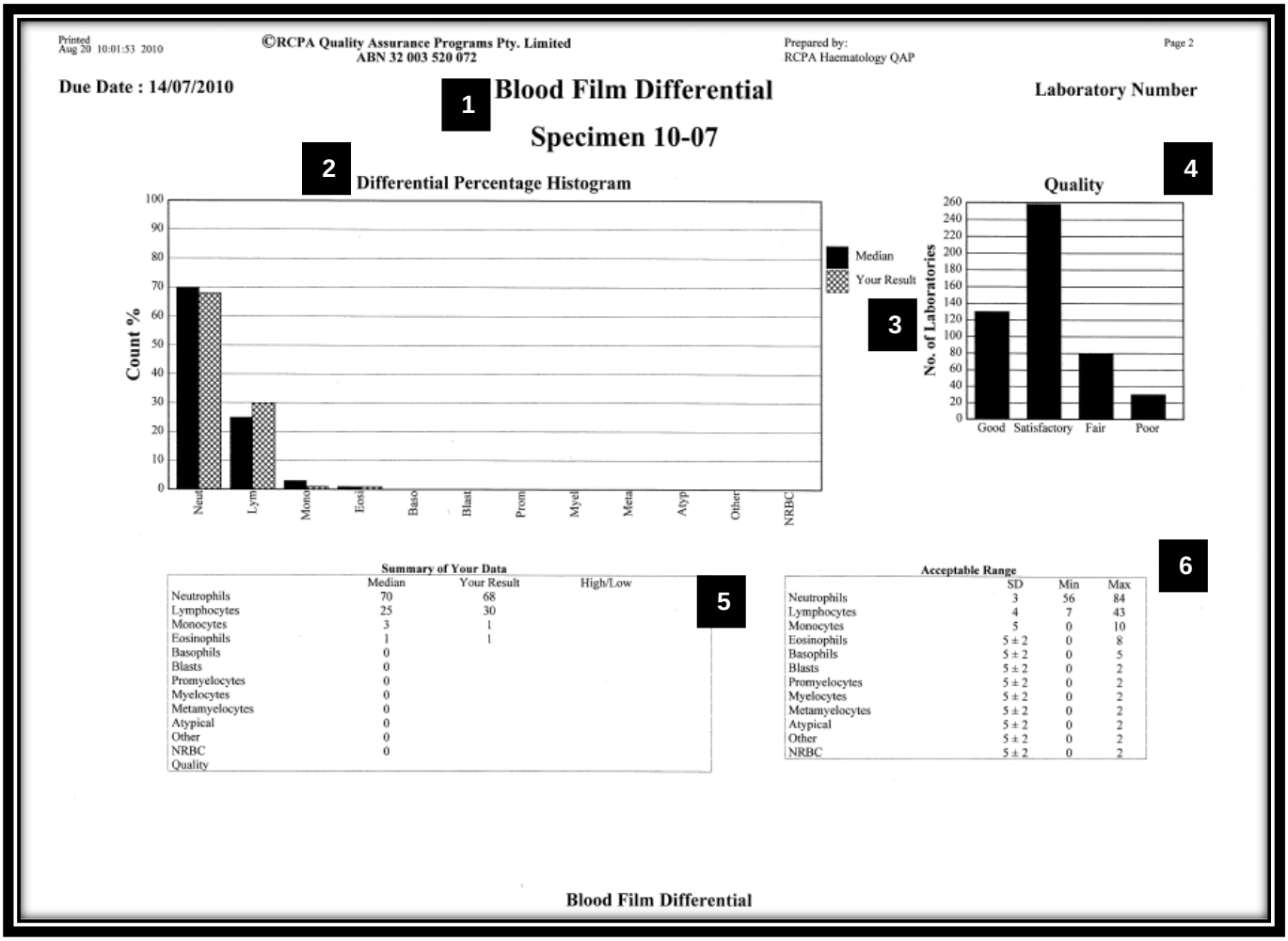
Diagnostic Interpretation Codes

Code	Diagnostic Interpretation
ATB	Heterozygous Alpha Thalassaemia or Normal Hb A2 Beta Thalassaemia
BT	Heterozygous Beta Thalassaemia
BTI	Beta Thalassaemia trait + Iron Deficiency
BTA	Heterozygous Beta Thalassaemia. Co-existing alpha thalassaemia not excluded.
BTN	Heterozygous Normal Hb A2 Beta Thalassaemia
FE	Iron Deficiency
EQ	Hb A2 results equivocal, Beta thalassaemia trait cannot be excluded
BPD	Beta Thalassaemia trait + Delta thalassaemia trait
AT	Alpha Thalassaemia
UC	Unacceptable Conclusion
NO	No haemoglobinopathy detected

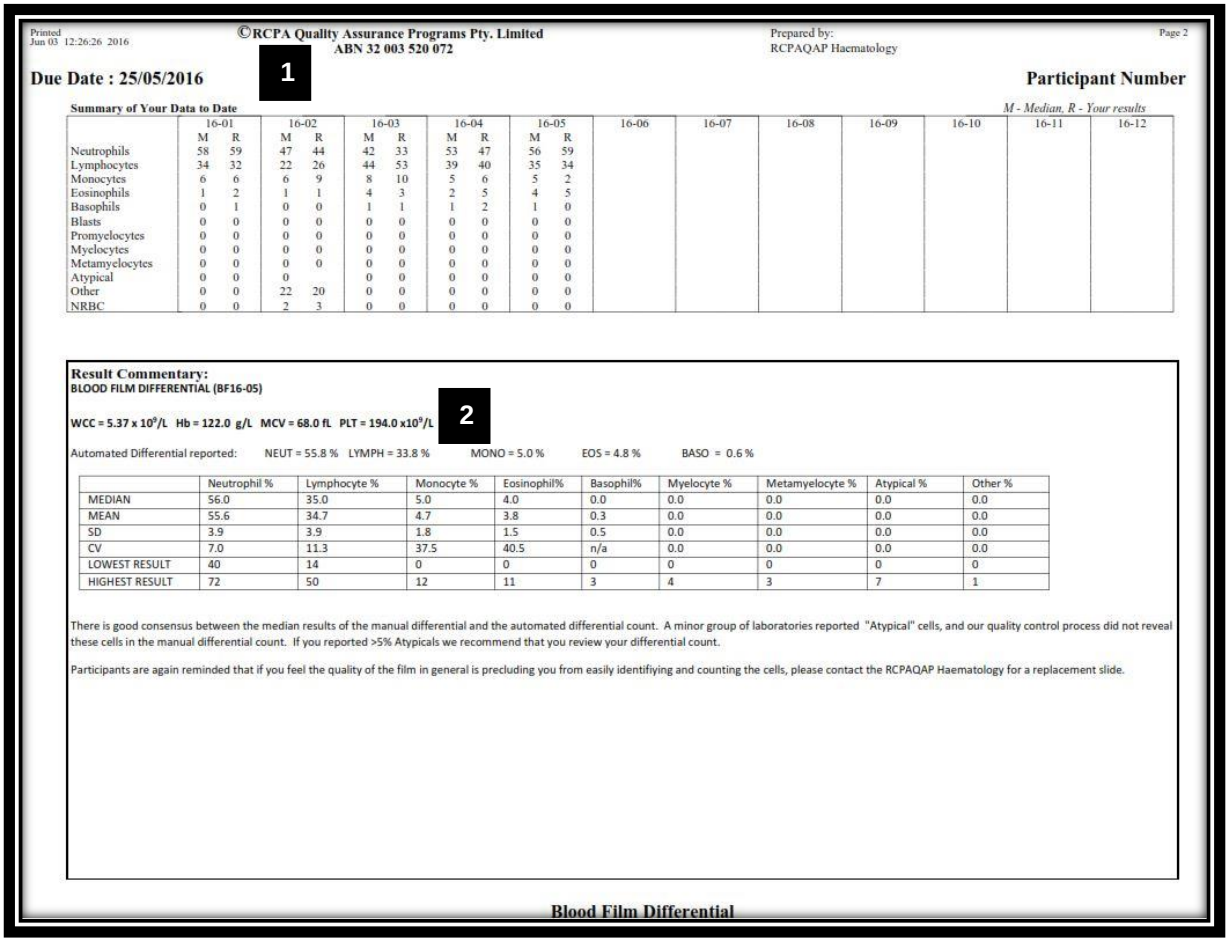
Haemoglobinopathy Program

Cumulative summary of participant's performance for current cycle

Survey Report – Differential Program



1. **TEST:** The specimen number and test.
2. **DIFFERENTIAL PERCENTAGE HISTOGRAM:** Histogram showing the distribution of results compared to the calculated median for each white cell reported in the differential count.
3. **LEGEND:** All Method Median Results are black while the laboratory result is hatched.
4. **QUALITY HISTOGRAM:** Histogram showing the distribution of comments made on the quality of the blood film sent in the survey.
5. **SUMMARY DATA:** This is the result summary comparing the laboratory's result to the All Method Median. Results outside the acceptable range are designated 'High' or 'Low'.
6. **ACCEPTABLE RANGE:** A table listing the acceptable range given to each cell line in the white cell differential count. The acceptable range is based on SD ranges. Some cells, which may not be seen so readily on a blood film may be given an SD +/- an absolute range of 2. For the majority of cell lines that follow a normal distribution, the acceptable range is based on the median. For abnormal cells (Blast, Lymphocytes-abnormal, promonocytes,etc.) where returned results do not follow a normal distribution, the acceptable range is determined using a combination of in-house assessment, clinical diagnosis (where available from the donating institution), and expert opinion. In these cases, the acceptable range for abnormal cells is adjusted on a case by case basis.



Printed Jun 03 12:26:26 2016

Prepared by: RCPAQAP Haematology

Due Date : 25/05/2016

1

Participant Number

Summary of Your Data to Date

M - Median, R - Your results

	16-01		16-02		16-03		16-04		16-05		16-06	16-07	16-08	16-09	16-10	16-11	16-12
	M	R	M	R	M	R	M	R	M	R							
Neutrophils	58	59	47	44	42	33	53	47	56	59							
Lymphocytes	34	32	22	26	44	53	39	40	35	34							
Monocytes	6	6	6	9	8	10	5	6	5	2							
Eosinophils	1	2	1	1	4	3	2	5	4	5							
Basophils	0	1	0	0	1	1	1	2	1	0							
Blasts	0	0	0	0	0	0	0	0	0	0							
Promyelocytes	0	0	0	0	0	0	0	0	0	0							
Myelocytes	0	0	0	0	0	0	0	0	0	0							
Metamyelocytes	0	0	0	0	0	0	0	0	0	0							
Atypical	0	0	0		0	0	0	0	0	0							
Other	0	0	22	20	0	0	0	0	0	0							
NRBC	0	0	2	3	0	0	0	0	0	0							

Result Commentary:
BLOOD FILM DIFFERENTIAL (BF16-05)

2

WCC = 5.37 x 10^9/L Hb = 122.0 g/L MCV = 68.0 fL PLT = 194.0 x 10^9/L

Automated Differential reported: NEUT = 55.8 % LYMPH = 33.8 % MONO = 5.0 % EOS = 4.8 % BASO = 0.6 %

	Neutrophil %	Lymphocyte %	Monocyte %	Eosinophil%	Basophil%	Myelocyte %	Metamyelocyte %	Atypical %	Other %
MEDIAN	56.0	35.0	5.0	4.0	0.0	0.0	0.0	0.0	0.0
MEAN	55.6	34.7	4.7	3.8	0.3	0.0	0.0	0.0	0.0
SD	3.9	3.9	1.8	1.5	0.5	0.0	0.0	0.0	0.0
CV	7.0	11.3	37.5	40.5	n/a	0.0	0.0	0.0	0.0
LOWEST RESULT	40	14	0	0	0	0	0	0	0
HIGHEST RESULT	72	50	12	11	3	4	3	7	1

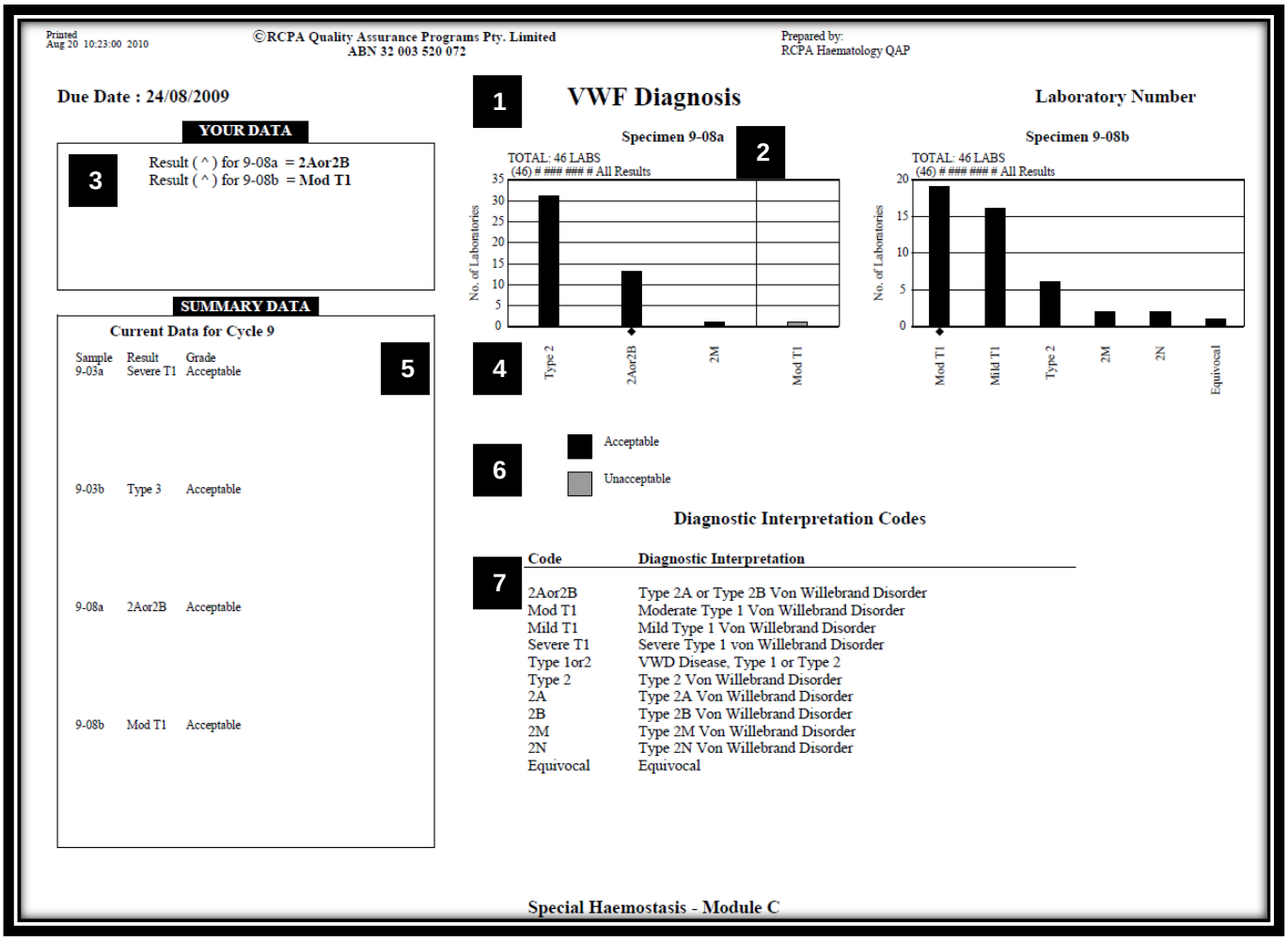
There is good consensus between the median results of the manual differential and the automated differential count. A minor group of laboratories reported "Atypical" cells, and our quality control process did not reveal these cells in the manual differential count. If you reported >5% Atypicals we recommend that you review your differential count.

Participants are again reminded that if you feel the quality of the film in general is precluding you from easily identifiying and counting the cells, please contact the RCPAQAP Haematology for a replacement slide.

Blood Film Differential

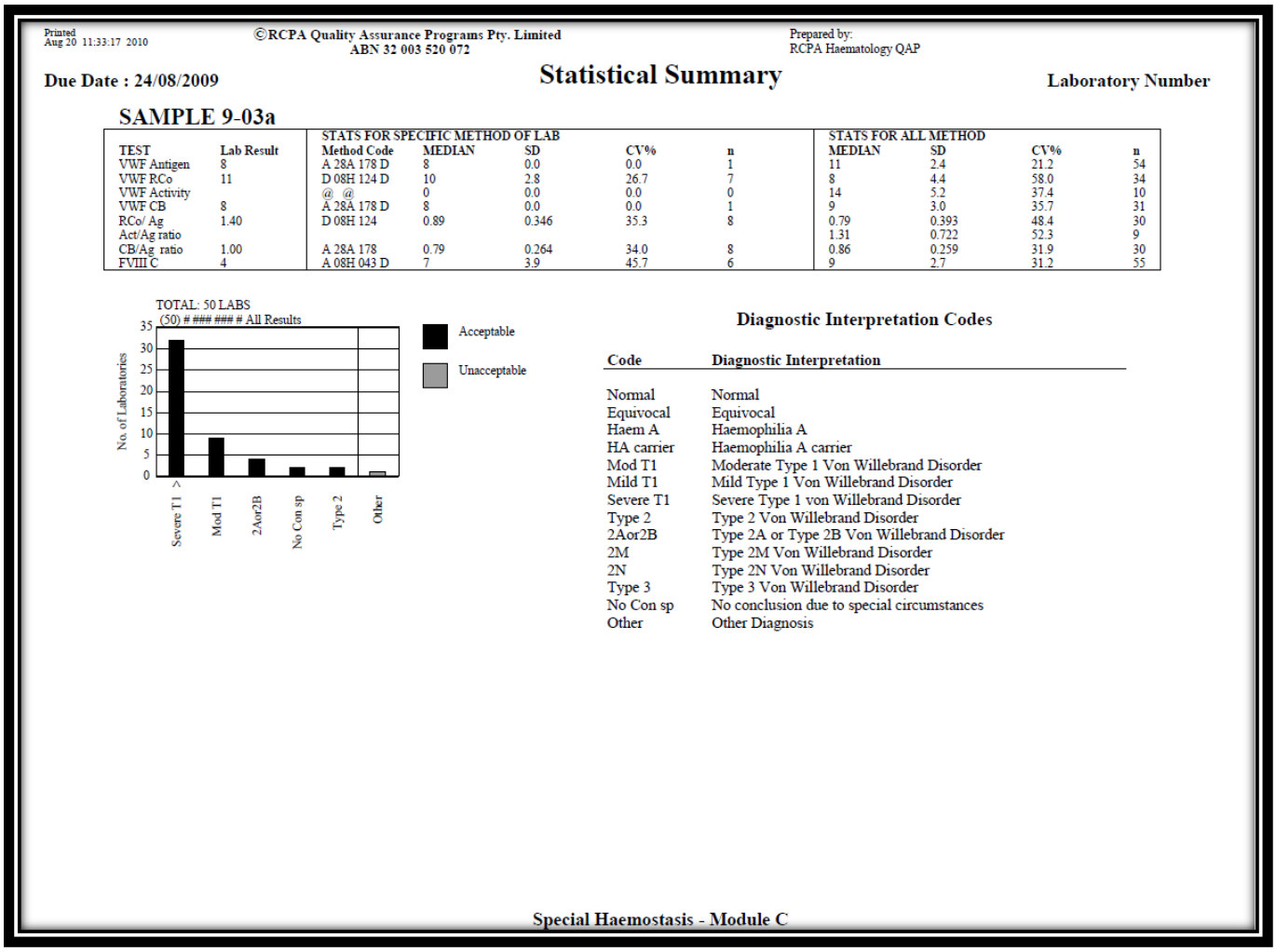
1. **SUMMARY OF DATA TO DATE:** A complete record of data for the cycle. The “M” column will indicate all method median result and the “R” column is the laboratory’s result. Results outside the acceptable range are designated ‘High’ or ‘Low’.
2. **RESULT COMMENTARY:** The FBC indices and clinical history (if relevant) are available is the ‘Result Commentary’ section. An automated differential count is also made available so laboratories can compare to their manual differential count. A statistical analysis is also presented for the different cell lines

Report - Special Haemostasis Program (SA, SB, SC, SD, SF, SG)



The 'Diagnosis' page used in Module A (Lupus anticoagulant) and Module C (VWF) contains histograms of the diagnostic interpretations for the specimen issued in the survey. This histogram indicates whether the result interpretations are acceptable or unacceptable. Participant's result indicated with a (♦). A list of codes is presented at the bottom of the page with the full description of the shortcut code shown on the histogram.

1. **TEST:** The test name.
2. **SAMPLE:** Illustrates the sample number used for the run.
3. **RESULT:** Laboratory result for each sample.
4. **DIAGNOSIS HISTOGRAM:** Histogram showing the distribution of diagnostic comments made showing acceptable and unacceptable comments. The comments are split into the two categories by a vertical line in the histogram.
5. **SUMMARY DATA:** This is the result summary listing the laboratory result and showing if acceptable or unacceptable.
6. **GRADING:** Grading used for the diagnostic interpretations for the exercise.
7. **DIAGNOSTIC INTERPRETATION CODES:** A list of all diagnostic interpretations, listing the short and full descriptions.



Printed Aug 20 11:33:17 2010

Prepared by:
RCPA Haematology QAP

Due Date : 24/08/2009

Statistical Summary

Laboratory Number

SAMPLE 9-03a

TEST	Lab Result	STATS FOR SPECIFIC METHOD OF LAB Method Code	MEDIAN	SD	CV%	n	STATS FOR ALL METHOD MEDIAN	SD	CV%	n
VWF Antigen	8	A 28A 178 D	8	0.0	0.0	1	11	2.4	21.2	54
VWF RCo	11	D 08H 124 D	10	2.8	26.7	7	8	4.4	58.0	34
VWF Activity		@ @	0	0.0	0.0	0	14	5.2	37.4	10
VWF CB	8	A 28A 178 D	8	0.0	0.0	1	9	3.0	35.7	31
RCo/ Ag	1.40	D 08H 124	0.89	0.346	35.3	8	0.79	0.393	48.4	30
Act/Ag ratio							1.31	0.722	52.3	9
CB/Ag ratio	1.00	A 28A 178	0.79	0.264	34.0	8	0.86	0.259	31.9	30
FVIII C	4	A 08H 043 D	7	3.9	45.7	6	9	2.7	31.2	55

Diagnostic Interpretation Codes

Code	Diagnostic Interpretation
Normal	Normal
Equivocal	Equivocal
Haem A	Haemophilia A
HA carrier	Haemophilia A carrier
Mod T1	Moderate Type 1 Von Willebrand Disorder
Mild T1	Mild Type 1 Von Willebrand Disorder
Severe T1	Severe Type 1 von Willebrand Disorder
Type 2	Type 2 Von Willebrand Disorder
2Aor2B	Type 2A or Type 2B Von Willebrand Disorder
2M	Type 2M Von Willebrand Disorder
2N	Type 2N Von Willebrand Disorder
Type 3	Type 3 Von Willebrand Disorder
No Con sp	No conclusion due to special circumstances
Other	Other Diagnosis

Special Haemostasis - Module C

Summary of participant's performance for current cycle

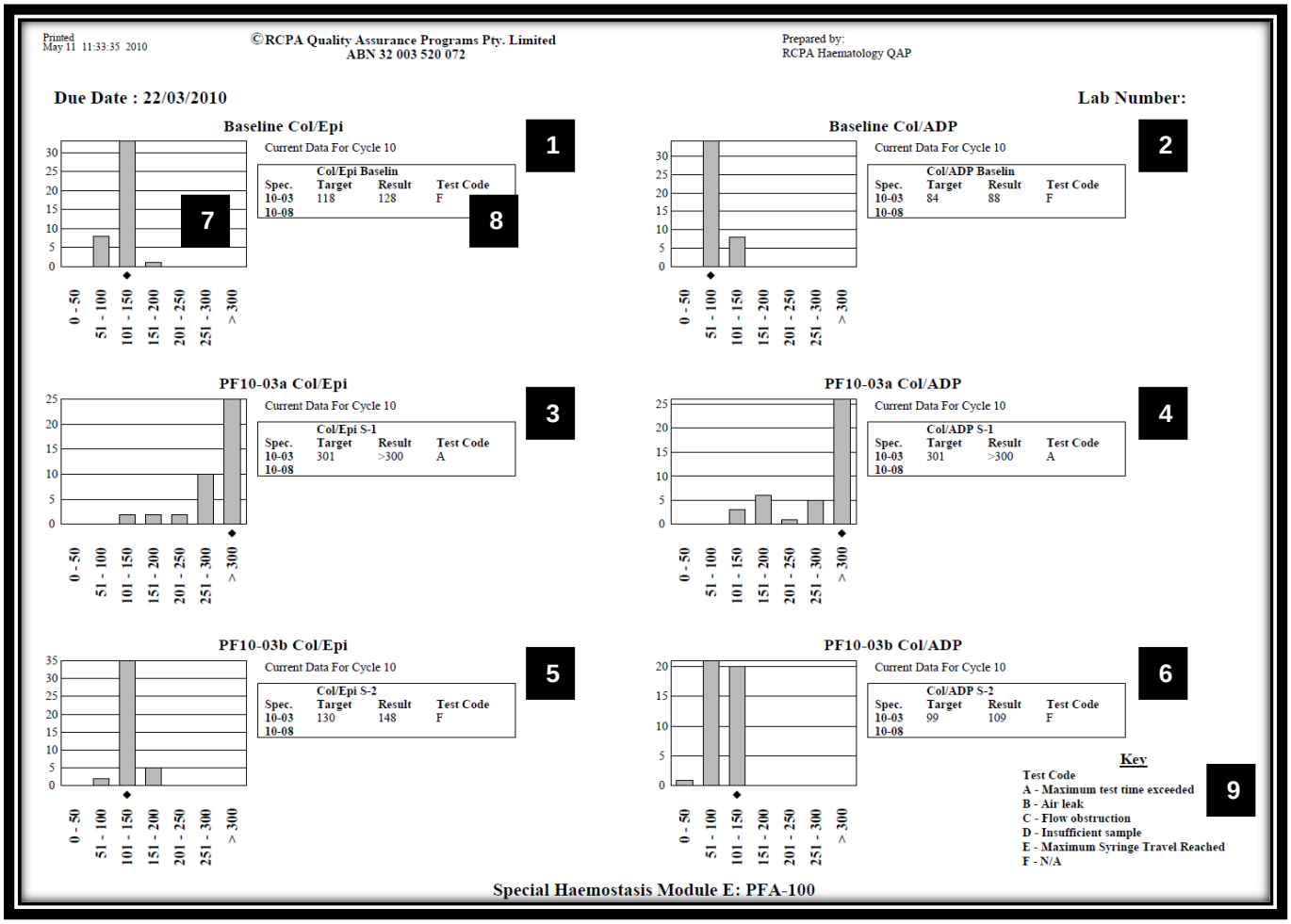
PLEASE NOTE: The quantitative evaluation for the Special Haemostasis tests uses the same principle as the Haemostasis program, where 2 samples are used to produce Youden plots, distribution histograms, Levey Jennings type plots and linearity graphs. The qualitative evaluation for interpretation of test results is also the same as the

Haemostasis program.
The cumulative summary of data for the cycle will also be illustrated.
The last page of your report is a summary page, which will list any result that has been outside the analytical performance specifications.

The Special Haemostasis Program also offers in the survey report a summary of the participant's performance for specimens submitted to date for the current cycle (above).

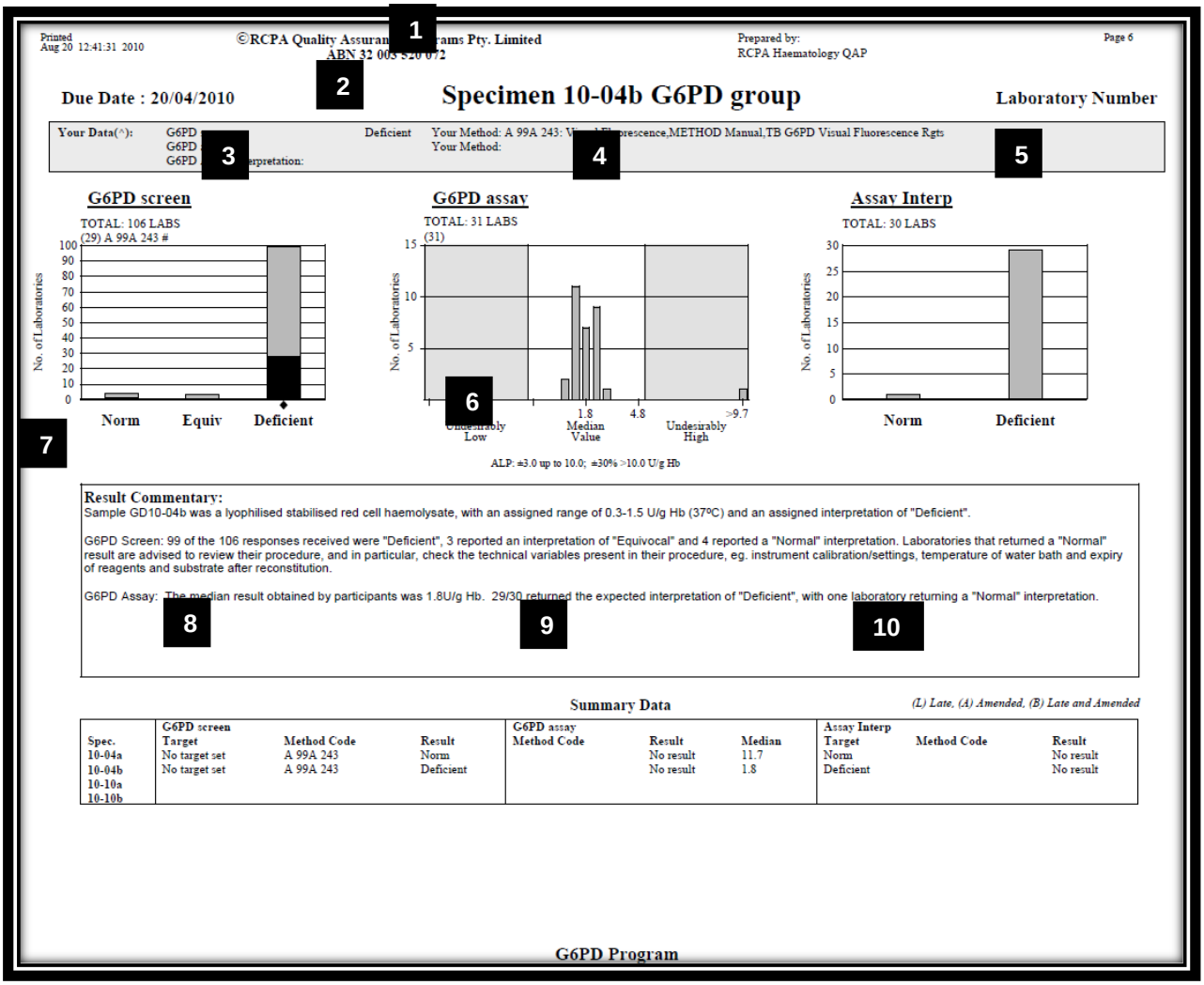
Modules A, B, C & D: A result commentary is provided on the nature of the samples and the performance of laboratories.

Survey Report - Special Haemostasis Program (SE)



1. Baseline results for Col/Epi.
2. Baseline results for Col/ADP.
3. Participant results for Sample 1(PF10-03a), using Col/Epi cartridge.
4. Participant results for Sample 1(PF10-03a), using Col/ADP cartridge.
5. Participant results for Sample 2(PF10-03b), using Col/Epi cartridge.
6. Participant results for Sample 2(PF10-03b), using Col/ADP cartridge.
7. Histograms have been used to review the results returned by laboratories, which have been grouped in bars of 50. The diamond represents the laboratory's result.
8. Summary of results, which will compare the target result with your result as well as the "Test Code" issued by your laboratory for that test cartridge. The target result is the median of all results returned.
9. The key displays the meaning for each "Test Code" reported by laboratories. Test code **"F"** (not applicable) is the default code if no other code is entered by the participant.

Survey Report - G6PD (Glucose 6 Phosphate Dehydrogenase)) *(the report example below is produced from the legacy software). In 2021 the program will be hosted on the eQuality platform and the report will take on the standardised format. A full explanation of the report will be available on the myQAP help page, once the first survey report is available.*



1. **TEST:** The specimen number and test.
2. **RESULTS:** The results reported for the specimen and the Method Classification submitted to the Haematology QAP.
3. **G6PD SCREEN - HISTOGRAM:** Distribution of results for the G6PD screen. Highlighted in black are the interpretation of results from users that have the same method classification, (♦) indicates a participant's result within the distribution.
4. **G6PD ASSAY RESULT HISTOGRAM:** Distribution of results compared to the median. This histogram will also indicate the undesirably high and low areas, highlighting the participant's result within the distribution with a (^).
5. **G6PD ASSAY - HISTOGRAM:** Distribution of results for the G6PD assay. Highlighted in black are the interpretation of results from users that have the same method classification, (♦) indicates participants result within the distribution**.**
6. **ANALYTICAL PERFORMANCE SPECIFICATIONS:** APS set for the G6PD assay results.
7. **COMMENTARY:** Comments which reflect the performance of the laboratories

8. **SUMMARY OF RESULTS - G6PD SCREEN:** Summary of the laboratory's results, which lists the method classification and the expected interpretation.
9. **SUMMARY OF RESULTS - G6PD ASSAY (quantitative):** Summary of the laboratory's results, which lists the method classification and the median result.
10. **SUMMARY OF RESULTS - G6PD ASSAY (qualitative):** Summary of the laboratory's results, which lists the method classification and the expected (target) interpretation.

ASSESSMENT OF PERFORMANCE – End of Cycle

This report is available for all measurands / tests with more than 6 specimens in a cycle (legacy software).

Note: *The survey reports produced from the eQuality platform now incorporate components of the legacy "end of cycle" reports to measure accuracy and precision. The survey reports display how accurate and precise survey results are over consecutive survey runs in every report. Report examples produced from the eQuality platform can be found on the myQAP help page.*

At the end of a cycle of specimens three reports are generated to allow your laboratory to have all the information at hand to completely review your analytical performance. These are the End of Cycle Report, the Error Analysis Report and the Performance Summary Report.

The End of Cycle Report provides useful information on the major components of error, bias and imprecision and also provides comprehensive peer review and summary data for participants. The Error Analysis Report highlights measurands / tests with one or more results outside the Analytical Performance Specifications. This report will not be issued if you have no results outside acceptable limits for the cycle. The Performance Summary Report is designed to allow quick assessment of an entire cycle of results and to identify measurands / tests that may need closer attention.

End of Cycle Report

At the end of each cycle of specimens an End of cycle report is prepared providing a comparison of a laboratory's results and derived statistics with other participants. Comparisons are made with all participants and those using the same principle, instrument, reagent and combination of analytical principle, instrument and reagent.

The data submitted for the cycle is recorded in the "Data Summary Table". Any method code changes, high or low results and late or amended results will be shown. Only data with exactly the same method code as the last pair of specimens is included in the End of cycle statistics. The basis for the calculations is simple least squares regression analysis of the results compared to median values.

A linearity graph plots a laboratory's data on the vertical axis against the median values for each specimen on the horizontal axis. The acceptable range of results, calculated from the Analytical Performance Specifications and the line of agreement (45 degree line) are shown. The line of best fit, slope and intercept and the laboratory's line of best fit values at the lowest and highest values are recorded.

Imprecision is summarised in two bar graphs: namely Standard Deviation and Coefficient of Variation. Using the coefficient of variation "corrects" for differences in concentration and so may be a better assessment of imprecision. The CV is the SD divided by the midpoint of the Laboratory's range of concentrations, expressed as a percentage.

The inaccuracy is summarised in the Average bias bar graph using the average bias of the laboratory's line of best fit at the lowest, highest and mid-point.

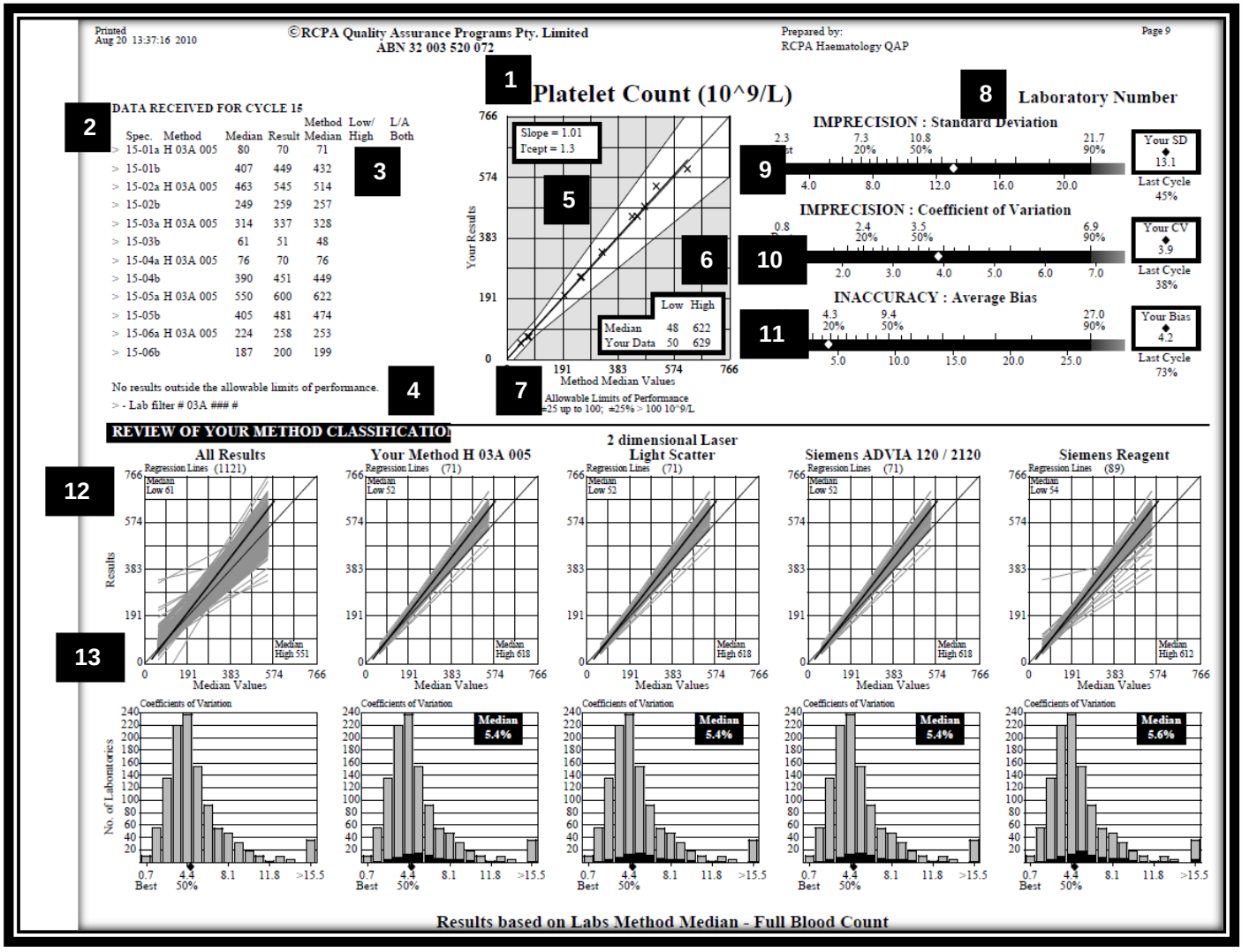
A review of the laboratory's method classification occurs using two graphs, Regression Lines and Coefficients of Variation to summarise the performance of a laboratory compared to that of all participants and to laboratories using the same or similar analytical systems. All results and selected subgroups of data, based on information provided in the method classification, are plotted as follows:

Regression Lines

The line of agreement and the individual regression lines of selected laboratories are plotted. Regression statistics are calculated and the laboratory's line of best fit is printed.

Coefficients of Variation

Histograms plotting the coefficients of variation of all participants. Data from all selected subgroups is highlighted in black and the median CV for this group is printed.
The End of cycle calculations provide a database for reviewing analytical principles, instruments, reagents and calibrators and are useful in showing the number of laboratories using particular systems. This data is printed in table format on the back of the laboratory report for each measurand.



1. **MEASURAND/TEST and UNITS:** The full name of the measurand or test and units of measure
2. **SUMMARY:** Summary of data submitted for the cycle. Method codes will be shown, showing any changes made in the cycle. If there is a method code change in the last pair of specimens, it will not be included in the 'End of Cycle' calculations
3. **COMMENTS:** Low, High, Amended or Late comments
4. **TOTAL COMMENT:** Comment, indicating the number of results outside acceptable limits or if the method codes have been altered

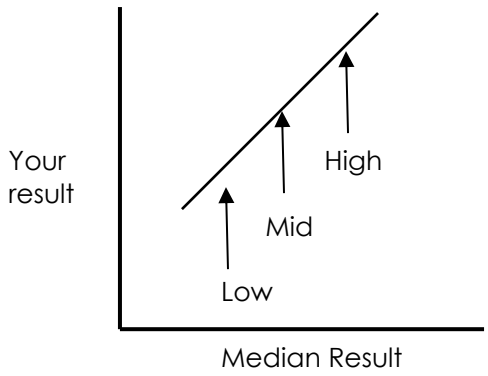
5. **LINEARITY GRAPH:** Simple least square linear regression analysis compared to the test median result is used for 'End of Cycle' calculations. The slope and intercept are recorded and your laboratory's line of best fit values at the lowest and highest values are shown. Individual data points and the line of best fit for your laboratory are shown in comparison to the line of agreement. Results outside the Analytical Performance Specifications fall in the shaded area
6. **SLOPE:** Using the slope and intercept the values of your line of best fit are determined compared to the lowest and highest target values for the cycle
7. **ANALYTICAL PERFORMANCE SPECIFICATIONS:** Unique for each measurand / test. These have been set based on clinical and statistical requirements
8. **BAR GRAPHS:** The standard deviation, coefficient of variation and average bias are summarised in bar graphs. Two scales appear on each bar graph. The lower scale is linear in the units of the statistics. The upper scale shows the percentile ranking, highlights the best, 20th, 50th and 90th percentiles and indicates the value of the statistic at this percentile. Your laboratory's statistic, (◊), is plotted within the bar and is recorded in the box with the percentile ranking for the last cycle recorded beneath the box (no ranking will be recorded beneath the box for the first cycle)
9. **STANDARD DEVIATION:** The Standard error of the estimate Sy.x can be regarded as the average standard deviation across the range of concentrations analysed. Standard deviation provides a value in the units of the test.
10. **COEFFICIENT OF VARIATION:** The SD divided by the mid-point of your laboratory's range of concentrations, expressed as a percentage.

$$CV\% = \frac{SD}{\frac{\text{Low value + High value}}{2}} \times 100$$

Please note: Using the (low lab value + high lab value)/2 will approximate the mean in a good set of linearly related results.

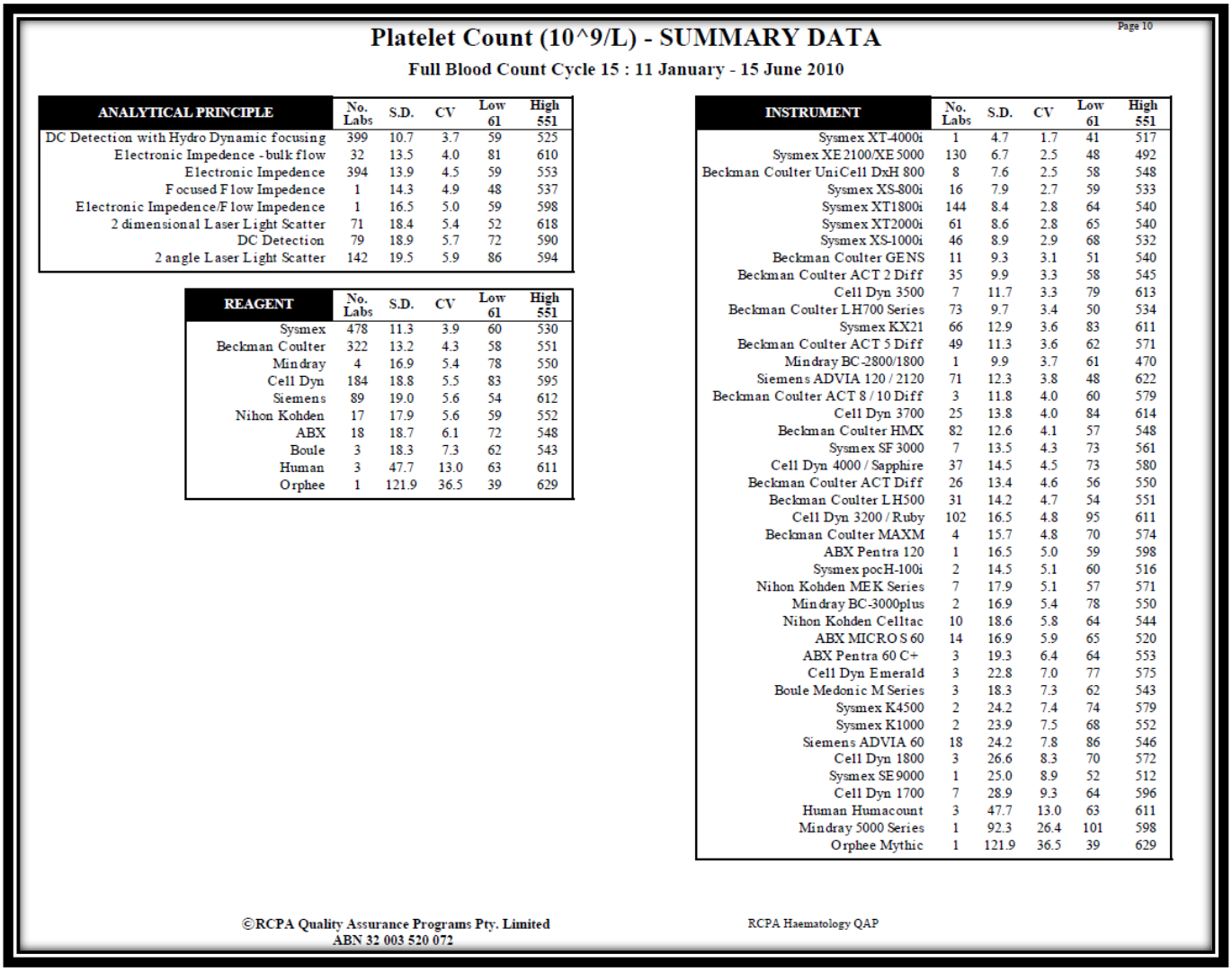
11. **AVERAGE BIAS:** Your bias at the low value, high value and mid value is determined. These are the differences between the line of expectation (45o line) and your line of best fit.

$$\text{Average bias} = \frac{\text{LOW BIAS + MID BIAS + HIGH BIAS}}{3}$$



12. **REGRESSION LINE REVIEW:** Plots of the line of best fit of selected laboratories highlighting your laboratory's line of best fit and showing the line of agreement. The number of laboratories in each group is shown in brackets. The low and high median for each subgroup is shown in the top left and bottom right corner. The graphs provide a summary of the accuracy of your laboratory and the laboratories selected in each subgroup.

13. **COEFFICIENT OF VARIATION:** A histogram showing the distribution of CV's for all laboratories and highlighting your laboratory's CV (♦). Histograms showing subgroups of data are superimposed in black on the columns and the median value of the precision of the laboratory and the laboratories selected in each sub group.



Platelet Count (10^9/L) - SUMMARY DATA

Page 10

Full Blood Count Cycle 15 : 11 January - 15 June 2010

ANALYTICAL PRINCIPLE	No. Labs	S.D.	CV	Low 61	High 551
DC Detection with Hydro Dynamic focusing	399	10.7	3.7	59	525
Electronic Impedence - bulk flow	32	13.5	4.0	81	610
Electronic Impedence	394	13.9	4.5	59	553
Focused Flow Impedence	1	14.3	4.9	48	537
Electronic Impedence/Flow Impedence	1	16.5	5.0	59	598
2 dimensional Laser Light Scatter	71	18.4	5.4	52	618
DC Detection	79	18.9	5.7	72	590
2 angle Laser Light Scatter	142	19.5	5.9	86	594

REAGENT	No. Labs	S.D.	CV	Low 61	High 551
Sysmex	478	11.3	3.9	60	530
Beckman Coulter	322	13.2	4.3	58	551
Mindray	4	16.9	5.4	78	550
Cell Dyn	184	18.8	5.5	83	595
Siemens	89	19.0	5.6	54	612
Nihon Kohden	17	17.9	5.6	59	552
ABX	18	18.7	6.1	72	548
Boule	3	18.3	7.3	62	543
Human	3	47.7	13.0	63	611
Orphee	1	121.9	36.5	39	629

INSTRUMENT	No. Labs	S.D.	CV	Low 61	High 551
Sysmex XT-4000i	1	4.7	1.7	41	517
Sysmex XE 2100/XE 5000	130	6.7	2.5	48	492
Beckman Coulter UniCell DxH 800	8	7.6	2.5	58	548
Sysmex XS-800i	16	7.9	2.7	59	533
Sysmex XT1800i	144	8.4	2.8	64	540
Sysmex XT2000i	61	8.6	2.8	65	540
Sysmex XS-1000i	46	8.9	2.9	68	532
Beckman Coulter GENS	11	9.3	3.1	51	540
Beckman Coulter ACT 2 Diff	35	9.9	3.3	58	545
Cell Dyn 3500	7	11.7	3.3	79	613
Beckman Coulter LH700 Series	73	9.7	3.4	50	534
Sysmex KX21	66	12.9	3.6	83	611
Beckman Coulter ACT 5 Diff	49	11.3	3.6	62	571
Mindray BC-2800/1800	1	9.9	3.7	61	470
Siemens ADVIA 120 / 2120	71	12.3	3.8	48	622
Beckman Coulter ACT 8 / 10 Diff	3	11.8	4.0	60	579
Cell Dyn 3700	25	13.8	4.0	84	614
Beckman Coulter HMX	82	12.6	4.1	57	548
Sysmex SF 3000	7	13.5	4.3	73	561
Cell Dyn 4000 / Sapphire	37	14.5	4.5	73	580
Beckman Coulter ACT Diff	26	13.4	4.6	56	550
Beckman Coulter LH500	31	14.2	4.7	54	551
Cell Dyn 3200 / Ruby	102	16.5	4.8	95	611
Beckman Coulter MAXM	4	15.7	4.8	70	574
ABX Pentra 120	1	16.5	5.0	59	598
Sysmex pocH-100i	2	14.5	5.1	60	516
Nihon Kohden MEK Series	7	17.9	5.1	57	571
Mindray BC-3000plus	2	16.9	5.4	78	550
Nihon Kohden Celltac	10	18.6	5.8	64	544
ABX MICROS 60	14	16.9	5.9	65	520
ABX Pentra 60 C+	3	19.3	6.4	64	553
Cell Dyn Emerald	3	22.8	7.0	77	575
Boule Medonic M Series	3	18.3	7.3	62	543
Sysmex K4500	2	24.2	7.4	74	579
Sysmex K1000	2	23.9	7.5	68	552
Siemens ADVIA 60	18	24.2	7.8	86	546
Cell Dyn 1800	3	26.6	8.3	70	572
Sysmex SE 9000	1	25.0	8.9	52	512
Cell Dyn 1700	7	28.9	9.3	64	596
Human Humacount	3	47.7	13.0	63	611
Mindray 5000 Series	1	92.3	26.4	101	598
Orphee Mythic	1	121.9	36.5	39	629

RCPA Haematology QAP

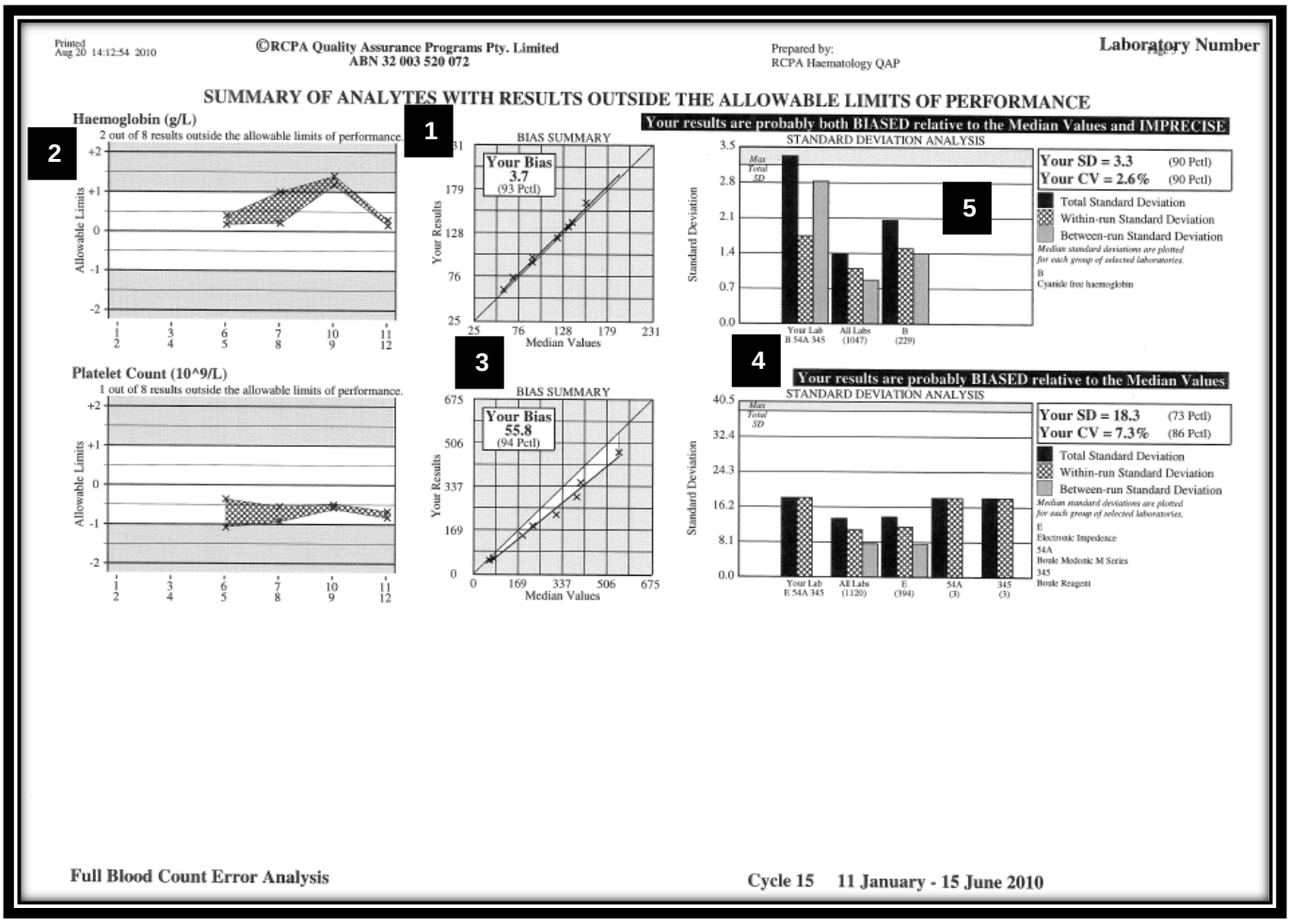
Summary Data

The 'End of Cycle' calculations provide a review of methods, instruments and reagents. This data is printed on the back of the laboratory report for each parameter.

The data is summarised into the Analytical Principle, Measurement System (Instrument) and the Reagent Source. The information shows the number of laboratories in each group, the median standard deviation of the group, the median CV of the group and the median LOW and HIGH values compared to the appropriate median value.

Error Analysis Report

The 'Error Analysis' report highlights measurands / tests with one or more result outside the APS. This report will not be issued if there are no results outside APS for the cycle.



1. **OUTLIERS:** Number of 'outliers' and the results returned.
2. **LEVY JENNINGS PLOTS:** Summarises the reported results.
3. **BIAS SUMMARY:** Your bias at the low value, high value and mid value are determined. These are the differences between the line expectation and your line of best fit. The average bias is then calculated as indicated by the formula.

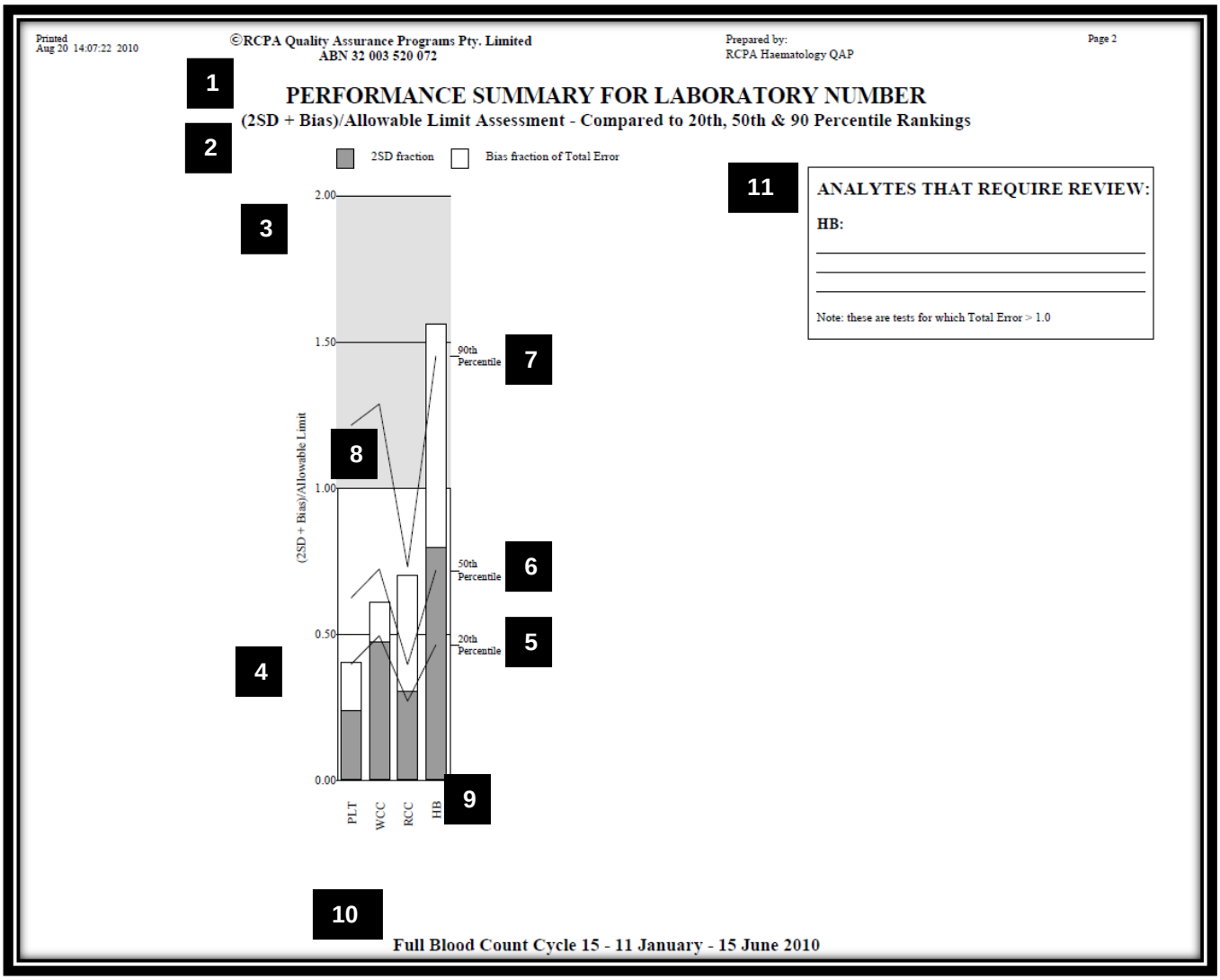
$$\frac{\text{LOW BIAS + MID BIAS + HIGH BIAS}}{3}$$

The bias summary plots your results against the expected values showing each result, your line of best fit, your bias and the percentile ranking (Pctl) of your bias relative to the biases of all participants.

4. **STANDARD DEVIATION ANALYSIS PLOT:** The linear regression standard deviation, which is calculated using each of the results returned, which is Sy.x (standard error of the estimate).
5. **STANDARD DEVIATION COLUMN GRAPHS:** Your first set of three columns shows your total standard deviation (black), your within run standard deviation (hatched) and your between run standard deviation (grey). The median standard deviations and the number of laboratories in each group are plotted for all laboratories, laboratories using the same principle, laboratories using the same analyser as your laboratory and laboratories using the same reagent as your laboratory.

Performance Summary Report

A single page summary report showing analytical performance of all measurands / tests submitted by your laboratory. Measurands / tests are ranked from best to worst, providing the 20th, 50th and 90th percentile performance of all participants for peer review.



1. **TITLE:** Participant number
2. **ASSESSMENT CRITERIA:** Defined as measurands / test performance. Analytical error is due to both imprecision and bias and here Total Error has been defined as follows.

$$Total\ Error = 2SD + Bias$$

The quality of your laboratory's performance is then determined by comparing the Total Error to the Analytical Performance Specification at the Mid-Point of the range concentrations:

$$Measurand\ Performance = \frac{2SD + Bias}{Analytical\ Performance\ Specification}$$

The examples below are to assist you in understanding the method of assessment

FBC specimen is as follows for WCC:

Median low = 2.5 *Median high = 25.5* *Midpoint concentration = 14*

APS WCC = +/- 0.5 up to 5.0 x 10^9/L, +/- 10% when greater than 5.0 x 10^9/L

The Analytical Performance Specification for the WCC = 1.4

LAB RESULTS:

SD = 0.26 x 10^9/L *Bias = 0.52 x 10^9/L* *Total Error = (2 x 0.26) + 0.52 = 1.04*

Test Performance *= 1.04 / 1.4 = 0.7*

When the total error is less than the Analytical Performance Specification then the parameter performance will be less than 1.0. This is the desired level of performance.

3. **GRAPHICAL PRESENTATION:** Each measurand / test performance is plotted as a column where the relative contribution of precision (2SD) appears as a shaded grey area and the bias appears as a clear area.
4. **LEVEL OF PERFORMANCE:** A scale using the measurand / test performance is on the left y axis (numerical scale). The right y axis shows the 20th, 50th and 90th percentile values. Measurands / test performance is determined for all participants and then the 20th, 50th and 90th percentile values are plotted for comparative purposes and peer review. The percentile performances are displayed by use of a line graph for each parameter as follows:
5. **20th PERCENTILE:**
6. **50th PERCENTILE:**
7. **90th PERCENTILE:**
8. **DESIRABLE LEVEL OF PERFORMANCE:** Set as less than 1.0. The shading when performance is above 1.0 highlights the tests that may require attention.
9. **MEASURANDS / TESTS:** Plotted in ascending order of your performance. Best to worst on the right.
10. **PROGRAM NAME:** Name of the program and the cycle number being summarised including the ending dates of the cycle. Also indicates whether results have been based on your Method Classification Medians, or are being compared to the All Method Medians.
11. **MEASURANDS FOR REVIEW:** Where Total Error > 1.0

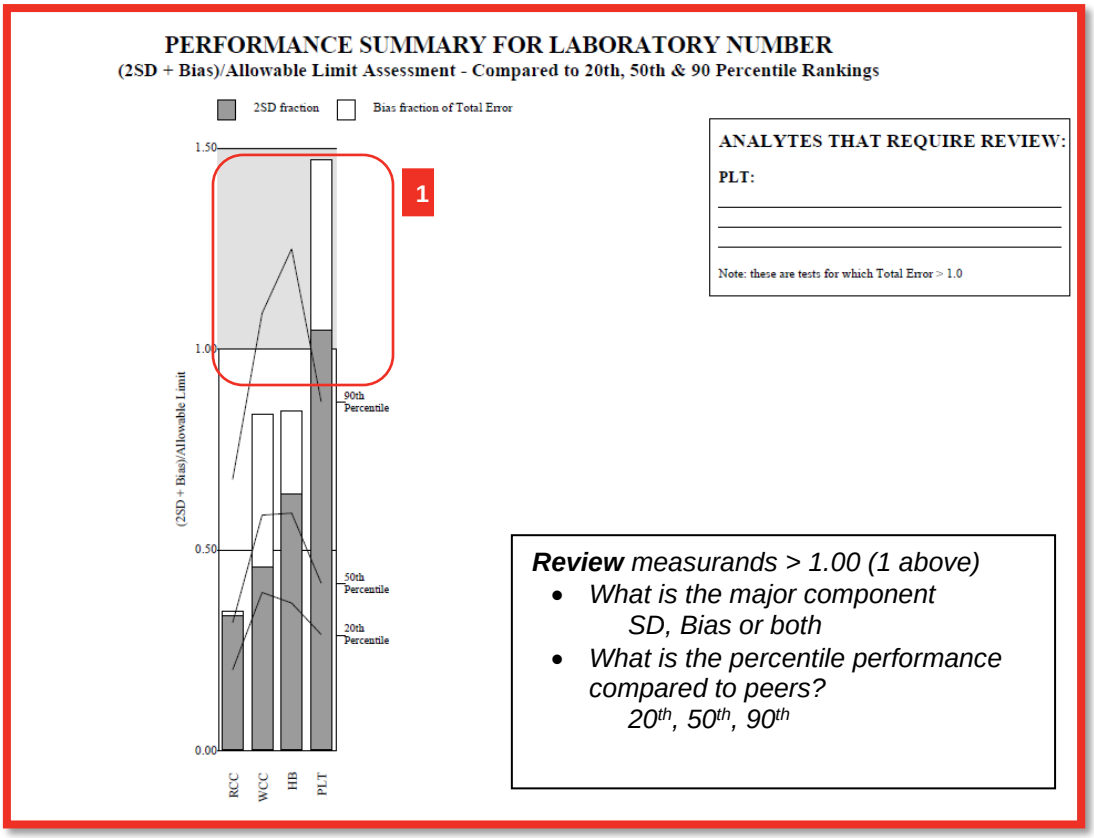
Please Note: Laboratories will be issued with a ‘Certificate of Participation’ at the end of each cycle for each program.

Laboratories that use FBC instruments that sphere red blood cells before passing through the aperture will obtain lower MCV results and will experience extreme bias because of this, and these are not used to calculate end of cycle statistics. The Haematocrit is also not used for end of cycle statistics as this is a calculated parameter.

If your laboratory has changed its method classification in the last run of the cycle, there will be insufficient data to obtain ‘End of Cycle’ statistics for the new classification.

Quantitative End of Cycle Report Interpretation Guide

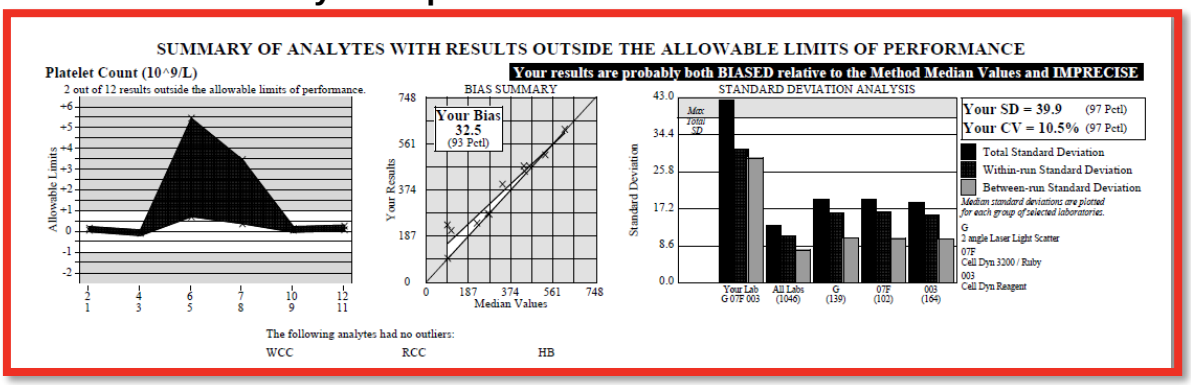
PART A – Performance Summary



Review *measurands > 1.00 (1 above)*

- *What is the major component*
  SD, Bias or both
- *What is the percentile performance compared to peers?*
  20th, 50th, 90th

PART B – Error Analysis Report



Is there an Imprecision comment?

Review Standard Deviation Analysis
Within run or between run SD
Compare your SD to
All Labs
Analytical Principle
Instrument
Reagent

Is there a Bias comment?

Review Bias Summary
Your line of best fit
Your bias
Percentile ranking

Review Levey-Jennings Plot

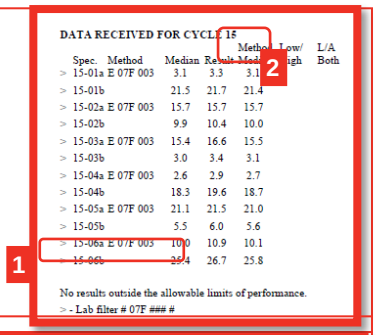
- *Are there any random errors that contribute to imprecision?*
- *Have random errors distorted the line of best fit?*
- *Is there a low/high trend across the cycle?*
- *Has there been a change in trend?*
- *Has there been a change in method?*

PART C – End of Cycle Report

Review Result Summary

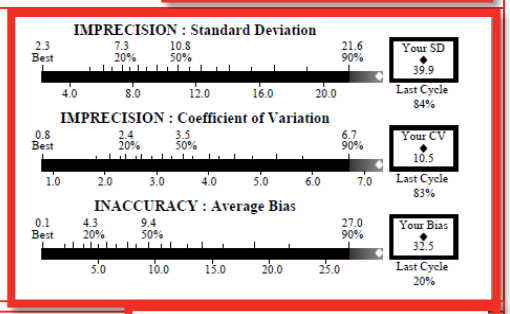
- *Check Lab filter (1) / Check Method Code details are correct*
- *Review results and check random errors causing any outliers (L / H)*

NOTE: If > 10 users in your filtered group - linear regression analysis uses results of "Your" Method Median - Method Median column will appear (2)
If < 10 users in your filtered group – linear regression analysis uses results of "All" Method Median



Review Bar Graphs

- *SD, %CV and Bias*
- *What is your percentile?*

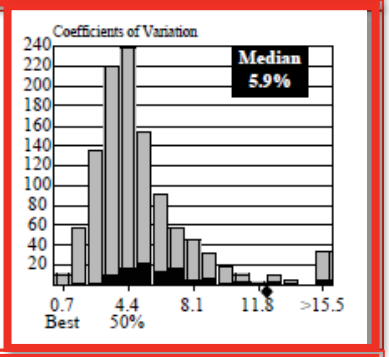


Review Method Classification %CV Histograms

- *All Results*
- *Your method Code, Instrument, Reagent*

Investigate

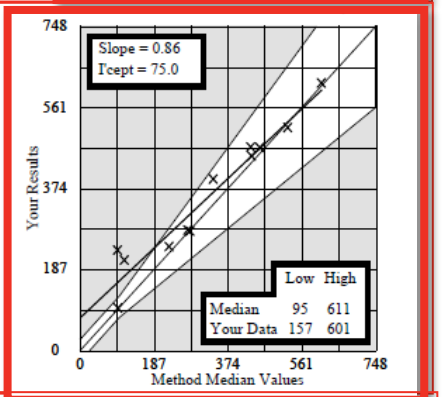
- *Calibrator change*
- *Reagent lot change*
- *Technique change*
- *Instrument maintenance*
- *QA material handling*



Review Linearity Graph

- *Note your slope and intercept*
- *Note your low and high values*
- *Compare to low and high values for your method*

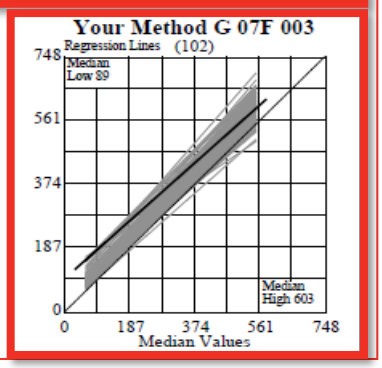
NOTE: Compared to "YOUR" Method Median values (Method filter)
If < 10 users this graph will be compared to the "ALL" Method Median values



Review method Classification Regression Lines

- *All ResultsYour Method Code*
- *Instrument*
- *Reagent*

Are you within your peer group?
NOTE: Compared to "ALL" Method Median values
Also Review Internal QC - look for shifts and trends

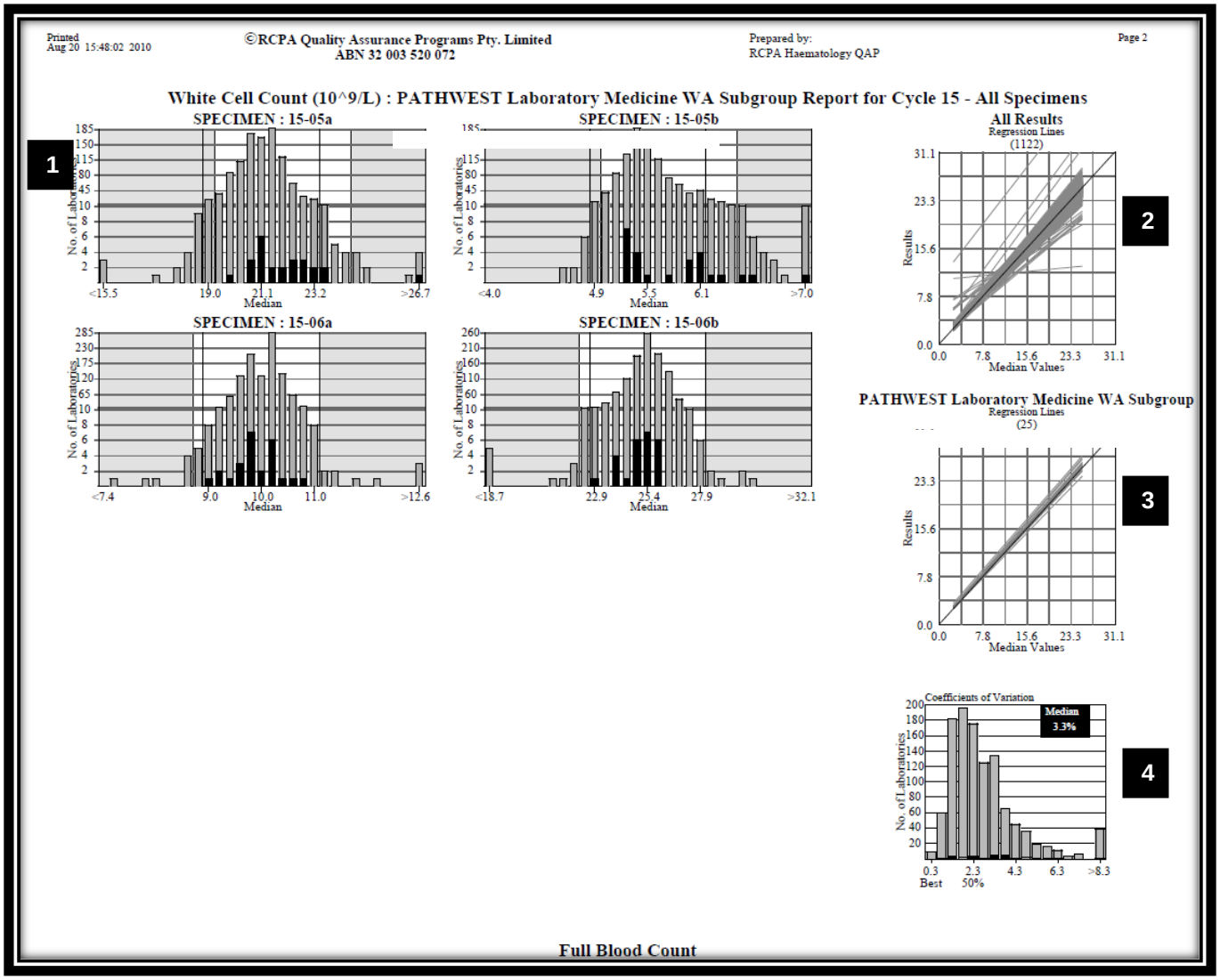


The Quantitative End of Cycle Report Interpretation Flowchart can be found by clicking on this **link**.

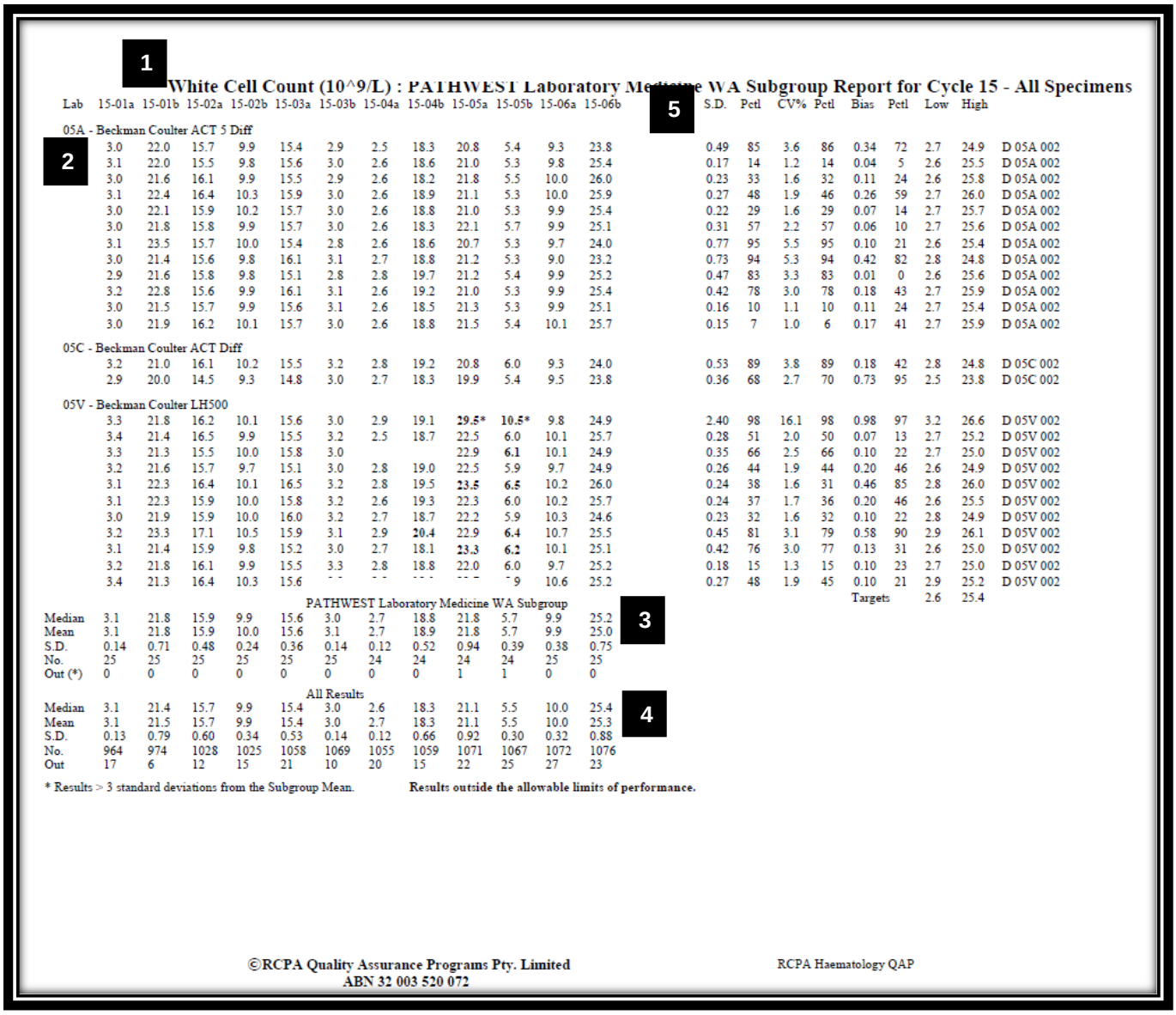
Supervisor Report

Subgroups are composed of participants in the RCPAQAP Haematology who have formed a collaborative group. Each group has a coordinator or supervisor who has the responsibility to disseminate information to members of the group and to maintain confidentiality of results. The Supervisor reports are provided to the coordinator or supervisor of the group after each run of a cycle.

Example of the Supervisor report produced from the eQuality software can be found by clicking on the myQAP help page.



1. **HISTOGRAMS:** The specimen number is located at the top of each histogram. Plots of all results submitted are compared to the All Method Median. The Analytical Performance Specifications range is within the bold central vertical lines. The area not shaded is the acceptable range based on the method group median and Analytical Performance Specifications. Group results are displayed in black.
2. **REGRESSION GRAPH**: All Results: If the End of Cycle data has been calculated the regression lines of all participants are plotted. The number of laboratories submitting results is in brackets.
3. **REGRESSION GRAPH:** Group Data: The regression lines of the group.
4. **COEFFICIENT OF VARIATION:** A histogram of CVs from all participants. Group results are printed in black and the median for the group is provided.



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White Cell Count (10^9/L) : PATHWEST Laboratory Medicine WA Subgroup Report for Cycle 15 - All Specimens

Lab	15-01a	15-01b	15-02a	15-02b	15-03a	15-03b	15-04a	15-04b	15-05a	15-05b	15-06a	15-06b	S.D.	Pctl	CV%	Pctl	Bias	Pctl	Low	High	
05A - Beckman Coulter ACT 5 Diff																					
2	3.0	22.0	15.7	9.9	15.4	2.9	2.5	18.3	20.8	5.4	9.3	23.8	0.49	85	3.6	86	0.34	72	2.7	24.9	D 05A 002
	3.1	22.0	15.5	9.8	15.6	3.0	2.6	18.6	21.0	5.3	9.8	25.4	0.17	14	1.2	14	0.04	5	2.6	25.5	D 05A 002
	3.0	21.6	16.1	9.9	15.5	2.9	2.6	18.2	21.8	5.5	10.0	26.0	0.23	33	1.6	32	0.11	24	2.6	25.8	D 05A 002
	3.1	22.4	16.4	10.3	15.9	3.0	2.6	18.9	21.1	5.3	10.0	25.9	0.27	48	1.9	46	0.26	59	2.7	26.0	D 05A 002
	3.0	22.1	15.9	10.2	15.7	3.0	2.6	18.8	21.0	5.3	9.9	25.4	0.22	29	1.6	29	0.07	14	2.7	25.7	D 05A 002
	3.0	21.8	15.8	9.9	15.7	3.0	2.6	18.3	22.1	5.7	9.9	25.1	0.31	57	2.2	57	0.06	10	2.7	25.6	D 05A 002
	3.1	23.5	15.7	10.0	15.4	2.8	2.6	18.6	20.7	5.3	9.7	24.0	0.77	95	5.5	95	0.10	21	2.6	25.4	D 05A 002
	3.0	21.4	15.6	9.8	16.1	3.1	2.7	18.8	21.2	5.3	9.0	23.2	0.73	94	5.3	94	0.42	82	2.8	24.8	D 05A 002
	2.9	21.6	15.8	9.8	15.1	2.8	2.8	19.7	21.2	5.4	9.9	25.2	0.47	83	3.3	83	0.01	0	2.6	25.6	D 05A 002
	3.2	22.8	15.6	9.9	16.1	3.1	2.6	19.2	21.0	5.3	9.9	25.4	0.42	78	3.0	78	0.18	43	2.7	25.9	D 05A 002
	3.0	21.5	15.7	9.9	15.6	3.1	2.6	18.5	21.3	5.3	9.9	25.1	0.16	10	1.1	10	0.11	24	2.7	25.4	D 05A 002
	3.0	21.9	16.2	10.1	15.7	3.0	2.6	18.8	21.5	5.4	10.1	25.7	0.15	7	1.0	6	0.17	41	2.7	25.9	D 05A 002
05C - Beckman Coulter ACT Diff																					
	3.2	21.0	16.1	10.2	15.5	3.2	2.8	19.2	20.8	6.0	9.3	24.0	0.53	89	3.8	89	0.18	42	2.8	24.8	D 05C 002
	2.9	20.0	14.5	9.3	14.8	3.0	2.7	18.3	19.9	5.4	9.5	23.8	0.36	68	2.7	70	0.73	95	2.5	23.8	D 05C 002
05V - Beckman Coulter LH500																					
	3.3	21.8	16.2	10.1	15.6	3.0	2.9	19.1	**29.5***	**10.5***	9.8	24.9	2.40	98	16.1	98	0.98	97	3.2	26.6	D 05V 002
	3.4	21.4	16.5	9.9	15.5	3.2	2.5	18.7	22.5	6.0	10.1	25.7	0.28	51	2.0	50	0.07	13	2.7	25.2	D 05V 002
	3.3	21.3	15.5	10.0	15.8	3.0			22.9	**6.1**	10.1	24.9	0.35	66	2.5	66	0.10	22	2.7	25.0	D 05V 002
	3.2	21.6	15.7	9.7	15.1	3.0	2.8	19.0	22.5	5.9	9.7	24.9	0.26	44	1.9	44	0.20	46	2.6	24.9	D 05V 002
	3.1	22.3	16.4	10.1	16.5	3.2	2.8	19.5	**23.5**	**6.5**	10.2	26.0	0.24	38	1.6	31	0.46	85	2.8	26.0	D 05V 002
	3.1	22.3	15.9	10.0	15.8	3.2	2.6	19.3	22.3	6.0	10.2	25.7	0.24	37	1.7	36	0.20	46	2.6	25.5	D 05V 002
	3.0	21.9	15.9	10.0	16.0	3.2	2.7	18.7	22.2	5.9	10.3	24.6	0.23	32	1.6	32	0.10	22	2.8	24.9	D 05V 002
	3.2	23.3	17.1	10.5	15.9	3.1	2.9	**20.4**	22.9	**6.4**	10.7	25.5	0.45	81	3.1	79	0.58	90	2.9	26.1	D 05V 002
	3.1	21.4	15.9	9.8	15.2	3.0	2.7	18.1	**23.3**	**6.2**	10.1	25.1	0.42	76	3.0	77	0.13	31	2.6	25.0	D 05V 002
	3.2	21.8	16.1	9.9	15.5	3.3	2.8	18.8	22.0	6.0	9.7	25.2	0.18	15	1.3	15	0.10	23	2.7	25.0	D 05V 002
	3.4	21.3	16.4	10.3	15.6					9	10.6	25.2	0.27	48	1.9	45	0.10	21	2.9	25.2	D 05V 002
																	Targets		2.6	25.4	
PATHWEST Laboratory Medicine WA Subgroup																					
3 Median	3.1	21.8	15.9	9.9	15.6	3.0	2.7	18.8	21.8	5.7	9.9	25.2									
Mean	3.1	21.8	15.9	10.0	15.6	3.1	2.7	18.9	21.8	5.7	9.9	25.0									
S.D.	0.14	0.71	0.48	0.24	0.36	0.14	0.12	0.52	0.94	0.39	0.38	0.75									
No.	25	25	25	25	25	25	24	24	24	24	25	25									
Out (*)	0	0	0	0	0	0	0	0	1	1	0	0									
All Results																					
4 Median	3.1	21.4	15.7	9.9	15.4	3.0	2.6	18.3	21.1	5.5	10.0	25.4									
Mean	3.1	21.5	15.7	9.9	15.4	3.0	2.7	18.3	21.1	5.5	10.0	25.3									
S.D.	0.13	0.79	0.60	0.34	0.53	0.14	0.12	0.66	0.92	0.30	0.32	0.88									
No.	964	974	1028	1025	1058	1069	1055	1059	1071	1067	1072	1076									
Out	17	6	12	15	21	10	20	15	22	25	27	23									

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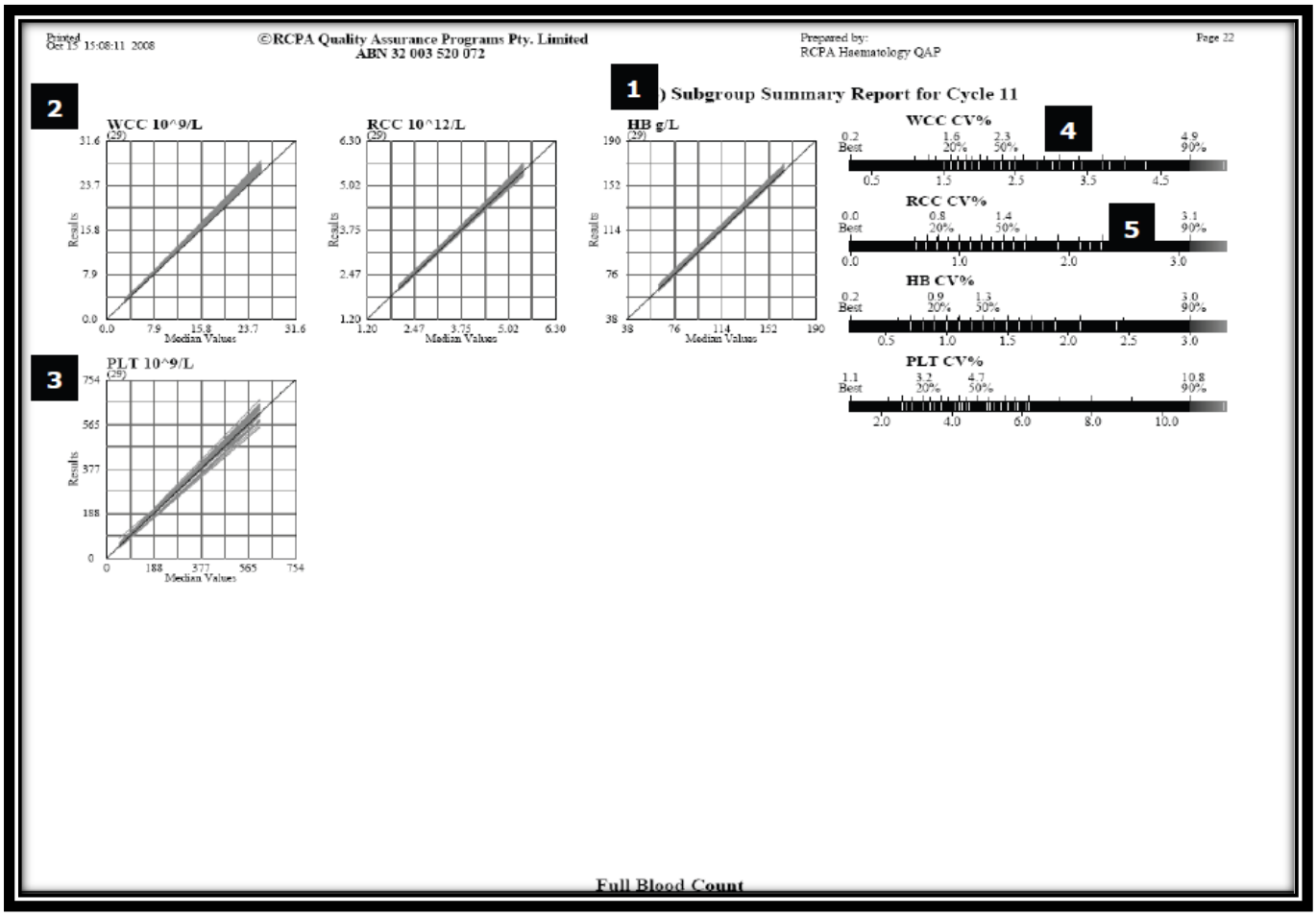
* Results > 3 standard deviations from the Subgroup Mean. **Results outside the allowable limits of performance.**

RCPA Haematology QAP

1. **TITLE:** The group, measurand / test, cycle and specimens being reported.
2. **RAW DATA TABLE:** A table of all data for each specimen number submitted by each laboratory in the group, listed under individual analytical systems. Results greater than the Analytical Performance Specification of performance from the all method median are printed in bold. Results greater than 3 standard deviations from the group mean for the specimen are highlighted with an asterisk (*).
3. **GROUP STATISTICS:** The median, mean and standard deviation of the group results. The number of results included in the mean calculation and the number of outliers (results greater than 3SD from the mean) are provided.
4. **ALL RESULT STATISTICS:** The median, mean and standard deviation of all results. The number of results included in the mean calculation and the number of outliers are provided. The End of Cycle statistics for each participant if available.
5. **IMPRECISION / ACCURACY REVIEW:** SD, SD percentile ranking, coefficient of variation, CV percentile ranking, bias, bias percentile ranking, the low and high values (compared to the low and high all method median values) and the method classification are printed.



Summary plots of each measurand for all laboratories in the group under consideration. These plots give sub group coordinators a graphical review of their group's accuracy and precision in an efficient and effective manner.

1. **TITLE:** The group, cycle and specimens being reported.
2. **MEASURAND AND UNITS:** The measurand and units being summarised.
3. **REGRESSION LINES:** Plots of the lines of best fit of laboratories in the group against the line of best fit for the All Method Median.
4. **MEASURAND CV%:** The measurand being summarised.
5. **COEFFICIENT OF VARIATION:** Each laboratory's CV% is recorded on a bar graph for each measurand.

Haematology Immunophenotyping

Module 1: Case Study Interpretation

This program is for laboratories who provide a Haematology Immunophenotyping service using flow cytometry. Laboratories are requested to use their usual technique to stain and analyse the sample. An image of a stained peripheral blood or bone marrow smear, supplied on the Haematology website, and a brief clinical synopsis are provided. Laboratories are requested to determine the percentage of abnormal cells expressing the relevant antigens and provide a diagnostic interpretation. It is now mandatory for participants to enter their results online via the internet.

Performance Assessment:

Participants are requested to enter their results on line within two weeks of the issue date. A core set of antigens are selected based on a consensus phenotype. Antigens are assessed individually, based on their result distribution profile i.e. where results form a cluster a mean and 2SDs will be applied and results outside this range will be flagged. Where the distribution is variable and a mean +/- 2SD cannot be applied then performance will be based on a consensus. Quantitative responses are not assessed if the results of a marker show variation greater than 50%.

Scatterplots are provided that illustrate results according to instrument/software, gating strategies, fluorochromes and staining reactions obtained from different manufacturers. The summary sheet provides a comprehensive overview of the participants' performance. The group median value is reported as well as the participant's result and interpretation for the antigens tested. A consensus diagnosis and participant diagnosis is also included.

Scatters of laboratory results are provided for the phenotypes required to make a correct diagnosis for the case study issued.

Module 2: PNH testing

This program issues laboratories with 2 samples in each dispatch to ascertain the percentage of the PNH clone in each sample and are expected to provide an interpretation. Participants are issued with a result sheet to record their results.

Performance Assessment:

Participants are requested to return their results within two weeks of the issue date. Participants are asked to report the markers that were used to detect the PNH clones for RBCs and WBCs.
Scatterplots are provided that illustrate results according to the manufacturer of each marker and marker fluorochrome. The summary sheet provides a comprehensive overview of the participants' performance. Assessment of performance is based on the Interpretation only.

CD34+

In 2021 the program will be hosted on the eQuality platform and the report will take on the standardised format. A full explanation of the report will be available on the myQAP help page, once the first survey report is available.

The CD34+ Program offers participants 2 samples of stabilised commercial material in each of 3 surveys per year. Participants are requested to give details of instruments, method and reagents for the "method categories", and to submit results for the WCC, %CD34 and CD34/µl.

To establish performance criteria for laboratories, the median used is calculated from all submitted results, irrespective of the method category. The limits of acceptability are shown below.

WBC less than 5 x 10^9/L, acceptable limit = median +/- 0.5 x 10^9/L

WBC above 5 x 10^9/L, acceptable limit = median +/- 10%

%CD34 below 0.2%, acceptable limit = median +/- 0.05 %CD34

%CD34 above 0.2%, acceptable limit = median +/- 25%

CD34 below 20/µl, acceptable limits = median +/- 5 CD34/µl

CD34 above 20/µl, acceptable limits = median +/- 25%

With the recent formation of the CD34+ Expert Committee, the limits of acceptability will be reviewed to ensure that the range of acceptable results is clinically relevant.

Transfusion

As the Transfusion discipline slowly transitions to the new software platform, some programs will remain to be hosted by the Legacy Software. As reports from the new software (eQuality) become available to be released, a guide to interpret the reports will become available on the myQAP help page.

Survey Report – General Information
Participant results are only assessed if the results on stability testing performed on or after the closing date are acceptable; if stability testing results are deemed unacceptable the survey will not be assessed and participants will be notified in writing. Participant consensus of 80% (or median response on quantitative results) is used to determine the expected survey target, a minimum of ten (10) responses is required to set a consensus target.

AG and AB Assessment (legacy software)

The General and Basic Compatibility module targets and acceptable responses are determined by consensus. The final acceptable responses are at the discretion of the RCPAQAP Transfusion Advisory Committee. Each response is allocated a score which is shown on the report as well as a pointer indicating your result.

Reports will show a table of all responses by method with your response highlighted. A corresponding double bar graph shows how many laboratories supplied results for each method.

Performance assessment is based on a numerical scoring system and the final page of the report indicates the number of points accrued by the laboratory compared to the target score. The scoring system for the general and basic compatibility modules has a maximum number of possible points and participants will lose points for errors. Report features for the basic compatibility module are an Assessment Summary, Cumulative Summary and Assessment scores obtained for each previous survey in the cycle. Report features for the general compatibility module are an Assessment Summary, Performance Level indicator and Assessment score obtained for each previous survey in the cycle.

The General Compatibility and Basic Compatibility modules are assessed separately and reports are designed for prompt identification of areas requiring corrective action.

The tables below show the numeric scoring and performance assessment systems:

GENERAL & BASIC COMPATIBILITY MODULES - PERFORMANCE ASSESSMENT SYSTEM		
Survey Component	**Points per Component (if applicable)**	**Total Points**
Patient Identification	5 points	20 points
Patient Blood Group*	2 points per mandatory reaction 50 points for blood group*	60 points
Patient DAT		20 points
Patient Antibody Screen*		50 points
Patient Antibody Identification		20 points
Phenotyping	5 points per assessed result	Variable
Donor Grouping*	2 point per mandatory reaction 50 points for blood group*	56 points per donor unit
Compatibility - Crossmatch Reaction*	50 points per donor unit	55 points per donor unit
- Transfuse Unit?	5 points per donor unit	

**** Indicates the critical areas of the Transfusion QAP surveys.***

GENERAL COMPATIBILITY MODULE - PERFORMANCE ASSESSMENT LEVELS	
Category Level	**Total Points Loss for Level**
Reference 100 Level	Corresponds to a loss of 0 points
Reference 99 Level	Corresponds to a loss of 1-19 points *(minor errors)*
Operational Level	Corresponds to a loss of 20-49 points *(minor errors)*
Review Level	Corresponds to a loss of 50-99 points *(1 critical error)*
Unsatisfactory Level	Corresponds to a loss of ≥ 100 points *(2 critical errors)*

AG Module: Cumulative Performance Levels:

Cumulative performance level (CPL) is calculated from a six survey cycle regardless of year. Each performance level is weighted and used in the calculation.

Survey Performance Level Weighting:

- Reference 100 Level weighting = 1
- Reference 99 Level weighting = 2
- Operational Level weighting = 3
- Review Level weighting = 4
- Unsatisfactory Level weighting = 5

Cumulative performance level = ∑ (survey performance level for last 6 surveys) divided by 6

- Then rounded up to the closest performance level

Exceptions:

- Unsatisfactory Survey Performance in current survey defaults to Unsatisfactory CPL
- Review Survey Performance Level in current survey defaults to Review CPL
- On the 3rd consecutive Ref 100 Survey Performance Level, the CPL resets to Ref 100

AP Assessment (legacy software)

Participants will be assessed on results submitted only for the Phenotyping module. Participants are expected to provide results for antigens with a method classification listed in our system. New participants and current participants introducing new antigen-testing profiles in their system must ensure the method classification is updated in RCPAQAP Transfusion systems. See 'Method Classifications used in RCPAQAP Transfusion Modules above.

The Phenotyping module targets and acceptable responses are determined by consensus. The final acceptable responses are at the discretion of the RCPAQAP Transfusion Advisory Committee.
Reports show a double bar graph indicating how many laboratories supplied results and the acceptable response for each measurand with your method highlighted in black. A table indicating your response and method classification is shown as well as a summary data table for each measurand indicating laboratory result and target for each survey.

Other features of the report is an Analysis of Results for the current survey, a Summary table indicating survey ID, total number of errors, total results submitted, and percentage of errors for each survey.

AA Assessment (legacy software)

The Antibody Titre module targets and acceptable range is determined by consensus. The final acceptable target is at the discretion of the RCPAQAP Transfusion Advisory Committee. In the case when a clear consensus cannot be

demonstrated, the target value and acceptable range will be set by the committee. Deviation of a survey target and acceptable range will be clearly enunciated on the survey report.

Reports show a table indicating your result and method and a graph indicating the target value and range with your response highlighted and a pointer indicating your result. A breakdown of your method is also provided as well as a summary data table indicating your laboratory result and target for each survey.

The report also shows an Analysis of Results for the current survey and an Analysis of Results outside the acceptable limits.

FM Assessment *(available on the eQuality platform)*

The survey report provides a simple, direct comparison of individual participant results with all results received and graphical representations showing results from the same method and reagent groups. Participant's results will be compared to a calculated median from all method classifications for a particular test as well as comparing results within a method or reagent group. Survey reports are issued for each measurand/test after the scheduled closing date. Analytical Performance Specifications (APS) are unique for each method. APSs are calculated from the target overall median value and are used in the histograms and youden plots. The APSs are based on clinical needs and are set and reviewed by program organisers and expert committee members.

Survey objective target values are determined by the RCPAQAP Transfusion Advisory Committee. Assessment of participant performance is based on the median for % foetal cells from submitted results. The selected values are used to calculate the target volume (mL) of cord blood and target dose of anti-D immunoglobulin recommended. Reports contain:

- Data for the current test samples
- Summary Data which includes all results for the current cycle, including cumulative method and target value data
- If results are late, amended or fall outside the APS, then an appropriate flagging message is printed along the sample number in current data table
- Data from each specimen is displayed in histograms, showing the distribution of all results compared to the all method median value using the APS
- Youden plots show results for paired specimens as a plot of the low value specimen (abscissa) against the high value specimen (ordinate)
- Individual participant results are highlighted
- Method groups are displayed in youden plots - each plot includes a central box which encompasses the APS based on the medians
- A Levy-Jennings plot is a plot of each pair of results showing the deviations from the target value in APS. The relative position of each pair of results is shown by the position of the specimen numbers on the abscissa. Acceptable results are within +/-1 APS of the target/median value (shaded)
- A linearity graph plots individual data against each specimen's central value. Shading shows the optimal range for results, calculated from APSs

The survey report will adopt the format used for all quantitative measurands that issue 2 samples in every survey. Note, *the survey reports produced from the eQuality platform now incorporate components of the legacy "end of cycle" reports to measure accuracy and precision. The survey reports display how accurate and precise survey results are over consecutive survey runs in every report. Report examples produced from the eQuality platform can be found on the myQAP help page.*

TC Assessment (legacy software)

The Transfusion Competency Program targets and acceptable responses are determined by consensus. The final acceptable responses are at the discretion of the RCPAQAP Transfusion Advisory Committee. Each response is allocated a score which is shown on the report as well as a diamond shaped pointer indicating your result. Reports will show a table of all responses by method with your response highlighted. A corresponding double bar graph shows how many laboratories supplied results for each method.

Performance assessment is based on a numerical scoring system each section of the report indicates the number of points accrued by the laboratory compared to the expected target score.

A commentary page is also issued with each report summarising participant performance in each module of the program.

TRANSFUSION COMPETENCY PROGRAM - PERFORMANCE ASSESSMENT SYSTEM		
Survey Component	**Points per Component (if applicable)**	**Total Points**
1. Patient Blood Group Reactions	2 points per mandatory reaction	60 points
Patient Blood Group Result	50 points	
2. Donor Unit Blood Group Reactions	2 points per mandatory reaction	56 points per donor unit
Donor Unit Blood Group Result	50 points	
3. Patient Weak D Testing	20 points	60 points
Donor Units Weak D Testing	20 points per donor unit	
4. Patient DAT		20 points
5. Patient Antibody Screen		50 points
6. Patient Antibody Identification		20 points
7. Patient Phenotyping	20 points	60 points
Donor Units Phenotyping	20 points per donor unit	
8. Compatibility - Crossmatch Reaction	50 points per donor unit	100 points

Blood Group and Antibody Program *(available on the eQuality platform)*

Acceptable responses for the Blood Group and Antibody programs are based on consensus. The final acceptable responses are at the discretion of the RCPAQAP Transfusion Advisory Committee. After the closing date of a survey, the survey results are reviewed and assessed and participants are issued with a survey report that will highlight the laboratory or individual performance. The survey report takes on the new standardised report format, produced from the eQuality platform (new reporting system). The report layout and interpretation can be found on the myQAP help page once released.

Performance is based on a numerical scoring system with points allocated for each correct answer (see table below). Survey reports provide Year to Date scores to allow participants to assess ongoing performance of the laboratory or individual and to highlight areas requiring corrective action.

All previous survey assessment reports for both B and I Programs (Legacy software) will no longer be accessible from the 1st March 2021 (website - http://dataentry.rcpaqap.com.au/transfusion/loginform2.cfm). Retrieve any information before this date by logging in to the website using the 'Member Log in' button, enter your participant number and password and select the 'View Assessment' button.

Blood Group and Antibody Program - Performance Assessment Scoring System

BLOOD GROUP & ANTIBODY PROGRAM - PERFORMANCE ASSESSMENT SYSTEM		
Survey Component	**Points per Component (if applicable)**	**Total Points**
1. Patient identification	2 points per correct identifier	8 points
2. Donor Unit Blood Group Reactions	2 points per mandatory reaction	20 points
Donor Unit Blood Group Result	10 points	
3. Patient Antibody Screen		10 points
4. Patient Antibody Identification		10 points

Snake Venom Program *(available on the eQuality platform)*

Note: The survey reports produced from the eQuality platform now incorporate components of the legacy "end of cycle" reports to measure accuracy and precision. The survey reports display how accurate and precise survey results are over consecutive survey runs in every report. Report examples and the interpretation, produced from the eQuality platform can be found on the myQAP help page.

The survey objectives and acceptable responses for the SV program are reviewed and assessed against RCPAQAP Transfusion survey objectives and in consultation with the Head of Toxinology to enable participant performance to be measured.

Reports show a table indicating your immunotype result, clinical interpretation and reaction strength and method. Graphs indicating the target results for the snake immunotype, clinical interpretation and reaction strength are provided with your responses indicated by the diamond pointer.

A breakdown of your reaction strength by method is also provided and comments from the Head of Toxinology are included on the second page of the report.

SNAKE VENOM DETECTION PROGRAM PERFORMANCE ASSESSMENT	
Test Component	**Component Assessment**
Snake Immunotype	Target Immunotype (Initial - Sheet 1)
Clinical Interpretation	Most appropriate Clinical Response (Initial - Sheet 1)

Participants in the SV program are also asked to provide a revised interpretation of results based on supplied clinical information, this is not an assessable element of the survey however it is a useful educational tool to aid laboratory staff in understanding the clinical implications of reported findings.

Immunology

Analysis of Participant results

For quantitative measurands the target set is the calculated median. Analysis of results using robust statistics requires a minimum of ten (10) or more results and assigned targets are determined by 80% consensus.

If there are less than 10 results and they are all in agreement, there is a consensus.

For all other measurands, targets are qualitative (e.g. Positive, Negative, Equivocal) or descriptive (e.g. ANA pattern). These targets are set based on the clinical information/gold standard test results and consultation with the clinical advisory committee or determined by 80% consensus.

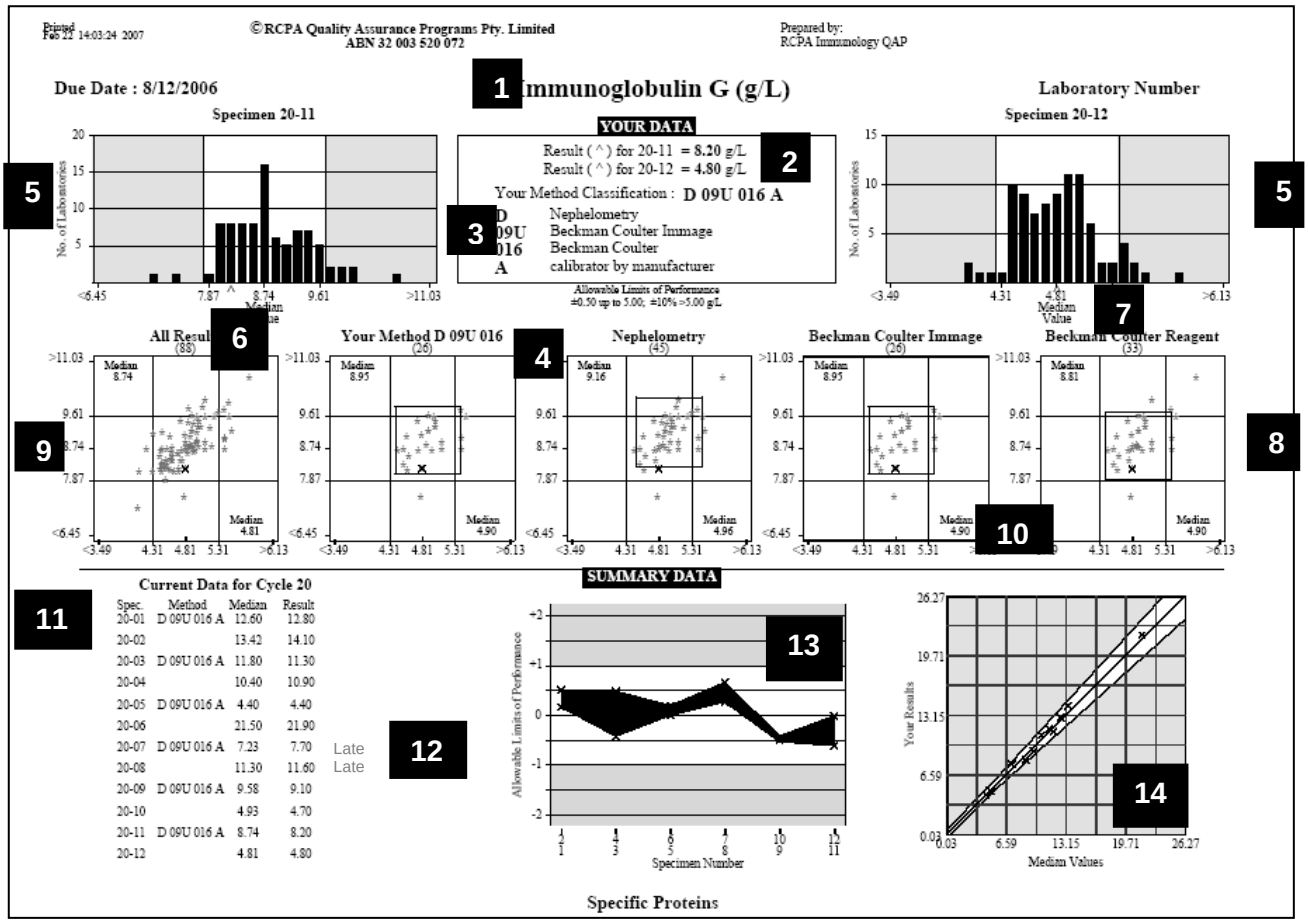
The Program provides several types of reports which have been tailored specifically for each module.

The following examples of reports are products of the legacy software, however as new programs are transitioned over to the eQuality software, the reports will adopt the standardised structure. A guide to interpret the reports will become available on RCPAQAP myQAP help page, once the survey report has been released

Analysis of results using Robust Statistics is performed on user groups of ten (10) or more participants using the same methodology.

Survey Report Format – IM, RF, IE, PH (These programs will produced by the eQuality software in 2021)

1. **MEASURAND:** The full name of the measurand.

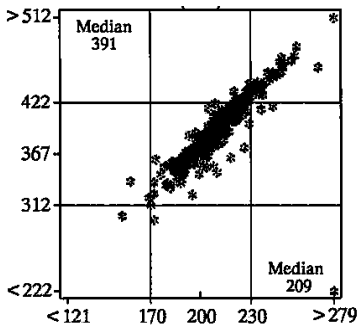


2. **RESULTS:** If both results were received by the closing date they will be listed. If results were not received an appropriate message is returned. *Please note: Late results will appear in the next report for the cycle. Reports will not be re-issued for late results.*
3. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted for the measurand. Please ensure your method classification is correct. If an alteration is submitted it is stored from the date advised to the end of the cycle. In this way it is possible to monitor method changes throughout the cycle.
   If the method classification information provided by the QAP does not allow for adequate definition of your method please contact us.
   Measurands with no method classification and no results will not be printed. Therefore if you wish to receive a report for an measurand for which you do not submit results you will need to provide a method classification.
4. **ANALYTICAL PERFORMANCE SPECIFICATIONS:** Unique for each measurand and based on clinical relevance and statistical evaluation. The acceptable range for each specimen is calculated from the central value (median). These ranges are used in histograms and Youden plots.
5. **HISTOGRAMS:** Histograms showing distribution of all results compared to the calculated median.
6. **YOUR RESULT:** Indicated by the position of the caret (^).
7. **MEDIAN VALUE:** The calculated median.
8. **YOUDEN PLOTS:** Plots of the low concentration specimen against the high concentration specimen for each survey. The laboratory's pair of results is marked by an '**X**' and each '✱' indicates another lab's results. If both results of your results are acceptable the point will be in the central square.

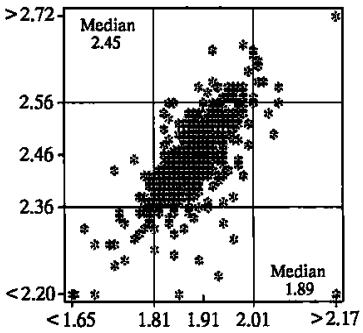
   Multiple plots are of all results and subgroups using the same method, analytical principle, instrument and reagent as your laboratory are displayed. The number of results in each group is shown in brackets above the plot.

Examples of Youden Plots:

Interlaboratory bias



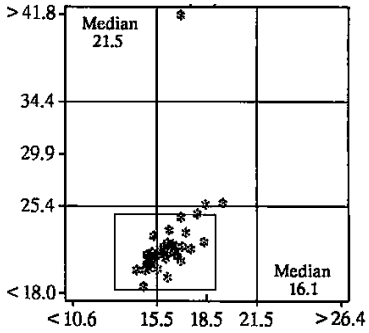
With-in laboratory Bias



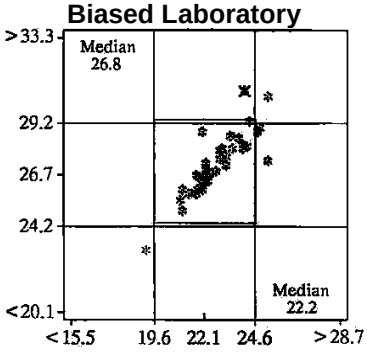
9. **MEDIANS (Youden Plots):** Median values for the pair of specimens for "All Results" and each subgroup.
10. **PEER REVIEW BOX (Youden Plots):** Youden plots of each subgroup include a box that is centred around the median values for the pair of specimens. The box encompasses the Analytical Performance Specifications based on subgroup median values rather than the calculated median of all results.
    Participants should consider their results in relation to these boxes as this provides a comparison with other participants using the same analytical systems.

Examples of Peer Review Boxes:

Biased Results



Biased Laboratory



11. **CURRENT DATA:** A complete summary table of the data for the whole cycle to date. The 'Method' column will show any method changes, the 'Median' column is the calculated median for each specimen based on all results submitted and the 'Result' column displays the results returned by your laboratory.

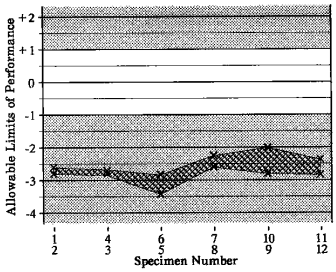
12. **LOW, HIGH, LATE AND AMENDED FLAGS (Current Data):** The comments 'Low' or 'High' are added if the result is outside the Analytical Performance Specification. 'Late' and 'Amended' flags are added if applicable.

13. **LEVEY JENNINGS STYLE PLOT:** A plot of each pair of sample results showing deviations from the calculated median (0) indicate performance against the Analytical Performance Specifications. Acceptable results are within +/- 1 Analytical Performance Specification of the calculated median, are indicated on the graph by the non-shaded area.

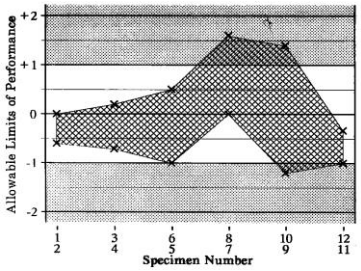
The scale of Analytical Performance Specifications is adjusted to accommodate your results up to a maximum of +/- 9 limits.

Examples of Levey Jennings Plots:

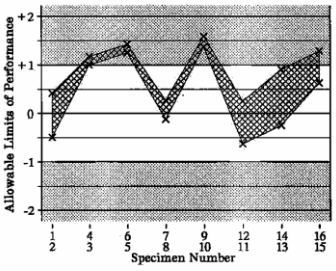
Biased Results



Poor Precision – Within Run

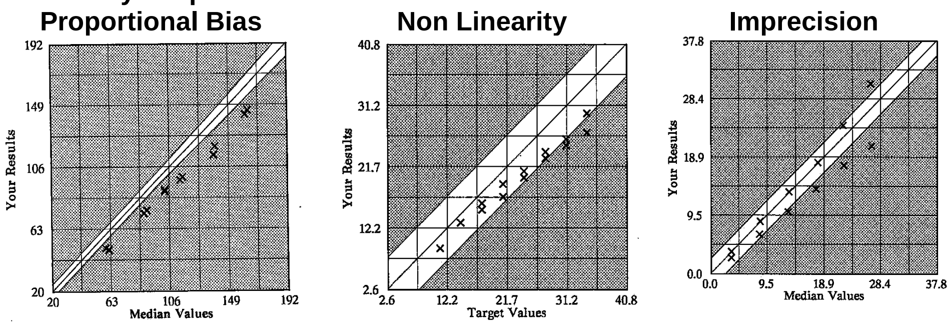


Poor Precision – Between Run



14. **LINEARITY GRAPH:** This graph shows non-linearity, imprecision and inaccuracy. Results falling in the shaded area are outside the Analytical Performance Specifications.

Examples of Linearity Graphs:



METHOD COMPARISON PAGE: Lists all participant IgE results grouped by method. Your result will be highlighted by a grey bar. *(Note – not available for IM, PH and RF reports)*

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ABN 32 003 520 072

Prepared by:
RCPAQAP Immunology

Due Date : 30/04/2018

Specimen 36-05

Laboratory Number

15

kU/L	IgE Method
11	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
13	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
13	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
13	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
14	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
14	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
14	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
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14	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
15	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
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15	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
16	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
16	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
16	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
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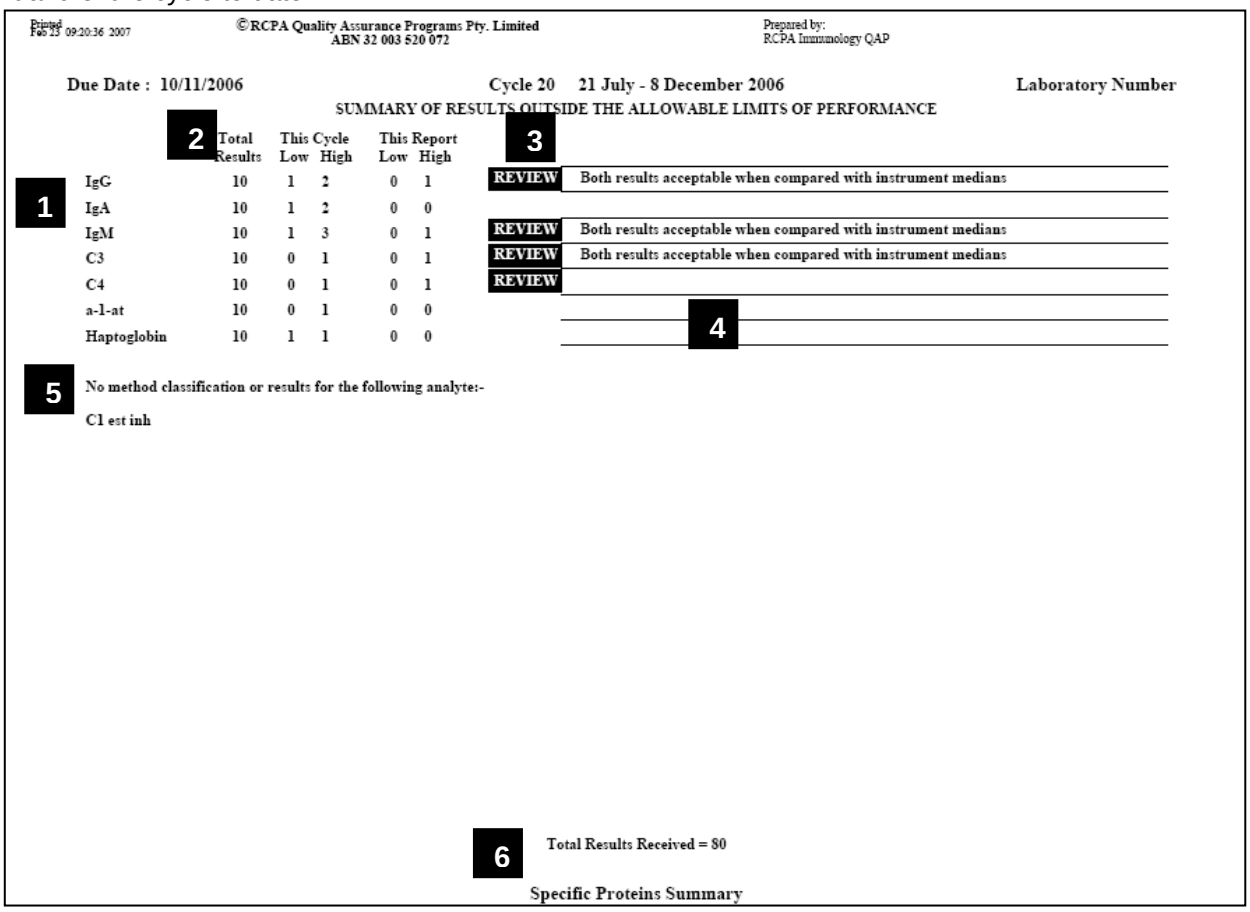
16	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
17	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
19	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
	CAP,Phadia ImmunoCAP 100/250/1000/2500,Phadia Diagnostics,Calibration with kit/instrument
14	Luminescent Immunoassay,? ?,Roche (Cobas)
11	Luminescent Immunoassay,Beckman Coulter Immage/Immage 800,Beckman Coulter
14	Luminescent Immunoassay,Roche Diagnostics Cobas c701/c702,Roche (Cobas),Calibration with kit/instrument
14	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
14	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
14	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
15	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
15	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
15	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
15	Luminescent Immunoassay,Roche Diagnostics E170/e601/e602/e801,Roche (Cobas),Calibration with kit/instrument
14	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
14	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
14	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
14	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
14	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
15	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
16	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument
	Luminescent Immunoassay,Siemens Diagnostic (DPC) Immulite 2000,Siemens Diagnostic (DPC),Calibration with kit/instrument

IgE

Summary of All Results for all Measurands

The last page of each report summarises all measurands outside the Analytical Performance Specifications in the current and entire cycle to date.



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ABN 32 003 520 072

Prepared by:
RCPA Immunology QAP

Due Date : 10/11/2006 Cycle 20 21 July - 8 December 2006 Laboratory Number

SUMMARY OF RESULTS OUTSIDE THE ALLOWABLE LIMITS OF PERFORMANCE

1	2 Total Results	This Cycle Low	This Cycle High	This Report Low	This Report High	3
IgG	10	1	2	0	1	REVIEW Both results acceptable when compared with instrument medians
IgA	10	1	2	0	0	
IgM	10	1	3	0	1	REVIEW Both results acceptable when compared with instrument medians
C3	10	0	1	0	1	REVIEW Both results acceptable when compared with instrument medians
C4	10	0	1	0	1	REVIEW
a-1-at	10	0	1	0	0	
Haptoglobin	10	1	1	0	0	

4

5 No method classification or results for the following analyte:-

C1 est inh

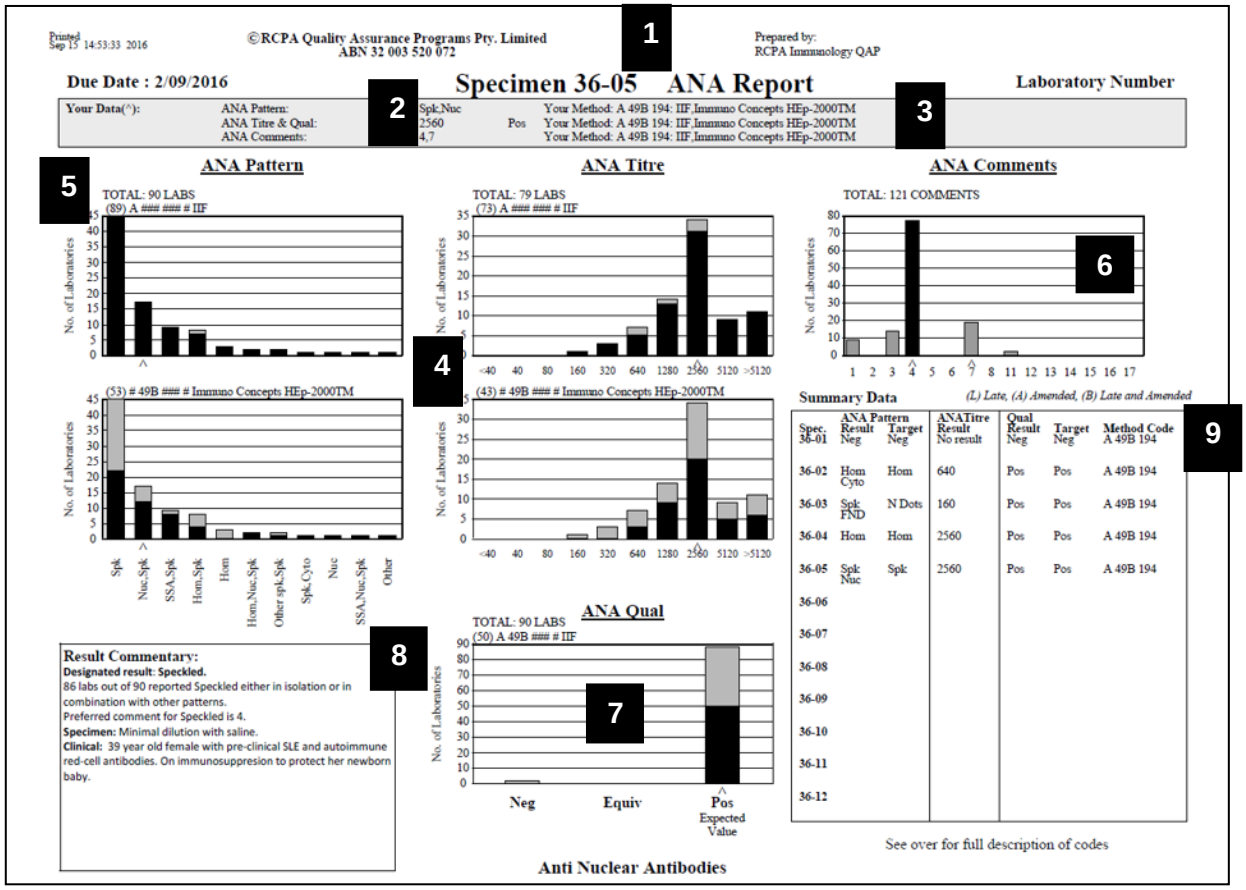
6 Total Results Received = 80

Specific Proteins Summary

1. **MEASURAND:** Measurand with results outside the Analytical Performance Specifications.
2. **NUMBER OF RESULTS:** Total results returned and the number of low and high results to date and in the current.
3. **REVIEW:** This comment is added to measurands with low or high results in this report. The comment “Both results acceptable when compared to instrument medians” is automatically added if the pair of results are encompassed within the Youden box for the laboratory’s specific method instrument *when five or more results are reported.*

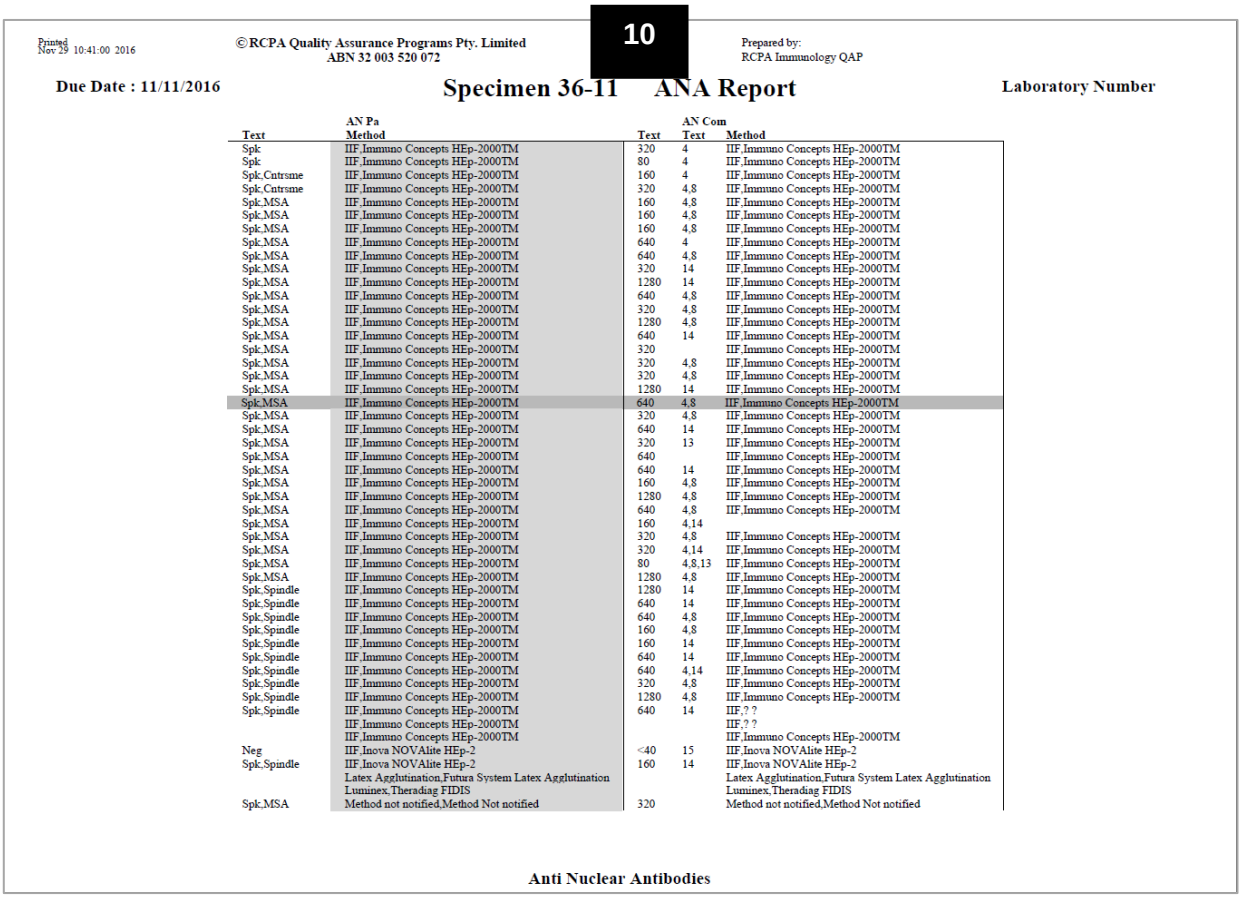
   A laboratory that falls outside the “Analytical Performance Specifications” set for the survey and is a member of a group containing less than 5 participants is unassessable by this method. Participants should review their results against those of their peers and determine if they are performing consistently or not.
   Likewise a laboratory that falls inside the quoted “Analytical Performance Specifications” but has no (or few) other laboratories in its peer group is performing adequately when assessed against the overall result statistics, giving it some measure of its competence, but may or may not be performing satisfactorily within its method group.
4. **COMMENTS AREA:** Space for comments to be written by laboratory staff.
5. **MEASURANDS WITH NO DATA:** Other measurands available in the module.
6. **SUMMARY STATISTICS:** The total number of results to date showing the number and percentage of Amended and Late results.

Report Format - AN



Please note: Target values are set in ANA Pattern and Qualitative results Titre histograms are included for information only. Interpretive Comments are included for educational purposes.

1. **MEASURAND:** One specimen is displayed per page, with two samples per survey.
2. **LABORATORY RESULTS:** A summary of the results submitted by your laboratory for the specimen displayed
3. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted.
4. **HISTOGRAMS:** ANA Pattern and Titre. Your results are indicated on the histograms by the position of the caret (^).
5. **HIGHLIGHTED METHOD CLASSIFICATION:** Your laboratory's method classification is indicated above each histogram. The top histogram displays all results from the same analytical principle (Category 1), and the bottom histogram displays all results from the same substrate or kit (Category 2).
   On the histograms for ANA Pattern, ANA Titre and ANA Qual the bars highlighted in black indicate how participants within your method group resulted.
6. **INTERPRETIVE COMMENT:** Selected by laboratories from a supplied list of clinical comments. The preferred Interpretive Comment is highlighted in black if applicable, the caret (^) indicates the result you reported.
7. **QUALITATIVE RESULT:** The qualitative results from all laboratories, 'Expected Value' denotes the target result.
8. **RESULT COMMENTARY:** Includes the designated result (target value), details of all results submitted including sub-classifications of pattern codes, specimen details and clinical information on the patient.
9. **SUMMARY DATA:** A complete summary of data for the cycle to date. The method column allows laboratories to track any method changes.



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10

Prepared by:
RCPA Immunology QAP

Due Date : 11/11/2016

Specimen 36-11 ANA Report

Laboratory Number

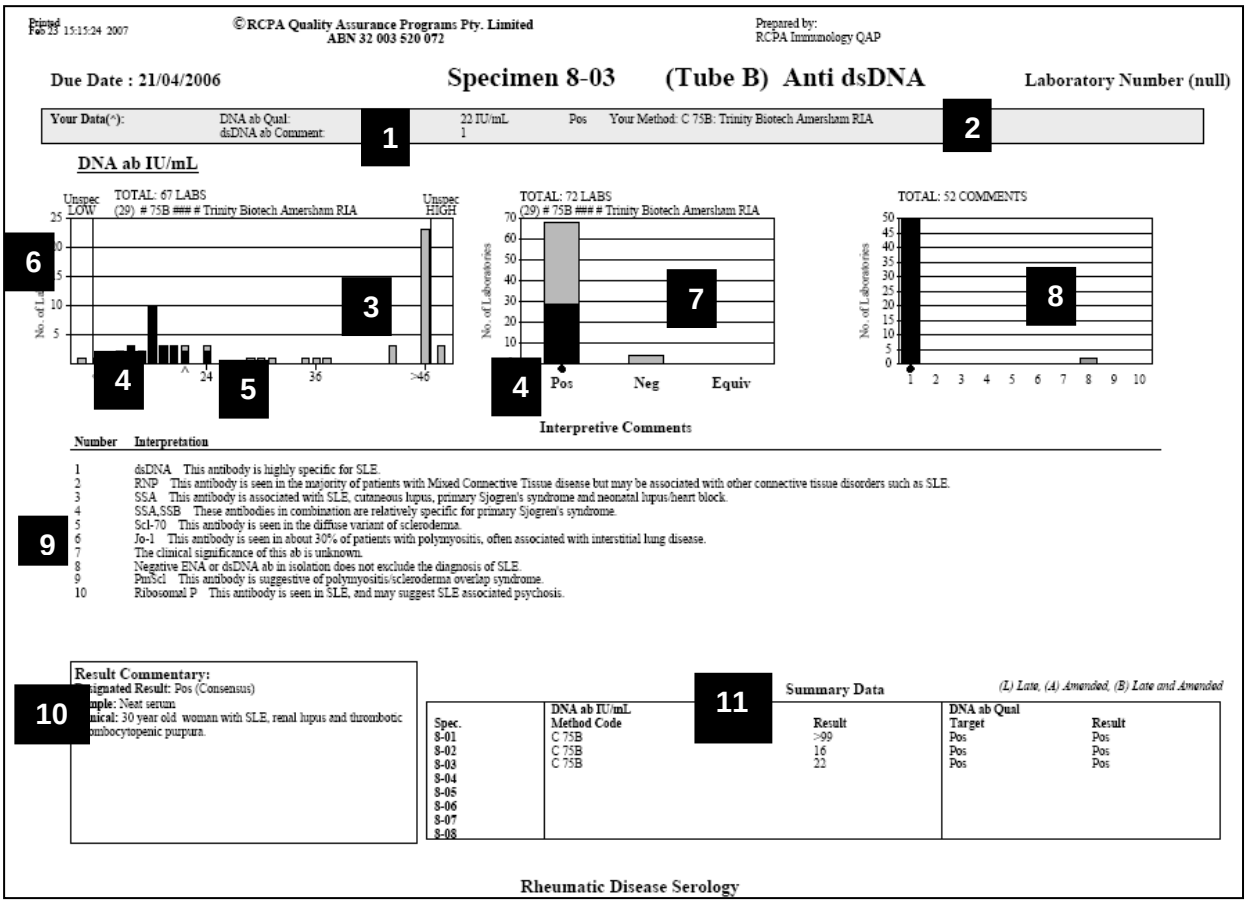
AN Pa Text	AN Pa Method	AN Com Text	AN Com Text	AN Com Method
Spk	IIF,Immuno Concepts HEp-2000TM	320	4	IIF,Immuno Concepts HEp-2000TM
Spk	IIF,Immuno Concepts HEp-2000TM	80	4	IIF,Immuno Concepts HEp-2000TM
Spk,Cntrsme	IIF,Immuno Concepts HEp-2000TM	160	4	IIF,Immuno Concepts HEp-2000TM
Spk,Cntrsme	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	160	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	160	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	160	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	4	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	1280	14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	1280	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320		IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	1280	14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	13	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640		IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	160	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	1280	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	640	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	160	4,14	
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	320	4,14	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	80	4,8,13	IIF,Immuno Concepts HEp-2000TM
Spk,MSA	IIF,Immuno Concepts HEp-2000TM	1280	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	1280	14	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	640	14	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	640	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	160	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	160	14	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	640	14	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	640	4,14	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	320	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	1280	4,8	IIF,Immuno Concepts HEp-2000TM
Spk,Spindle	IIF,Immuno Concepts HEp-2000TM	640	14	IIF,? ?
	IIF,Immuno Concepts HEp-2000TM			IIF,? ?
	IIF,Immuno Concepts HEp-2000TM			IIF,Immuno Concepts HEp-2000TM
Neg	IIF,Inova NOVAlite HEp-2	<40	15	IIF,Inova NOVAlite HEp-2
Spk,Spindle	IIF,Inova NOVAlite HEp-2	160	14	IIF,Inova NOVAlite HEp-2
	Latex Agglutination,Futura System Latex Agglutination Luminex,Theradiag FIDIS			Latex Agglutination,Futura System Latex Agglutination Luminex,Theradiag FIDIS
Spk,MSA	Method not notified,Method Not notified	320		Method not notified,Method Not notified

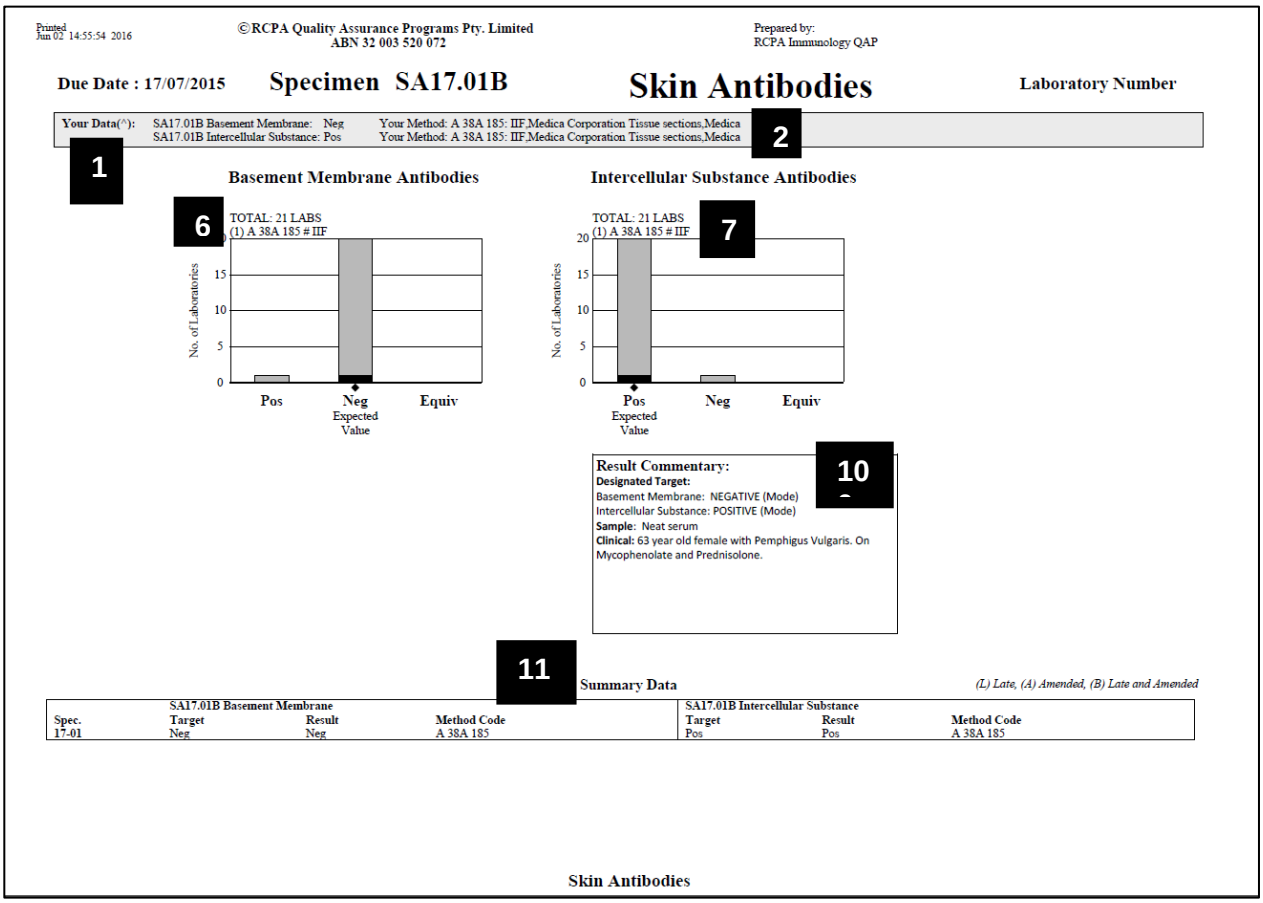
Anti Nuclear Antibodies

10. METHOD COMPARISON PAGE: Lists all participant ANA Pattern and Titre results grouped by method. Your result will be highlighted by a grey bar

Report Format - SA, DA, TA, EN, MP, MG, MY, TH

Autoimmune reports are designed around common elements, although the reports differ subtly from each other.





1. **LABORATORY RESULTS:** A summary of the results submitted by your laboratory for the specimen displayed
2. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted.
3. **HISTOGRAM:** Displays distribution of results reported. Bars for 'All Results' are in grey and results from your method group are in highlighted black.
4. **< OR > BINS:** Results reported as '<x' or '>x' are included in separate bins to the left and right of the histogram.
5. **YOUR RESULT:** Indicated by a caret ^ or ♦.
6. **TOTAL:** Total number of laboratories reporting on this measurand, and the total number of laboratories in Your Method group.
7. **QUALITATIVE RESULTS:** 'All Results' are in grey and results from your method group are highlighted in black. 'Expected Value' denotes the target result.
8. **INTERPRETIVE COMMENT GRAPH:** Displays the comments selected by participants, from the Interpretive Comment table **(9). '**All Responses' are shown in grey and the 'Preferred Interpretive Comment', if applicable, is shown in black.
9. **INTERPRETIVE COMMENT TABLE.** Selected by laboratories from a supplied list of clinical comments. The preferred Interpretive Comment is highlighted in black if applicable, ^ or ♦.indicates the result you reported.
10. **RESULT COMMENTARY BOX:** Displays the Designated Result (Target) information about the specimen, clinical notes and any relevant discussion.
11. **SUMMARY DATA BOX:** Displays summary data for the cycle to date, with columns showing methodology, target (designated) result and your result for each specimen. Interpretive comments are not summarised here as they are educational in nature and do not contribute to assessment of performance at present. Quantitative results are printed here and displayed graphically but, due to poor intra- and inter-method precision and standardisation, are for comparative information purposes only.
12. **METHOD COMPARISON PAGE:** Lists all participant results grouped by method. Your result will be highlighted by a grey bar**.**

12

Printed
Jul 04 15:35:27 2017

Prepared by:
RCPAQAP Immunology

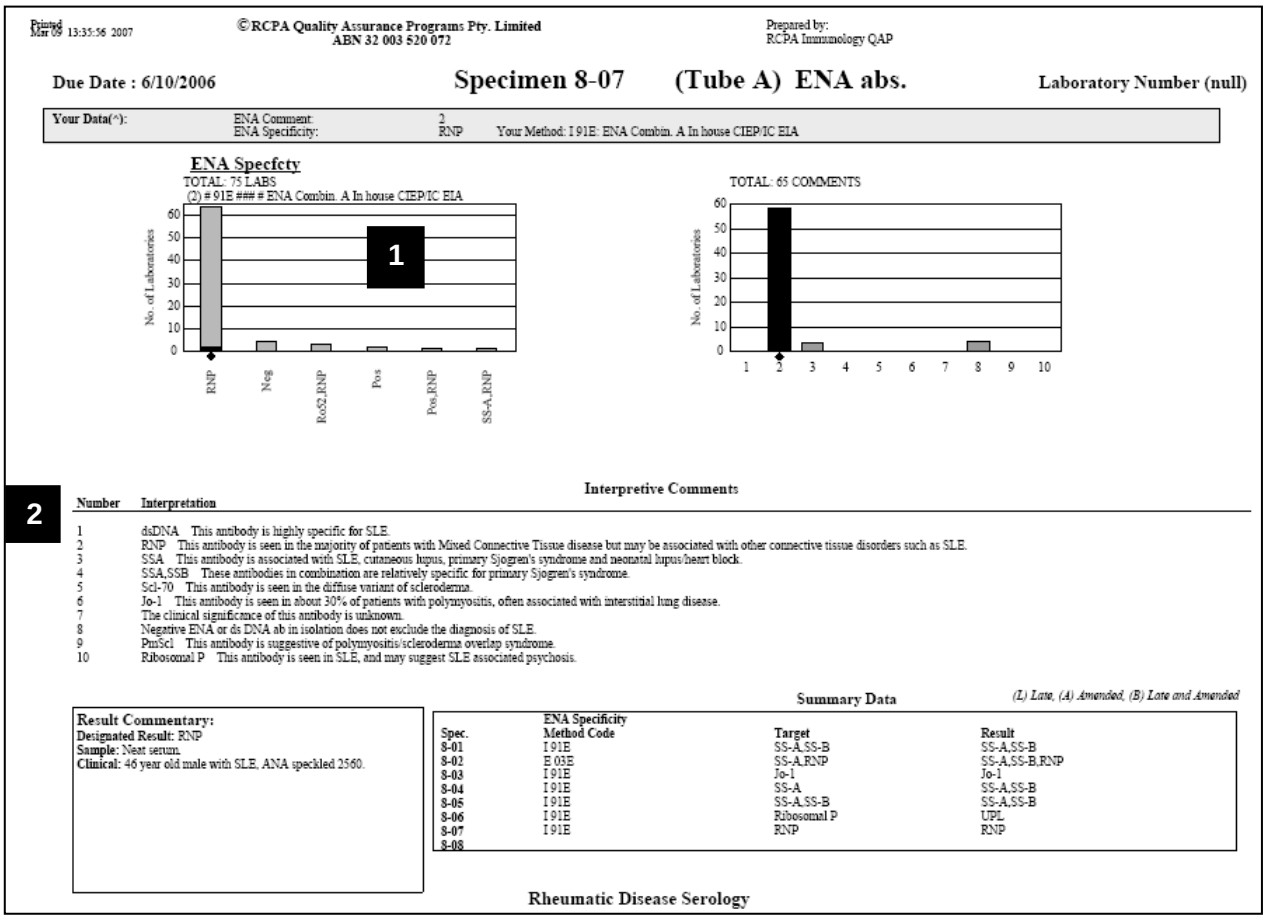
Due Date : 26/06/2017

Specimen 19-04 (Tube B) Anti dsDNA

Laboratory Number

IU/mL	DNAQul Score	Method	DNACom Text	DNACom Method
1204	Pos	? ?		
41	Pos	Aesku/Triturus ELISA		
508	Pos	Aesku/Triturus ELISA	1	
36	Equiv	Axis Shield Diagnostics Diastat EIA		
3	Neg	Bio-Rad BioPlex 2200	8	
>200	Pos	Bio-Rad ELISA	1	
>200	Pos	Bio-Rad ELISA	1	
>200	Pos	Bio-Rad ELISA	1	
61	Pos	Bio-Rad ELISA	1	
62	Pos	Bio-Rad ELISA	1	
100	Pos	Bio-Rad ELISA		
148	Pos	Bio-Rad ELISA	1	
158	Pos	Bio-Rad ELISA		
601	Pos	Bio-Rad ELISA		
G200	Pos	Bio-Rad ELISA	1	
	Pos	Demeditec ELISA		
	Neg	DTS Crithidia	8,12	
	Pos	DTS Crithidia	1	
	Pos	DTS Crithidia	1,17	
80	Neg	Euroimmun dsDNA NcX ELISA	8	
324	Pos	Euroimmun dsDNA NcX ELISA	1	
346	Pos	Euroimmun dsDNA NcX ELISA	1	
448	Pos	Euroimmun dsDNA NcX ELISA	1	
460	Pos	Euroimmun dsDNA NcX ELISA	1	
471	Pos	Euroimmun dsDNA NcX ELISA		
479	Pos	Euroimmun dsDNA NcX ELISA	1	
509	Pos	Euroimmun dsDNA NcX ELISA	1	
		Euroimmun dsDNA NcX ELISA		
73	Pos	Hycor ELISA	1	
117	Pos	Hycor ELISA		
		Immuno Concepts Crithidia		
	Pos	Immuno Concepts Crithidia	1	
13	Pos	Immunobiological Laboratories RIA	1	
14	Pos	Immunobiological Laboratories RIA	17	
16	Equiv	Immunobiological Laboratories RIA	1	
19	Pos	Immunobiological Laboratories RIA	1	
20	Pos	Immunobiological Laboratories RIA	1	
20	Pos	Immunobiological Laboratories RIA	1	
23	Pos	Immunobiological Laboratories RIA	1,17	
28.2	Pos	Immunobiological Laboratories RIA	1	
44	Pos	Immunobiological Laboratories RIA	1	
82	Pos	Immunobiological Laboratories RIA	1	
855	Pos	Inova QUANTAlite ELISA	1	
1032	Pos	Inova QUANTAlite ELISA	1	
1067	Pos	Inova QUANTAlite ELISA	1	
		Method Not notified		
42	Pos	Orgentec ELISA		
<10	Neg	Phadia 100/250/2500 ELiA	8	
2	Neg	Phadia 100/250/2500 ELiA	8	
2	Neg	Phadia 100/250/2500 ELiA	8	
2	Neg	Phadia 100/250/2500 ELiA	8	

Rheumatic Disease Serology



Printed Mar 09 13:35:56 2007 ©RCPA Quality Assurance Programs Pty. Limited ABN 32 003 520 072 Prepared by: RCPA Immunology QAP

Due Date : 6/10/2006 **Specimen 8-07 (Tube A) ENA abs.** Laboratory Number (null)

Your Data(^): ENA Comment: 2 ENA Specificity: RNP Your Method: I 91E: ENA Combin. A In house CIEP/IC EIA

ENA Specfcty

TOTAL: 75 LABS

(2) # 91E ### # ENA Combin. A In house CIEP/IC EIA

1

No. of Laboratories

RNP Neg Ro52,RNP Pos Pos,RNP SS-A,RNP

TOTAL: 65 COMMENTS

No. of Laboratories

2

Interpretive Comments

Number	Interpretation
1	dsDNA This antibody is highly specific for SLE.
2	RNP This antibody is seen in the majority of patients with Mixed Connective Tissue disease but may be associated with other connective tissue disorders such as SLE.
3	SSA This antibody is associated with SLE, cutaneous lupus, primary Sjogren's syndrome and neonatal lupus/heart block.
4	SSA,SSB These antibodies in combination are relatively specific for primary Sjogren's syndrome.
5	Scl-70 This antibody is seen in the diffuse variant of scleroderma.
6	Jo-1 This antibody is seen in about 30% of patients with polymyositis, often associated with interstitial lung disease.
7	The clinical significance of this antibody is unknown.
8	Negative ENA or ds DNA ab in isolation does not exclude the diagnosis of SLE.
9	PmScl This antibody is suggestive of polymyositis/scleroderma overlap syndrome.
10	Ribosomal P This antibody is seen in SLE, and may suggest SLE associated psychosis.

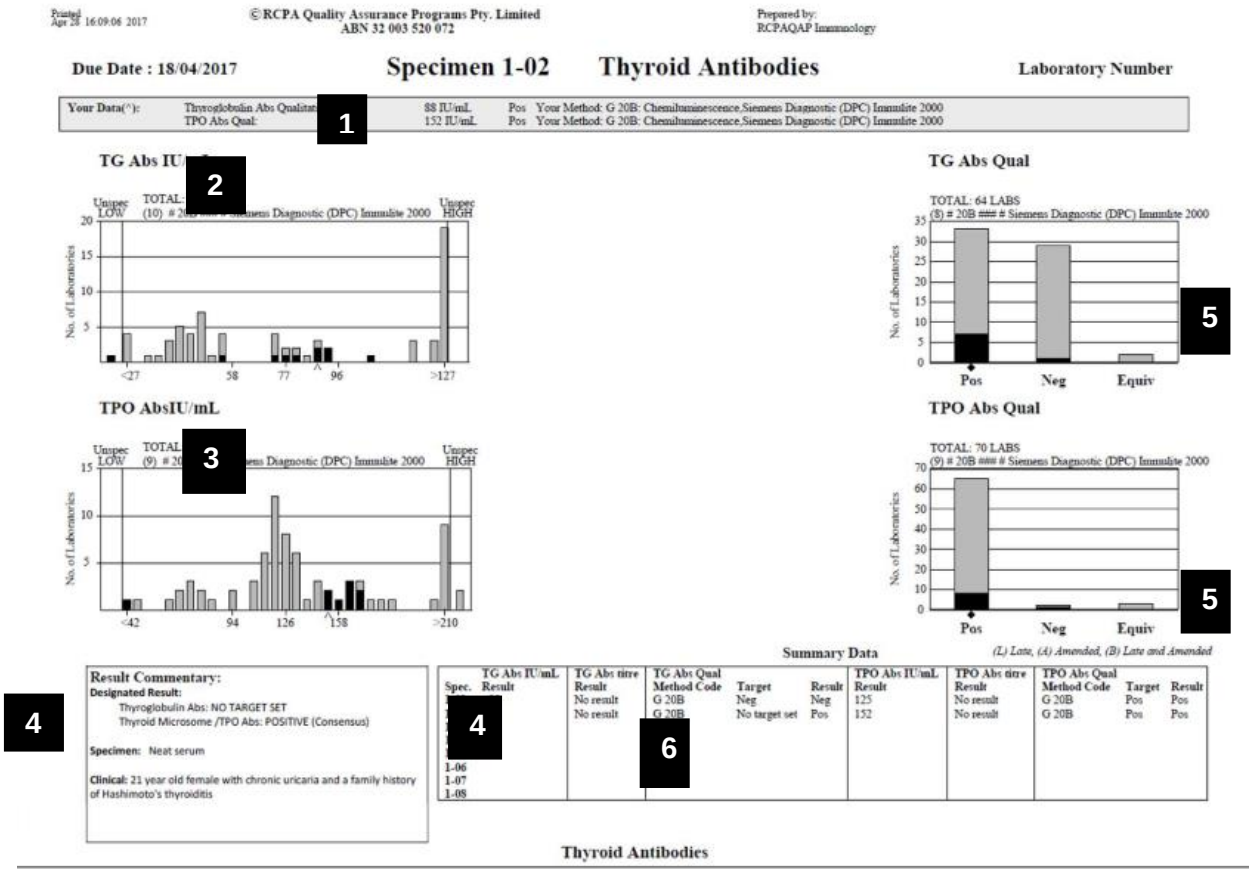
Result Commentary:
Designated Result: RNP
Sample: Neat serum.
Clinical: 46 year old male with SLE, ANA speckled 2560.

Summary Data (L) Late, (A) Amended, (B) Late and Amended

Spec.	ENA Specificity Method Code	Target	Result
8-01	I 91E	SS-A,SS-B	SS-A,SS-B
8-02	E 03E	SS-A,RNP	SS-A,SS-B,RNP
8-03	I 91E	Jo-1	Jo-1
8-04	I 91E	SS-A	SS-A,SS-B
8-05	I 91E	SS-A,SS-B	SS-A,SS-B
8-06	I 91E	Ribosomal P	UPL
8-07	I 91E	RNP	RNP
8-08			

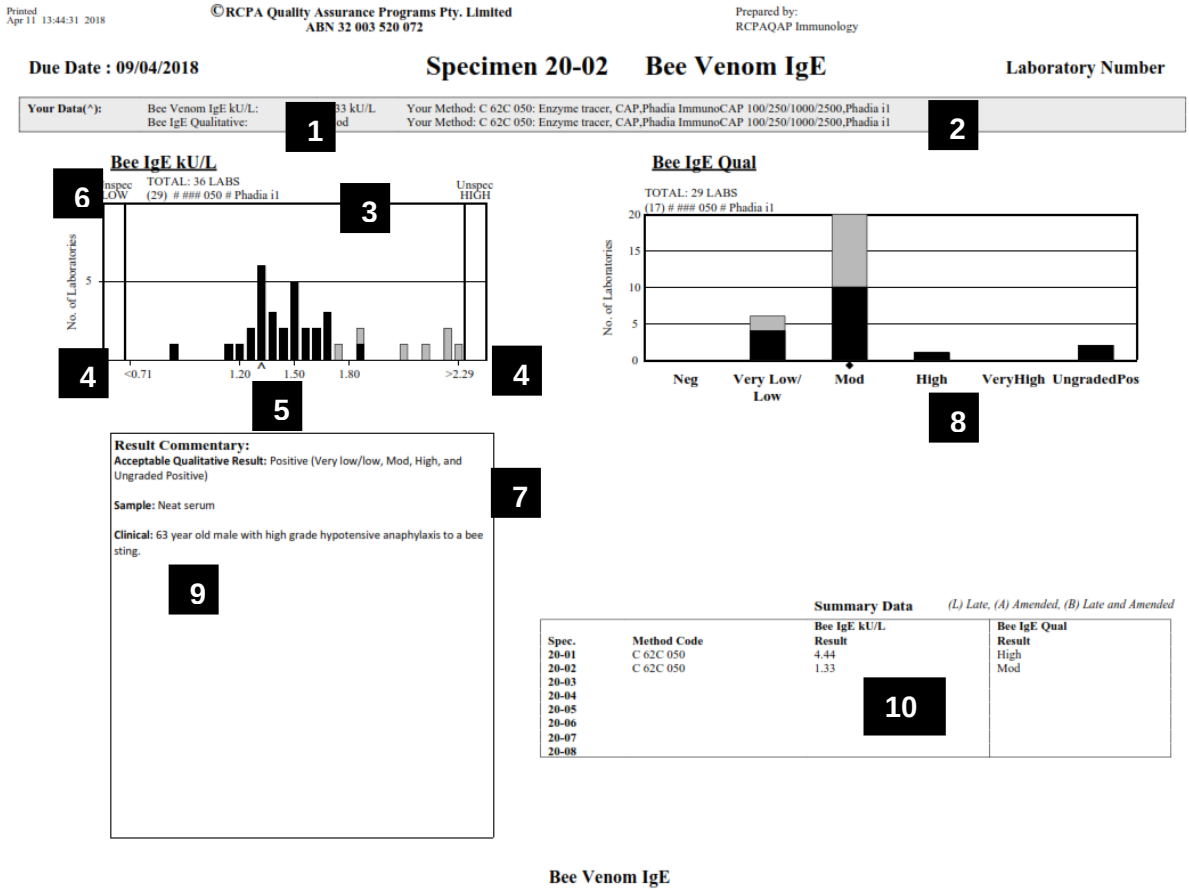
Rheumatic Disease Serology

1. **BAR GRAPH:** Displays ENA antibody results according to specificity. Your result is indicated by ♦ and results for your method group are highlighted in black compared to 'All Results' which are shaded in grey.
2. **INTERPRETIVE COMMENT GRAPH:** Displays the comments selected from the Interpretive Comments table. These comments have been prepared by the QAP Advisory Committee and they are intended as an optional educational exercise.



1. **YOUR RESULTS:** A summary of your reported results for the survey and their respective methods.
2. **THYROGLOBULIN ANTIBODY RESULTS:** IU/ml and qualitative interpretation.
3. **MICROSOMAL (TPO) ANTIBODY RESULTS:** IU/ml and qualitative interpretation.
4. **HISTOGRAMS:** Display results in IU/ml, including separate bins to the left and right of the histogram for results reported as '<x' or '>x'. No target values are set for quantitative results. These results are included for comparative information purposes only.
5. **QUALITATIVE RESULTS:** 'All Results' are in shown in grey and results from your method group are highlighted in black. Target values are set on qualitative results only.
6. **TITRE RESULTS:** From 2019 titres will no longer be reportable.

Report Format – IN, FA, BE and DU

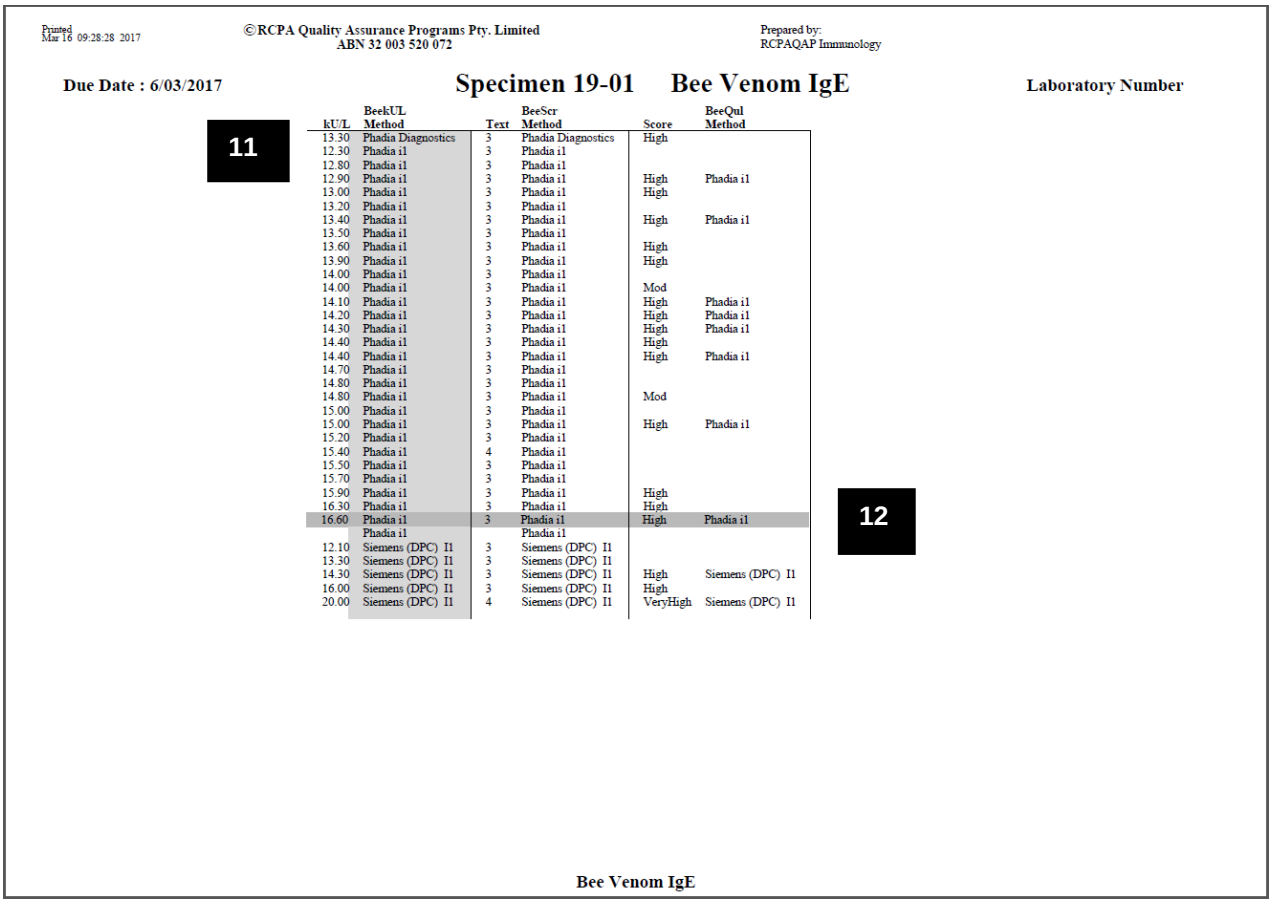


Allergy Serology reports are designed around common elements, although the reports differ subtly from each other.

1. **YOUR DATA:** The results reported by your laboratory.
2. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted.
3. **HISTOGRAM:** Displays distribution of results reported. 'All Results' are in grey and results from your method group are in black.
4. **< OR > BINS:** Results reported as '<x' or '>x' are included in separate bins to the left and right of the histogram.
5. **YOUR RESULT:** Indicated by a caret ^ or ♦.
6. **TOTAL:** Total number of laboratories reporting on this measurand, and the total number of laboratories in Your Method group (Category 3, Allergen Reagent).
7. **TARGET:** Target values are based on consensus reporting by participants, clinical criteria (using skin prick tests if available) and may also be set by an expert advisory group. A range may be set as the target. The target qualitative sensitization is indicated in the result commentary box.
   Prior to 2017, scores were used for target setting. From 2017, target setting is on qualitative sensitization.
8. **BAR GRAPH - QUALITATIVE:** Displays the distribution of qualitative results. 'All Results' are in grey and results from your method group are in black.
9. **RESULT COMMENTARY BOX:** Displays the Target, information about the specimen, clinical notes and any relevant discussion.
10. **SUMMARY DATA BOX:** Displays summary data for the cycle to date, with columns showing methodology, target result and your result for each specimen. Quantitative results are included and displayed but are for comparative information purposes only.

11. **DATA TABLE:** Displays all data received on the specimen, sorted on quantitation and ordered within method groups

12. YOUR RESULTS: Results provided by your laboratory are highlighted with shading.



Printed Mar 16 09:28:28 2017

Prepared by:
RCPAQAP Immunology

Due Date : 6/03/2017

Specimen 19-01 Bee Venom IgE

Laboratory Number

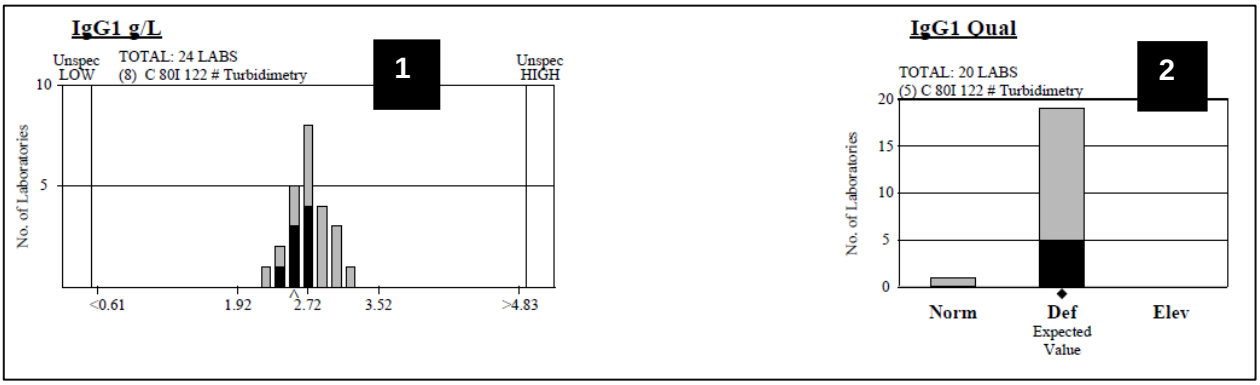
11

kU/L	BeekUL Method	Text	BeeScr Method	Score	BeeQul Method
13.30	Phadia Diagnostics	3	Phadia Diagnostics	High	
12.30	Phadia i1	3	Phadia i1		
12.80	Phadia i1	3	Phadia i1		
12.90	Phadia i1	3	Phadia i1	High	Phadia i1
13.00	Phadia i1	3	Phadia i1	High	
13.20	Phadia i1	3	Phadia i1		
13.40	Phadia i1	3	Phadia i1	High	Phadia i1
13.50	Phadia i1	3	Phadia i1		
13.60	Phadia i1	3	Phadia i1	High	
13.90	Phadia i1	3	Phadia i1	High	
14.00	Phadia i1	3	Phadia i1		
14.00	Phadia i1	3	Phadia i1	Mod	
14.10	Phadia i1	3	Phadia i1	High	Phadia i1
14.20	Phadia i1	3	Phadia i1	High	Phadia i1
14.30	Phadia i1	3	Phadia i1	High	Phadia i1
14.40	Phadia i1	3	Phadia i1	High	
14.40	Phadia i1	3	Phadia i1	High	Phadia i1
14.70	Phadia i1	3	Phadia i1		
14.80	Phadia i1	3	Phadia i1		
14.80	Phadia i1	3	Phadia i1	Mod	
15.00	Phadia i1	3	Phadia i1		
15.00	Phadia i1	3	Phadia i1	High	Phadia i1
15.20	Phadia i1	3	Phadia i1		
15.40	Phadia i1	4	Phadia i1		
15.50	Phadia i1	3	Phadia i1		
15.70	Phadia i1	3	Phadia i1		
15.90	Phadia i1	3	Phadia i1	High	
16.30	Phadia i1	3	Phadia i1	High	
16.60	Phadia i1	3	Phadia i1	High	Phadia i1
	Phadia i1		Phadia i1		
12.10	Siemens (DPC) I1	3	Siemens (DPC) I1		
13.30	Siemens (DPC) I1	3	Siemens (DPC) I1		
14.30	Siemens (DPC) I1	3	Siemens (DPC) I1	High	Siemens (DPC) I1
16.00	Siemens (DPC) I1	3	Siemens (DPC) I1	High	
20.00	Siemens (DPC) I1	4	Siemens (DPC) I1	VeryHigh	Siemens (DPC) I1

12

Bee Venom IgE

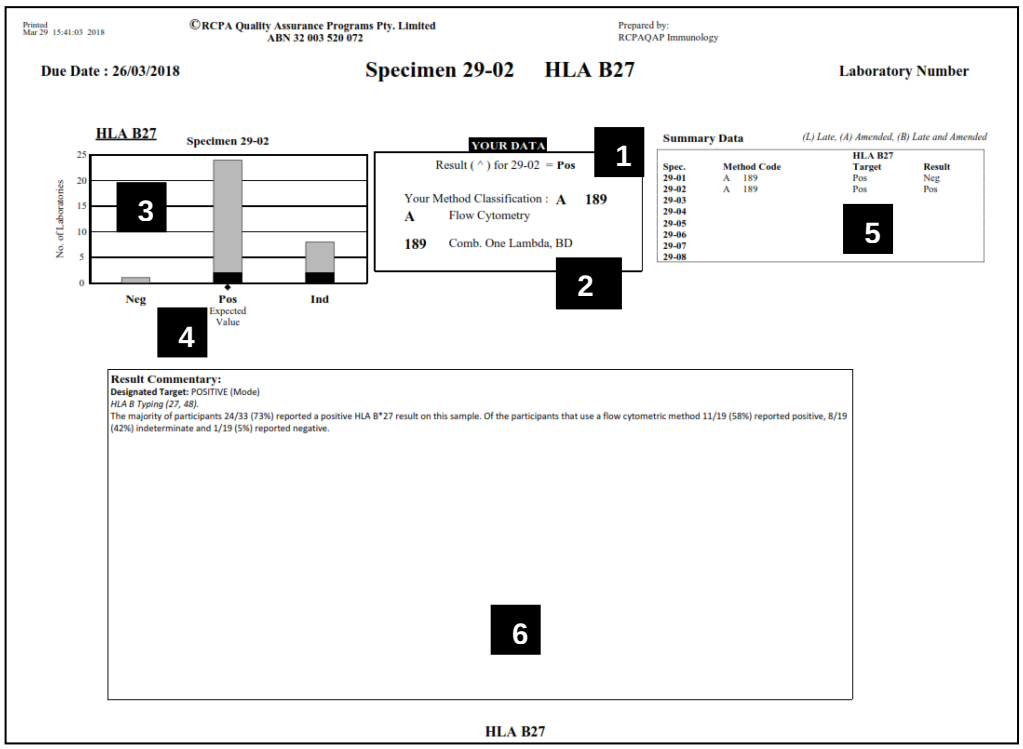
Report Format – AV, GS, CC

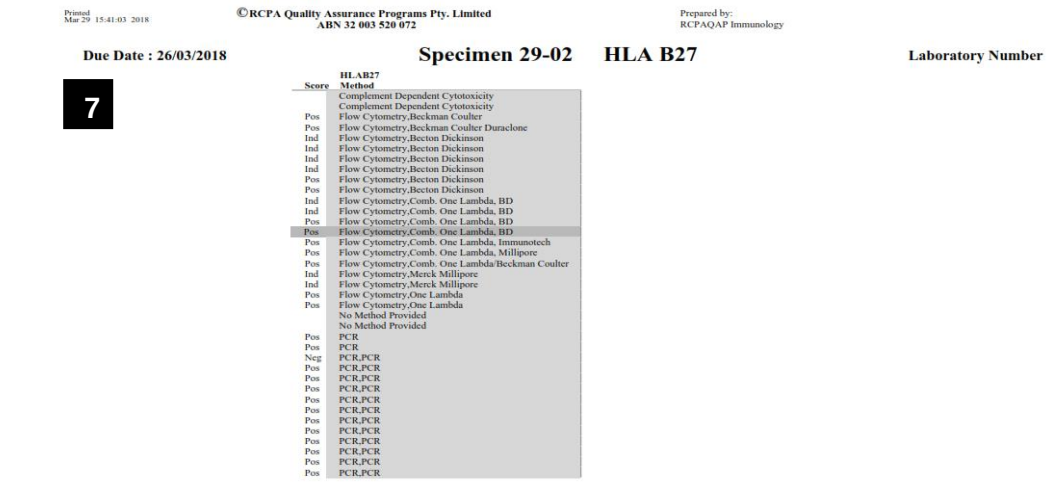


Note: For AV module only qualitative results are reported.

1. **HISTOGRAM:** As for other quantitative values. Results reported as '<x' or '>x' are included in separate bins to the left and right of the histogram.
2. **QUALITATIVE GRAPH:** Results expressed as a qualitative interpretation. For the GS module the target value is set with reference to clinical criteria or the consensus of qualitative results.

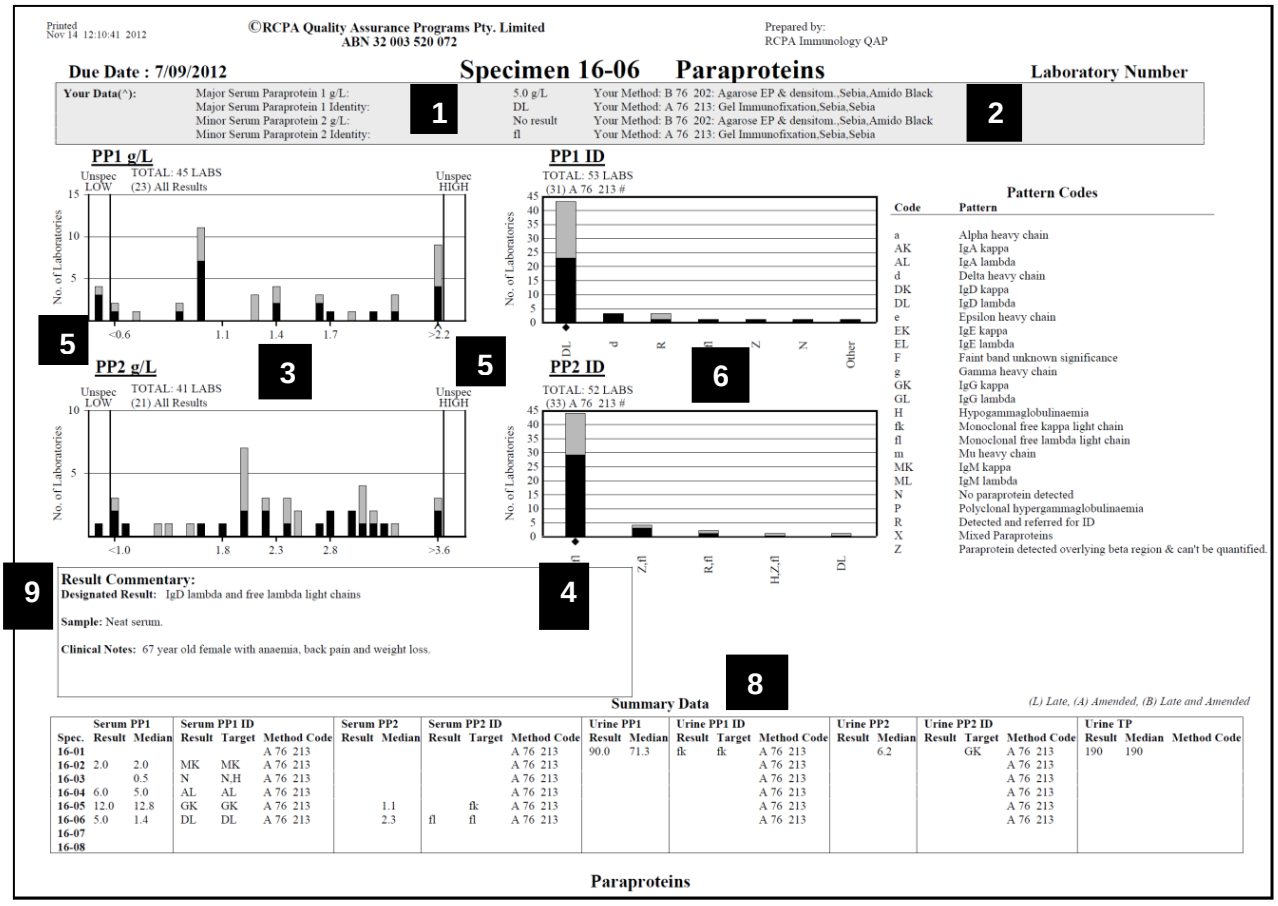
Report Format – HL





1. **YOUR DATA:** The results reported by your laboratory.
2. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted.
3. **OVERALL RESULTS:** Results from all laboratories graphed.
4. **EXPECTED VALUE:** The target or expected value for each specimen, based on consensus and/or tissue typing of B locus phenotype by a reference laboratory using reference methodology.
5. **SUMMARY DATA:** Displays summary data for the cycle to date, with columns showing methodology, target and your result for each specimen.
6. **RESULT COMMENTARY:** Displays the target for each specimen, tissue typing of B locus phenotype and any relevant discussion.
7. **METHOD COMPARISON PAGE:** Lists all participant IgE results grouped by method. Your result will be highlighted by a grey bar. *(Note – not available for IM, PH and RF reports)*

Report Format – PP, LC



1. **YOUR DATA:** The results reported by your laboratory and include specimen type (serum or urine).
2. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted.
3. **HISTOGRAMS:** Display quantitative results for major and minor paraprotein bands, expressed as g/L of paraprotein or mg/L for serum free light chains. “All Results’ are in grey, with your method group highlighted in black. Overall and method group numbers, ‘TOTAL’, shown above histograms.
4. **YOUR RESULT:** Indicated by a caret ^ or ♦.
5. **< OR > BINS:** Results reported as ‘<x’ or ‘>x’ are included in separate bins to the left and right of the histogram.
6. **PARAPROTEIN IDENTITY:** Displays the distribution of Paraprotein ID results, selected by laboratories from a coded list (shown to the right). ‘All Results’ are in grey, with your method group highlighted in black. Overall and method group totals are shown above the chart.
7. **KAPPA:LAMBDA RATIO:** Displays the distribution of quantitative and qualitative Kappa:Lambda ratios submitted.
8. **SUMMARY DATA BOX:** Displays summary data for the cycle to date, with columns showing methodology, target and your result for each specimen. Separate columns are provided for serum and urine. Targets are given for qualitative (identification) results only.
9. **RESULT COMMENTARY BOX:** Displays the target (Paraprotein identity) and its derivation, information about the specimen, clinical notes and any relevant discussion.
10. **DATA TABLE:** Displays all data received on the specimen, ordered within method groups.
11. **YOUR RESULTS:** Results provided by your laboratory are highlighted with shading.
12. **QUALITATIVE GRAPH:** Results expressed as a qualitative interpretation. For the LC module the target value is set with reference to clinical criteria or the consensus of qualitative results.

Printed
Apr 23 09:10:53 2018

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ABN 32 003 520 072

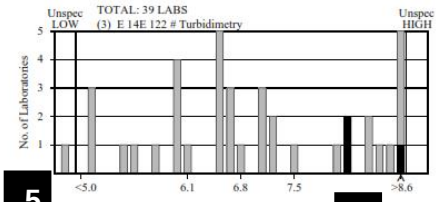
Prepared by:
RCPAQAP Immunology

Due Date : 09/04/2018 **Specimen 2-02** **Serum Free Light Chain** **Laboratory Number**

Your Data(^):	Kappa Free Light Chain:	8.8 mg/L	Your Method: E 14E 122: Turbidimetry,Roche Diagnostics Cobas c501/c502,The Binding Site
	Lambda Free Light chain:	42.8 mg/L	Your Method: E 14E 122: Turbidimetry,Roche Diagnostics Cobas c501/c502,The Binding Site
	Kappa:Lambda Ratio:	0.21 mg/L	Your Method:

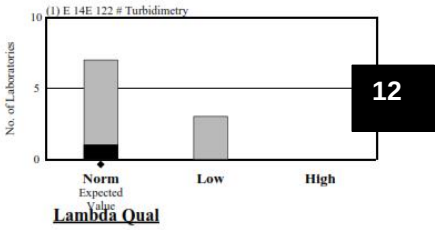
1 2

Kappa FLC



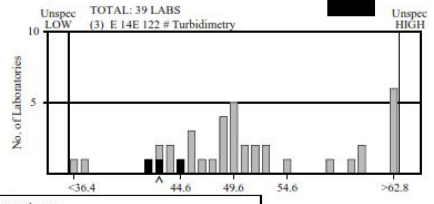
3 5 4

Kappa Qual

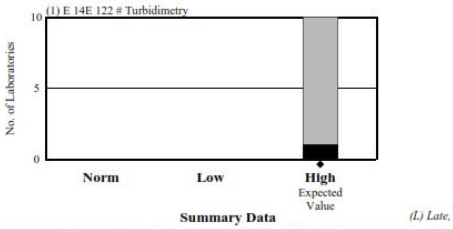


12

Lambda FLC



Lambda Qual



Result Commentary:
Specimen: Converted plasma in minimal human albumin.

Clinical: 56 year old male diagnosed with B Cell Non Hodgkin Lymphoma. History of Sjogren's syndrome and consistently elevated IgM levels.

REMINDER: Participants are reminded that light chain qualitative results can now be reported.

9

Summary Data *(L) Late, (A) Amended, (B) Late and Amended*

Spec.	Kappa FLC Result	Kappa FLC Median	Kappa Qual Target	Kappa Qual Result	Lambda FLC Result	Lambda FLC Median	Lambda Qual Target	Lambda Qual Result
2-01	25.3	23.4	High	No result	12.5	12.7	Norm	No result
2-02	8.8	6.8	Norm	Norm	42.8	49.6	High	High
2-03								
2-04								
2-05								
2-06								
2-07								
2-08								

8

Serum Free Light Chains

Printed
Apr 23 09:10:54 2018

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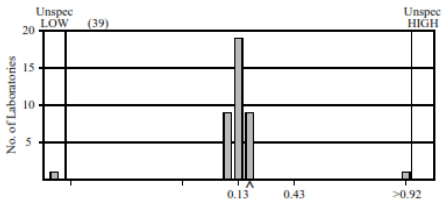
ABN 32 003 520 072

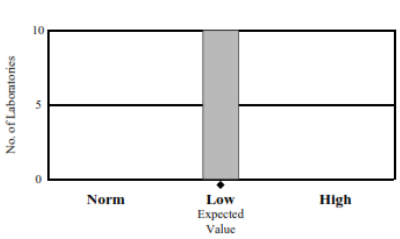
Prepared by:
RCPAQAP Immunology

Due Date : 09/04/2018 **Specimen 2-02** **Serum Free Light Chain** **Laboratory Number**

K:L Ratio



K:L Ratio-Q



7

Result Commentary:
Specimen: Converted plasma in minimal human albumin.

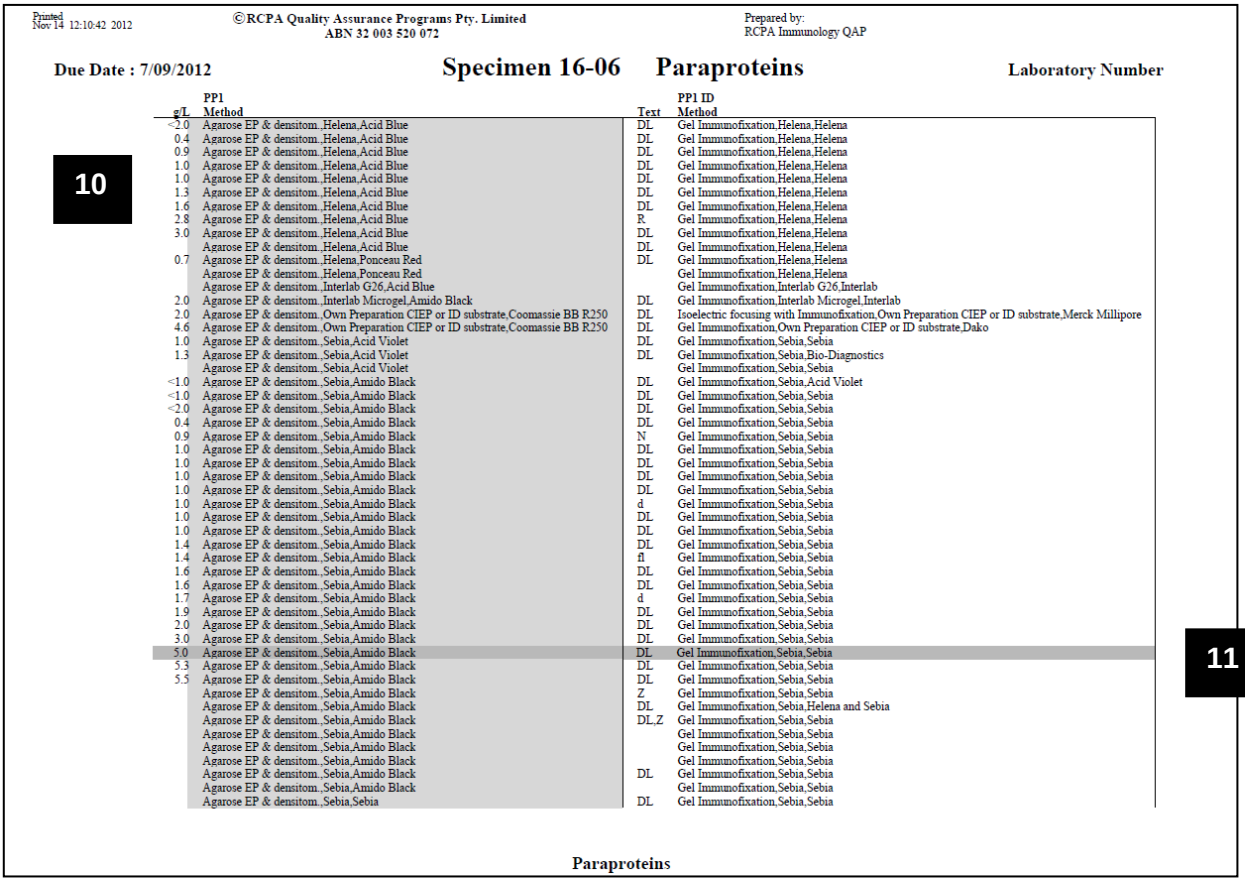
Clinical: 56 year old male diagnosed with B Cell Non Hodgkin Lymphoma. History of Sjogren's syndrome and consistently elevated IgM levels.

REMINDER: Participants are reminded that light chain qualitative results can now be reported.

Summary Data *(L) Late, (A) Amended, (B) Late and Amended*

Spec.	K:L Ratio Result	K:L Ratio Median	K:L Ratio Qual Target	K:L Ratio Qual Result
2-01	2.02	1.90	High	No result
2-02	0.21	0.13	Low	Low
2-03				
2-04				
2-05				
2-06				
2-07				
2-08				

Serum Free Light Chains



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ABN 32 003 520 072

Prepared by:
RCPA Immunology QAP

Due Date : 7/09/2012

Specimen 16-06 Paraproteins

Laboratory Number

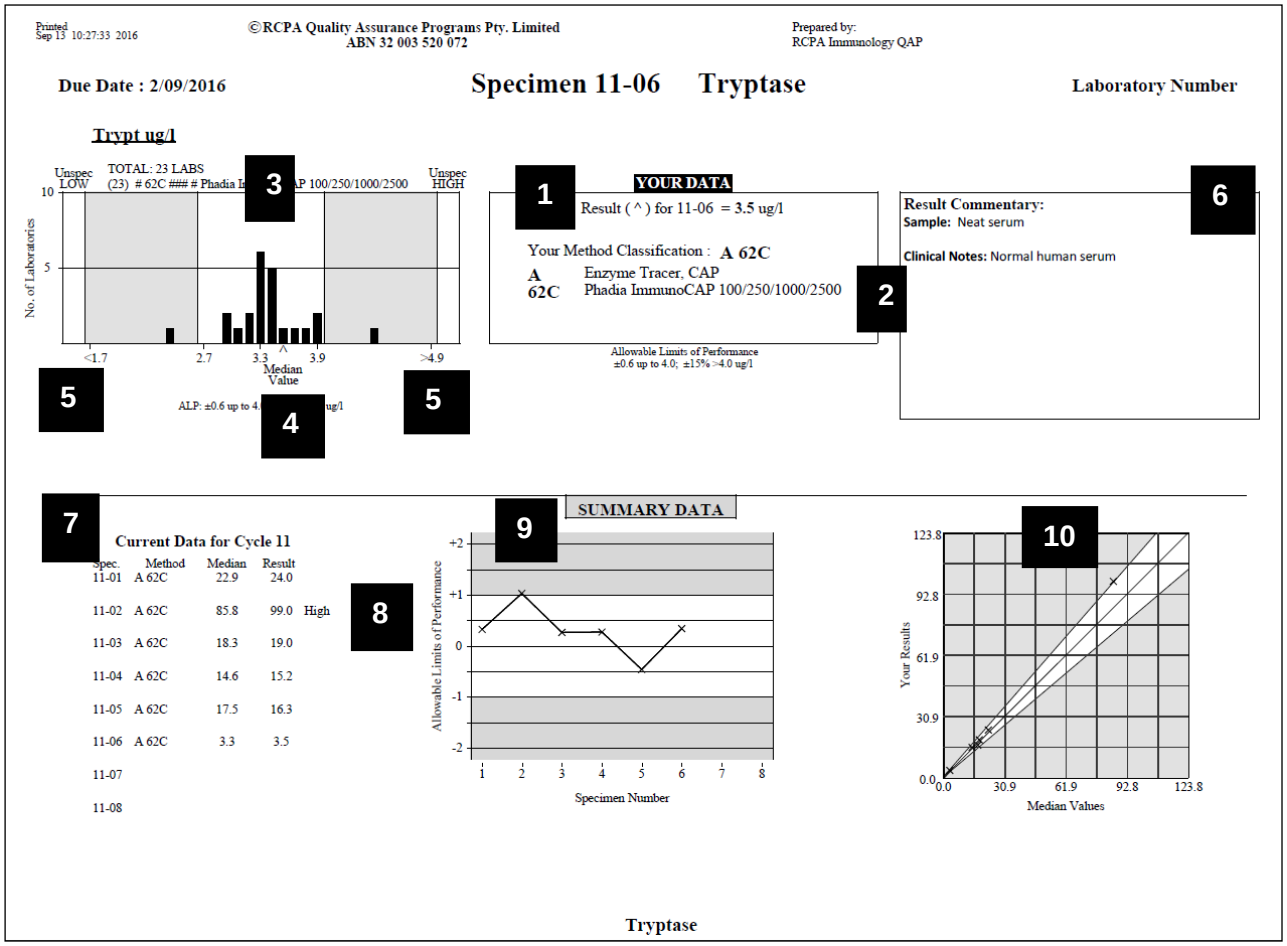
10

PP1 g/L	PP1 Method	PP1 ID Text	PP1 ID Method
<2.0	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
0.4	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
0.9	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
1.0	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
1.0	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
1.3	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
1.6	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
2.8	Agarose EP & densitom.,Helena,Acid Blue	R	Gel Immunofixation,Helena,Helena
3.0	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
	Agarose EP & densitom.,Helena,Acid Blue	DL	Gel Immunofixation,Helena,Helena
0.7	Agarose EP & densitom.,Helena,Ponceau Red	DL	Gel Immunofixation,Helena,Helena
	Agarose EP & densitom.,Helena,Ponceau Red		Gel Immunofixation,Helena,Helena
	Agarose EP & densitom.,Interlab G26,Acid Blue		Gel Immunofixation,Interlab G26,Interlab
2.0	Agarose EP & densitom.,Interlab Microgel,Amido Black	DL	Gel Immunofixation,Interlab Microgel,Interlab
2.0	Agarose EP & densitom.,Own Preparation CIEP or ID substrate,Coomassie BB R250	DL	Isoelectric focusing with Immunofixation,Own Preparation CIEP or ID substrate,Merck Millipore
4.6	Agarose EP & densitom.,Own Preparation CIEP or ID substrate,Coomassie BB R250	DL	Gel Immunofixation,Own Preparation CIEP or ID substrate,Dako
1.0	Agarose EP & densitom.,Sebia,Acid Violet	DL	Gel Immunofixation,Sebia,Sebia
1.3	Agarose EP & densitom.,Sebia,Acid Violet	DL	Gel Immunofixation,Sebia,Bio-Diagnostics
	Agarose EP & densitom.,Sebia,Acid Violet		Gel Immunofixation,Sebia,Sebia
<1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Acid Violet
<1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
<2.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
0.4	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
0.9	Agarose EP & densitom.,Sebia,Amido Black	N	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	d	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.4	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.4	Agarose EP & densitom.,Sebia,Amido Black	fl	Gel Immunofixation,Sebia,Sebia
1.6	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.6	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
1.7	Agarose EP & densitom.,Sebia,Amido Black	d	Gel Immunofixation,Sebia,Sebia
1.9	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
2.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
3.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
5.0	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
5.3	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
5.5	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black	Z	Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Helena and Sebia
	Agarose EP & densitom.,Sebia,Amido Black	DL,Z	Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black		Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black		Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black		Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black	DL	Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Amido Black		Gel Immunofixation,Sebia,Sebia
	Agarose EP & densitom.,Sebia,Sebia	DL	Gel Immunofixation,Sebia,Sebia

11

Paraproteins

Report Format – TR, PC, HS



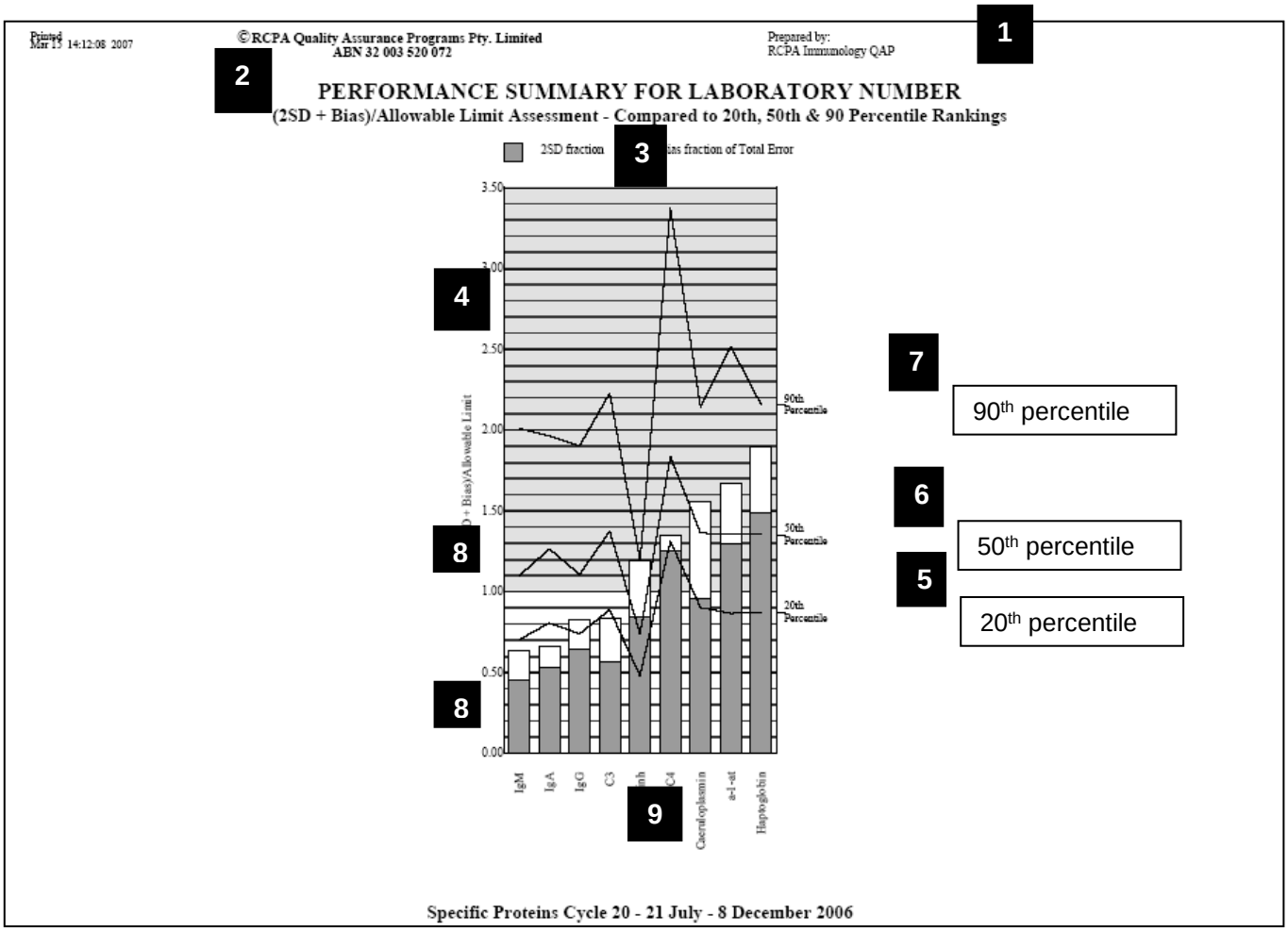
1. **YOUR DATA:** The results reported by your laboratory.
2. **METHOD CLASSIFICATION:** The method classification your laboratory has submitted.
3. **HISTOGRAM:** Displays results in ug/l. 'All Results' are in grey, with your method group highlighted in black. Overall and method group numbers, 'TOTAL', shown above histograms.
4. **YOUR RESULT:** Indicated by a caret ^ or ♦.
5. **< OR > BINS:** Results reported as '<x' or '>x' are included in separate bins to the left and right of the histogram.
6. **RESULT COMMENTARY BOX (Tryptase Only):** Displays information about the specimen, clinical notes and any relevant discussion.
7. **CURRENT DATA:** Displays summary data for the cycle to date, with columns showing methodology, target and your result for each specimen. The 'Method' column will show any method changes.
8. **LOW, HIGH, LATE AND AMENDED FLAGS:** The comments 'Low' or 'High' are added if the result is outside the Analytical Performance Specification. 'Late' and 'Amended' flags are added if applicable.
9. **LEVEY JENNINGS STYLE PLOT:** A plot of each pair of sample results showing deviations from the calculated median (0) indicate performance against the Analytical Performance Specifications. Acceptable results are within +/- 1 Analytical Performance Specification of the calculated median, are indicated on the graph by the non-shaded area.
   The scale of Analytical Performance Specifications is adjusted to accommodate your results up to a maximum of +/- 9 limits.
10. **LINEARITY GRAPH:** This graph shows non-linearity, imprecision and inaccuracy. Results in the shaded area are outside the Analytical Performance Specifications.

End of Cycle Report – IM, RF, IE

End of Cycle Reports are issued for those modules for which this type of detailed statistical analysis is appropriate. At the end of a cycle, three reports are generated to allow your laboratory to easily review your analytical performance. These are the Performance Summary, End of Cycle and Error Analysis reports.
The Performance Summary report is designed to allow rapid assessment of an entire cycle of results and to identify measurands which may need closer attention. The End of Cycle report provides useful information on the major components of error, bias and imprecision and also provides comprehensive peer review and summary data for participants. The Error Analysis report highlights measurands with one or more results outside the Analytical Performance Specifications. This report will not be issued if your laboratory has no results outside acceptable limits for the cycle.
Note: The survey reports produced from the eQuality platform now incorporate components of the legacy "end of cycle" reports to measure accuracy and precision. The survey reports display how accurate and precise survey results are over consecutive survey runs in every report. Report examples produced from the eQuality platform can be found on the myQAP help page.

Performance Summary Report

This is a single-page summary showing the analytical performance of all measurands submitted by your laboratory. Measurands are ranked from best to worst, based on the 'Measurand Performance' (see below). The 20th, 50th and 90th percentile performance of all participants is also provided for peer review.



1. **TITLE:** Name of report and your laboratory number.

2. ASSESSMENT CRITERION:

The assessment criteria is defined as measurand performance. As analytical error is due to both imprecision and bias, Total Error has been defined as follows:

Total Error = 2SD + Bias

The quality of your laboratory's performance is then determined by comparing the Total Error to the Analytical Performance Specification at the mid-point of the range of measurand concentrations for the cycle as follows:

$$\text{Measurand Performance} = \frac{2SD + Bias}{\text{Analytical Performance Specification}}$$

The following example of IgM analysis may assist in understanding this method of assessment.

Median Low Level = 0.42 g/l Median High Level = 4.62 g/l

The mid-point concentration is therefore 2.52 g/l

The Analytical performance Specifications for IgM is:

± 0.5 g/l up to 0.55 g/l; ± 10% >0.55 g/l

The Analytical Performance Specifications at the mid-point (2.52 g/l) is therefore 0.25 g/l

For a sample laboratory:

SD = 0.14 g/l Bias = 0.10 g/l

Total Error = (2 x 0.14) + 0.10 = 0.38

$$\textbf{Measurand Performance} = \frac{0.38}{0.25} = 1.52$$

When the Total Error is less than the Analytical Performance Specification then the Measurand Performance will be less than 1.00. This is the desired level of performance.

3. GRAPHICAL PRESENTATION: Each individual Measurand Performance is plotted as a column where the relative contribution of imprecision (2SD) appears as a shaded grey area and that of Bias appears as a clear area.

4. LEVEL OF PERFORMANCE: A scale using the Measurand Performance is on the left y axis (numerical scale).

The right y axis displays the 20th, 50th and 90th percentile values. Measurand performance is determined for all participants and the 20th, 50th and 90th percentile values are plotted for comparative purposes and peer review. The percentile performances are displayed by use of a line graph for each measurand as follows:

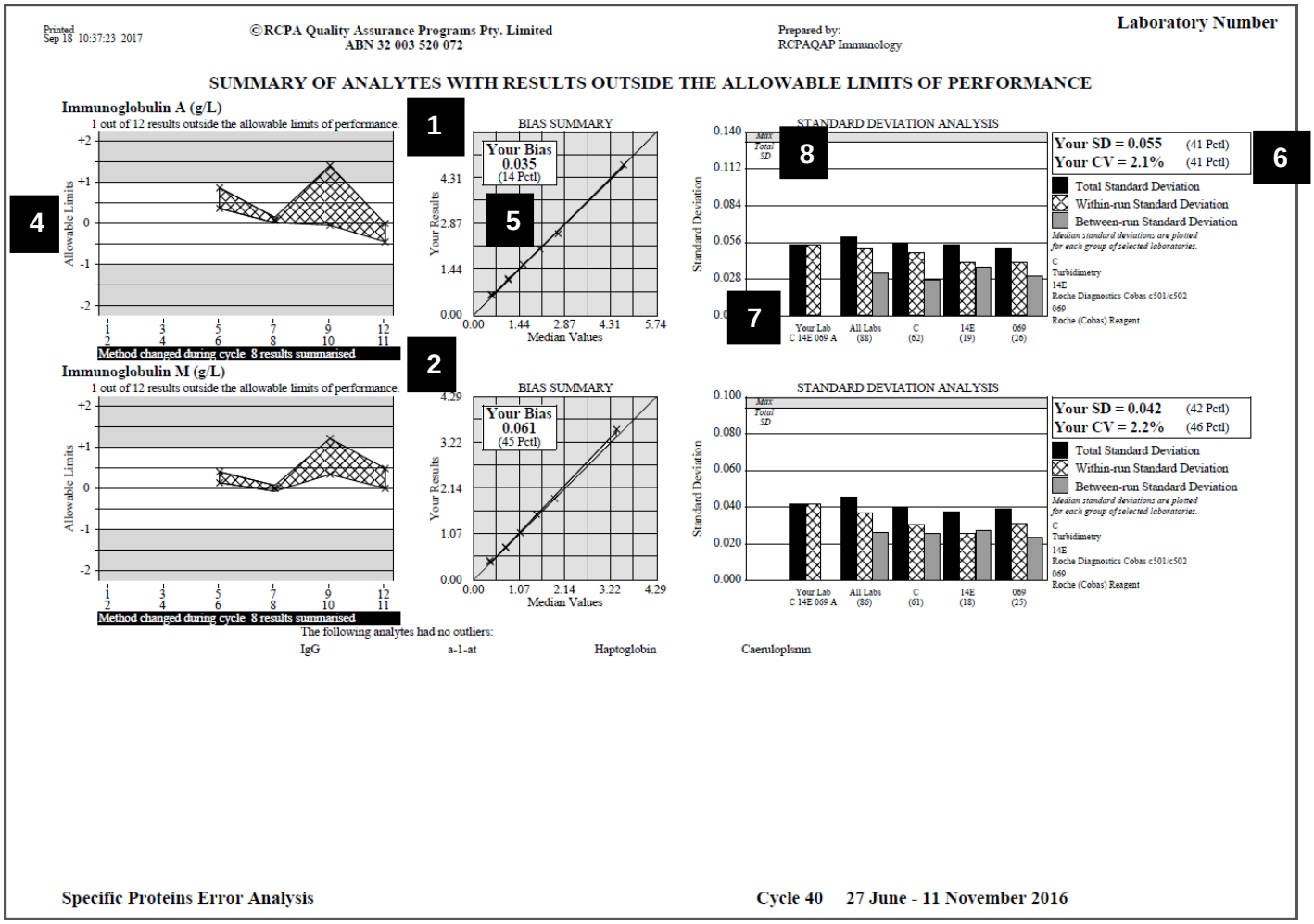
5	20th percentile
6	50th percentile
7	90th percentile

8. DESIRABLE LEVEL OF PERFORMANCE: The desirable Measurand Performance is less than 1.00. The shading when Measurand Performance is above 1.00 highlights the measurands which may require attention.

9. **MEASURANDS:** The measurands are plotted in ascending order of your Measurand Performance, with the best measurand on the left and ascending to the worst measurand on the right.

10. **MODULE NAME:** Name of the module and cycle number being summarised including the start and end dates of the cycle.

End of Cycle Error Analysis Report



1. **NUMBER OF OUTLIERS AND RESULTS:** The number of outliers and results returned.
2. **METHOD CHANGE:** If your method code is changed during the cycle, only results with the most recent classification are considered. A comment “Method changed during cycle will appear under the Analytical Performance Specifications graph. # results summarised” is printed on the report.

3. **ATYPICAL RESULTS (if applicable):** All results are tested to determine whether atypical results have been reported. These are results not consistent with your usual analytical performance and consequently affect end of cycle summary statistics. It is inappropriate to comment on such end of cycle statistics.

   A result is defined as atypical when it is:
   a. More than 3 standard deviations and

b. More than the Analytical Performance Specification of performance from your regression line.

The atypical data is summarised using:

- A Levy-Jennings style plot
- An atypical result graph highlighting each atypical result
- A list of your affected SD, CV and bias

Atypical results are excluded, the end of cycle statistics recalculated and the measurand reported again in the usual manner.

4. **LEVEY-JENNINGS PLOT:** Summarises the reported results.

5. **BIAS SUMMARY:** Your bias at the low value, high value and mid value is determined. These are the differences between the line of expectation and your line of best fit. The average bias is then calculated by the following formula:

$$\textbf{BIAS} = \frac{[\text{low bias}] + [\text{mid bias}] + [\text{high bias}]}{3}$$

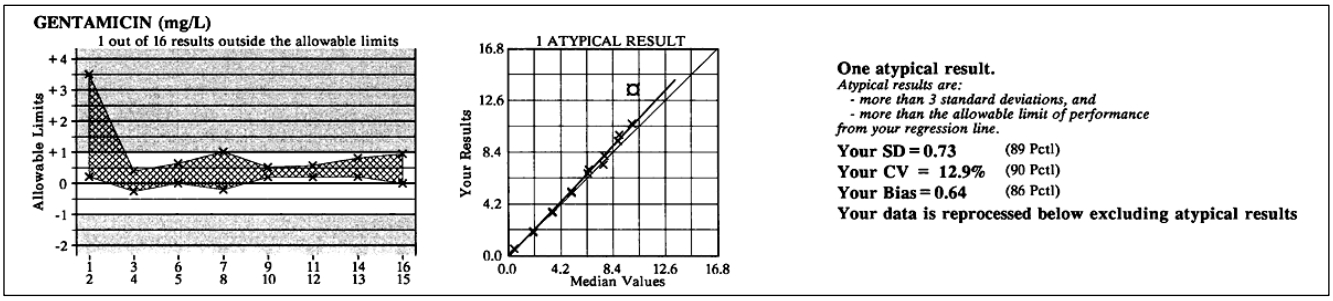
The bias summary plots your results against the expected values showing each result, your line of best fit, your bias and the percentile ranking (Pctl) of your bias relative to the bias of all participants.

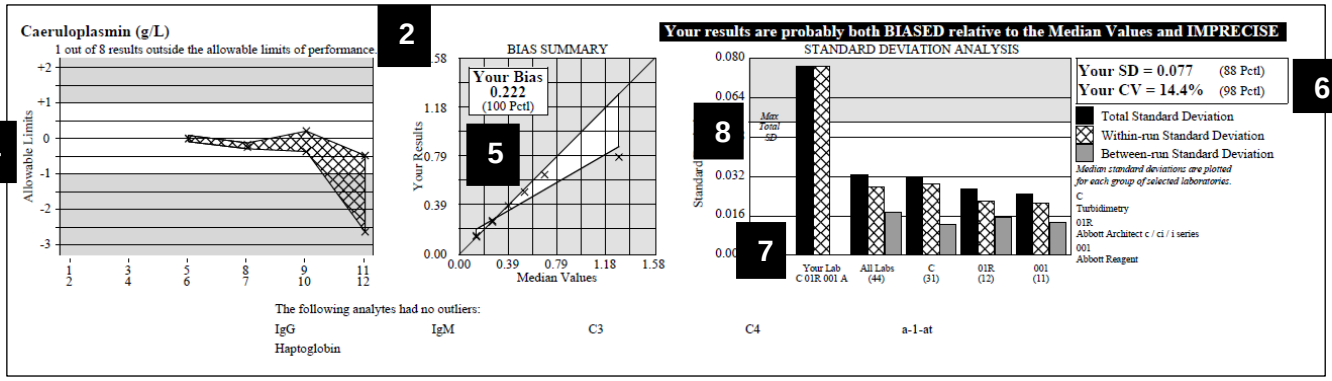
6. **STANDARD DEVIATION ANALYSIS PLOT:** The linear regression standard deviation, which is calculated using each of the results returned, is Sy.x (the standard error of the estimate). This value can be regarded as the average standard deviation over the range of values analysed and is the total SD.

7. **STANDARD DEVIATION COLUMN GRAPHS:** The first set of 3 columns displays your total standard deviation (black), your within-run standard deviation (hatched) and your between-run standard deviation (grey). Each remaining set of 3 columns represents the median standard deviations and the number of laboratories in each group plotted for: all laboratories, laboratories using the same analytical principle as your laboratory, laboratories using the same analyser as your laboratory, and laboratories using the same reagent as your laboratory.

8. **MAXIMUM TOTAL STANDARD DEVIATION:** The standard deviations are compared to the Maximum Total Standard Deviation. This SD is derived from the allowable limit of performance for the measurand being reviewed.

9. **COMMENTS ON PERFORMANCE:** Computer generated comments are provided for most measurands reviewed.





The basis for these comments are:

- Total standard deviation greater than the Maximum Allowable Standard Deviation.
- Bias with a percentile ranking greater than 50.

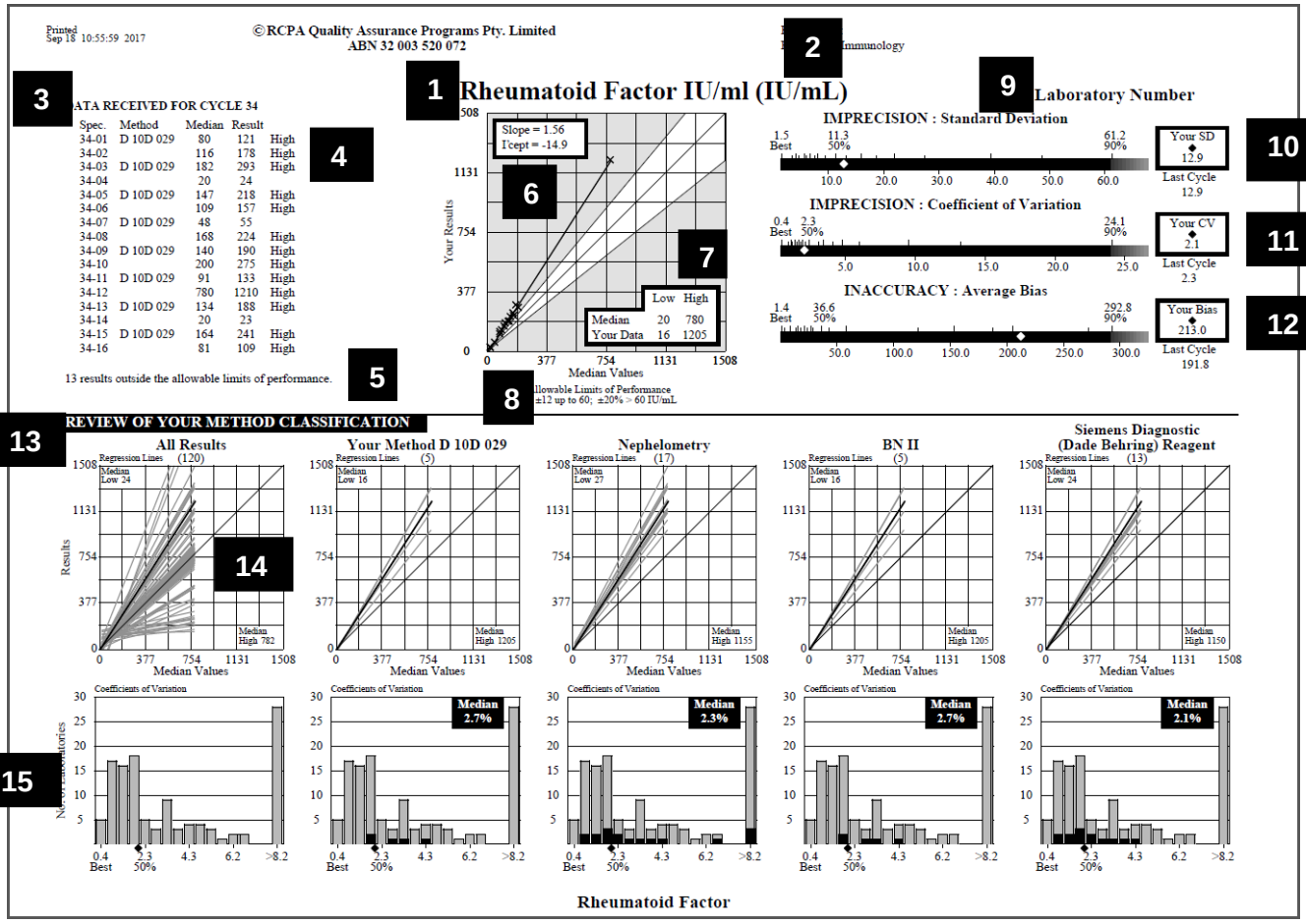
Failure of these criteria results in comments:

- “Probably IMPRECISE” and
- “Probably BIASED” compared to the relevant central values.

As these comments are computer generated, they are intended as a suggestion only and you are advised to review your data.

End of Cycle Report

At the end of each cycle of specimens an End of cycle Report is prepared, providing a comparison of a laboratory's results and derived statistics with other participants. Comparisons are made with all participants and those using the same analytical principle, instrument, reagent and combination of all 3 categories.
The key to obtaining maximum information from this report format is to ensure that you have accurately provided your method classification.



1. **MEASURAND:** The full name of the measurand.
2. **UNITS**: For the measurand being reported.
3. **DATA SUMMARY FOR CYCLE:** A record of all data submitted for the cycle, including method codes. Only data with the same method code as the last pair of specimens is included in end of cycle calculations.
4. **COMMENT FLAGS:** Comments High, Low, Late or Amended are added if applicable.
5. **ADDITIONAL COMMENTS:** Comments will be included on the number of results outside the Analytical Performance Specifications, and also if all results are not used in the calculations i.e. if the method code has been altered or a > or < result has been submitted.
6. **LINEARITY GRAPH:** Simple least squares linear regression analysis compared to the target value (median) is used for end of cycle calculations. The slope and intercept are recorded and your laboratory's line of best fit values at the lowest and highest values analysed are shown. Individual data points and the line of best fit for your laboratory are shown in comparison to the line of agreement. Results outside the Analytical Performance Specifications fall in the shaded area.
7. **LOW AND HIGH VALUES:** Using the slope and intercept the values of your line of best fit are determined compared to the lowest and highest 'target' values for the cycle.

8. **ANALYTICAL PERFORMANCE SPECIFICATIONS:** These are unique for each measurand and are based on statistical and clinical requirements.
9. **BAR GRAPHS:** The standard deviation, coefficient of variation and average bias are summarised in bar graphs. Two scales appear on each bar graph. The lower scale is linear in the units of the statistic. The upper scale shows the percentile scale, highlights the Best, 20th, 50th and 90th percentiles and indicates the value of the statistic at these percentiles. Your laboratory's statistic (◊) is plotted within the bar and is recorded in the box with the percentile ranking for the last cycle recorded beneath the box.
10. **STANDARD DEVIATION:** The standard deviation is the standard error of the estimate Sy.x and can be regarded as the average standard deviation across the range of concentrations analysed. Standard deviation provides a value in the units of the test. SD will tend to be high if you report high results and low if you report low results.
11. **COEFFICIENT OF VARIATION:** The standard deviation divided by the mid-point of your laboratory's range of concentrations, expressed as a percentage.

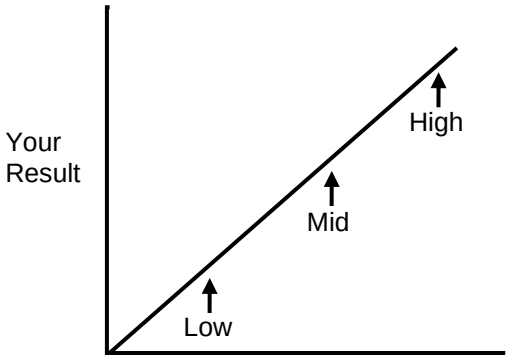
$$\textbf{CV\%} = \frac{\text{SD}}{\text{[(low value + high value) / 2]}} \times 100$$

Coefficient of variation 'corrects' for differences in concentration and so may be a better assessment of imprecision.

12. **AVERAGE BIAS:** Your biases at the low value, high value and mid value are determined. These are the differences between the line of expectation (45° line) and your line of best fit.

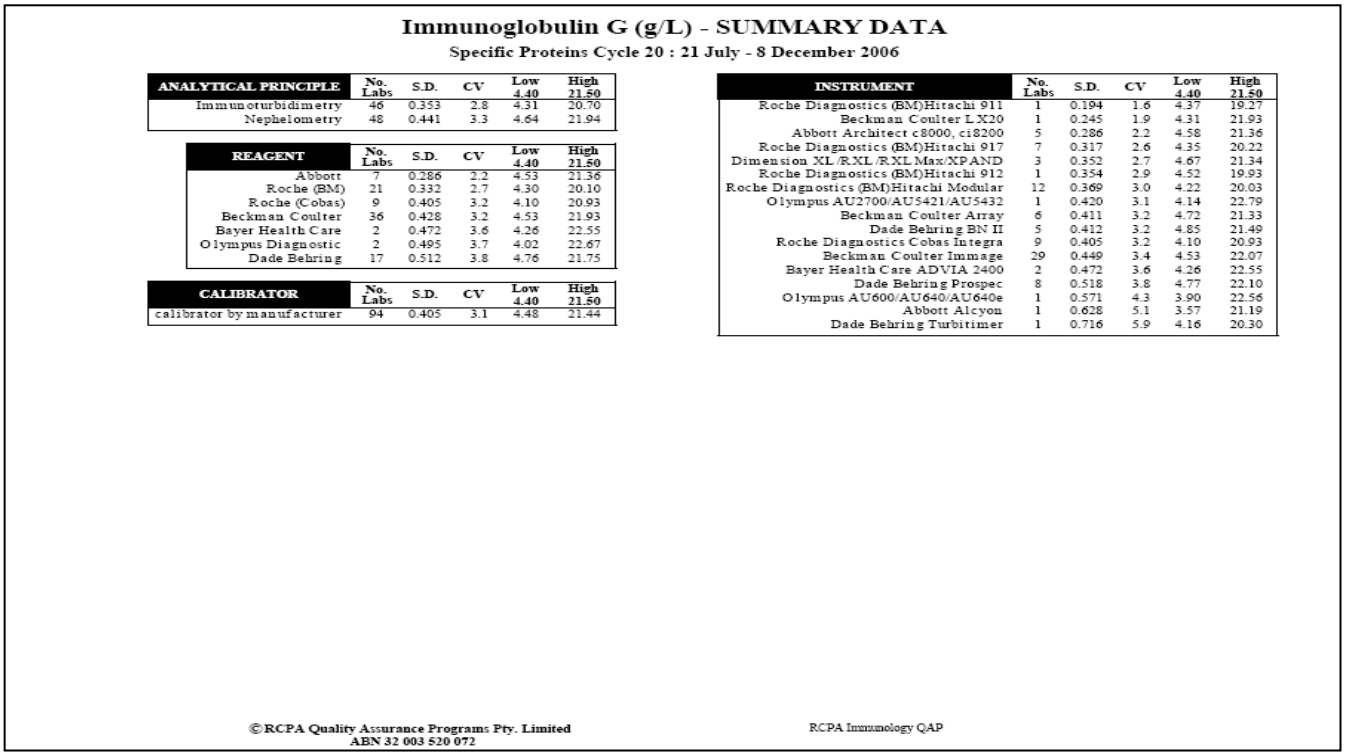
The average bias is calculated as:

$$\textbf{BIAS} = \frac{\text{LOW BIAS + MID BIAS + HIGH BIAS}}{3}$$



13. **REVIEW OF METHOD CLASSIFICATION:** The accuracy and precision of the laboratory are compared to all other participants and subgroups using the same method, instrument and reagent as the laboratory.
14. **REGRESSION LINES REVIEW:** Plots of the lines of best fit of selected laboratories highlighting your laboratory's line of best fit and showing the line of agreement. The number of laboratories in each group is shown in parentheses. The low and high median for each subgroup is shown in the top left and bottom right corner. The graphs provide a summary of the accuracy of your laboratory and the laboratories selected in each subgroup.
15. **COEFFICIENTS OF VARIATION:** A histogram showing the distribution of CV's for all laboratories and highlighting the laboratory's CV (♦). Histograms showing subgroups of data are superimposed in black on the columns and the median value for the subgroup is provided. The graphs provide a summary of the precision of the laboratory and the laboratories selected in each subgroup.

Summary Data



Immunoglobulin G (g/L) - SUMMARY DATA

Specific Proteins Cycle 20 : 21 July - 8 December 2006

ANALYTICAL PRINCIPLE	No. Labs	S.D.	CV	Low 4.40	High 21.50
Immunoturbidimetry	46	0.353	2.8	4.31	20.70
Nephelometry	48	0.441	3.3	4.64	21.94

REAGENT	No. Labs	S.D.	CV	Low 4.40	High 21.50
Abbott	7	0.286	2.2	4.53	21.36
Roche (BM)	21	0.332	2.7	4.30	20.10
Roche (Cobas)	9	0.405	3.2	4.10	20.93
Beckman Coulter	36	0.428	3.2	4.53	21.93
Bayer Health Care	2	0.472	3.6	4.26	22.55
Olympus Diagnostic	2	0.495	3.7	4.02	22.67
Dade Behring	17	0.512	3.8	4.76	21.75

CALIBRATOR	No. Labs	S.D.	CV	Low 4.40	High 21.50
calibrator by manufacturer	94	0.405	3.1	4.48	21.44

INSTRUMENT	No. Labs	S.D.	CV	Low 4.40	High 21.50
Roche Diagnostics (BM)Hitachi 911	1	0.194	1.6	4.37	19.27
Beckman Coulter LX20	1	0.245	1.9	4.31	21.93
Abbott Architect c8000, ci8200	5	0.286	2.2	4.58	21.36
Roche Diagnostics (BM)Hitachi 917	7	0.317	2.6	4.35	20.22
Dimension XL /RXL /RXL Max/XPAND	3	0.352	2.7	4.67	21.34
Roche Diagnostics (BM)Hitachi 912	1	0.354	2.9	4.52	19.93
Roche Diagnostics (BM)Hitachi Modular	12	0.369	3.0	4.22	20.03
Olympus AU2700/AU5421/AU5432	1	0.420	3.1	4.14	22.79
Beckman Coulter Array	6	0.411	3.2	4.72	21.33
Dade Behring BN II	5	0.412	3.2	4.85	21.49
Roche Diagnostics Cobas Integra	9	0.405	3.2	4.10	20.93
Beckman Coulter Immage	29	0.449	3.4	4.53	22.07
Bayer Health Care ADVIA 2400	2	0.472	3.6	4.26	22.55
Dade Behring Prospec	8	0.518	3.8	4.77	22.10
Olympus AU600/AU640/AU640e	1	0.571	4.3	3.90	22.56
Abbott Alcyon	1	0.628	5.1	3.57	21.19
Dade Behring Turbitimer	1	0.716	5.9	4.16	20.30

RCPA Immunology QAP

The end of cycle calculations provide a review of methods, instruments and reagents. This data is printed on the back of the laboratory report for each measurand.
Data is summarised in up to 4 categories depending on the measurand:

- Analytical principle
- Measurement system
- Reagent source
- Calibrator

Information provided is:

- Number of laboratories in each group
- Median standard deviation of the group
- Median CV of the group
- Median Low and High values compared to the appropriate target value.

Groups are ordered in ascending %CV.

Case Study Module
The Case Study Module consists of case studies that may be helpful for training staff. This module is for educational purposes only and participants are not scored. This module is distributed as an online survey and the link sent via email to all contacts enrolled in the Case Study Module on myQAP. Participants returning results for this module will receive an Individual Report and a General Discussion Report. Individual survey reports are emailed to the laboratory's primary contact for distribution to all respondents. The General Discussion Report is emailed to all respondents and uploaded on myQAP.

Report Interpretation Flowcharts:
The Quantitative Survey Report Interpretation Flowchart can be found by clicking on this **link.**
The Quantitative End of Cycle Report Interpretation Flowchart can be found by clicking on this link.

Serology

The Serology discipline commenced using the new RCPAQAP software platform in 2019/20 to structure survey programs, analyse survey results and assess performance. The report format has also been updated to follow a standard structure used by all programs offered by the RCPAQAP.

The following information provides participants with a guide to understand the data analysis system used to assess participant performance.

Participant Performance

The RCPAQAP Serology discipline provides proficiency testing programs to participants that are designed to monitor methods that detect and/or measure levels of antibodies and/or antigens within a sample as a result of exposure to a bacteria or virus.

While the expected results for survey samples (based on pre-testing) are known to RCPAQAP Serology, overall participant performance is based on consensus results returned for the interpretative (qualitative) component of the program. The quantitative component of the survey is also reviewed to assess the variation seen by individual methods currently being used to detect the antibodies and /or antigens in the program.

Analysis of Qualitative results

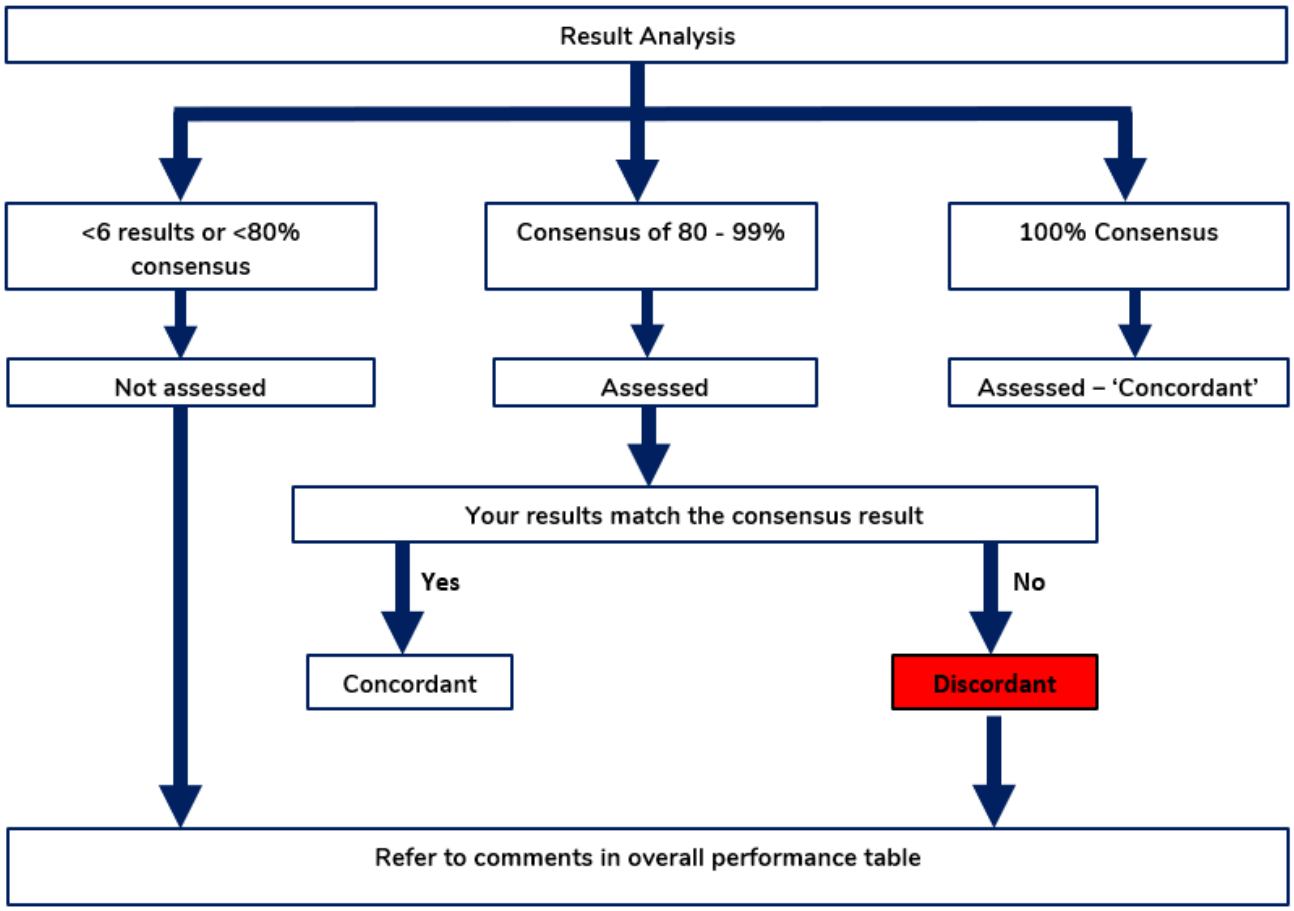
The expected results for all qualitative survey results (e.g. Positive/Negative) are determined from the consensus of all results. Results are only assessed where ≥ 80% of participants return the same value and provided there are 6 or more results.

- If a test achieves ≥80% consensus/agreement from 6 or more results, this is then listed as the expected value. Participants who return the expected value are assessed as “CONCORDANT”
- If a test achieves ≥80% consensus from 6 or more results, participants in the minority group are assessed as inconsistent from the consensus and their results are listed as “DISCORDANT”.
- When <80% or < 6 labs agree, the uncertainty of the results increases so no assessment is made and all results are reported as “NOT ASSESSED”.

Analysis of Quantitative Results

Quantitative analysis is performed on all tests where a numerical result is provided (e.g. S/CO). Results are illustrated in a scatterplot for all methods. The scatterplot illustrates the median value and an indicator of the upper and lower (+/- 3SD) range. Participants should troubleshoot results that lie outside the upper and lower range.

Criteria for assessment of qualitative participant results



All participants should investigate all non-assessed or discordant results using their internal quality system. Participants should form their conclusions on each method's performance based on the accumulation of data and information that is supplied in the survey, the report commentary, raw data and other information available to the participant.

To assist in troubleshooting your non-assessed or discordant results, consider the following:

- Are discordant results method group (kit) related?
- Are your results discordant compared to others in your method group?
- Are discordant results related to your analytical principle?
- Are discordant results lot number related?
- Has the specimen type been validated for the method?
- Do the results appear to be related to sensitivity/specificity?
- If this was a duplicate sample from a previous survey (as noted in the commentary) with discordant results were your results previously concordant??

Survey Reports

The RCPAQAP Serology report format follows a standard structure that will be adopted by other programs offered by the RCPAQAP. This single report replaces the previous generic and survey reports.

The structure of the new reports provides participants with a summary of performance, reviews the performance of participant result, providing a method breakdown review with commentary and provides cumulative performance.

An example of the report can be seen below:

Section 1: Summary of Performance

Summary of Performance

Survey: **1** Open Date: **25 January 2021** Closing Date: **15 February 2021**

Measurement system used by your laboratory

Measurand	Kit	Analytical principle	Measurement system	Units
Rubella virus IgG	Abbott Architect Rubella IgG	Chemiluminescent microparticle immunoassay (CMIA)	Abbott Architect	International Units per millilitre (IU/mL)
Rubella virus IgM	Abbott Architect Rubella IgM	Chemiluminescent microparticle immunoassay (CMIA)	Abbott Architect	Index

Performance Assessment (Results are only assessed when greater than or equal to 80% consensus is achieved using 6 or more results)

	Sample: SE-RUB-21-01					Sample: SE-RUB-21-02				
Measurand	Your Result	Your Assessment	Consensus Result	Consensus %	n Part.	Your Result	Your Assessment	Consensus Result	Consensus %	n Part.
Rubella virus IgG Interpretation	Positive	Concordant	Positive	100.0	142	Positive	Concordant	Positive	97.9	142
Rubella virus IgM Interpretation	Equivocal	Discordant	Negative	96.2	79	Negative	Concordant	Negative	98.7	78
Rubella virus IgG avidity Interpretation	Not Tested	Not Assessed	High	100.0	5	Not Tested	Not Assessed	High	100.0	5

Overall Performance

Please review results returned for Sample(s):	SE-RUB-21-01
Rubella virus IgM Interpretation	Discordant

Please review any results where the assessment criteria were not met.

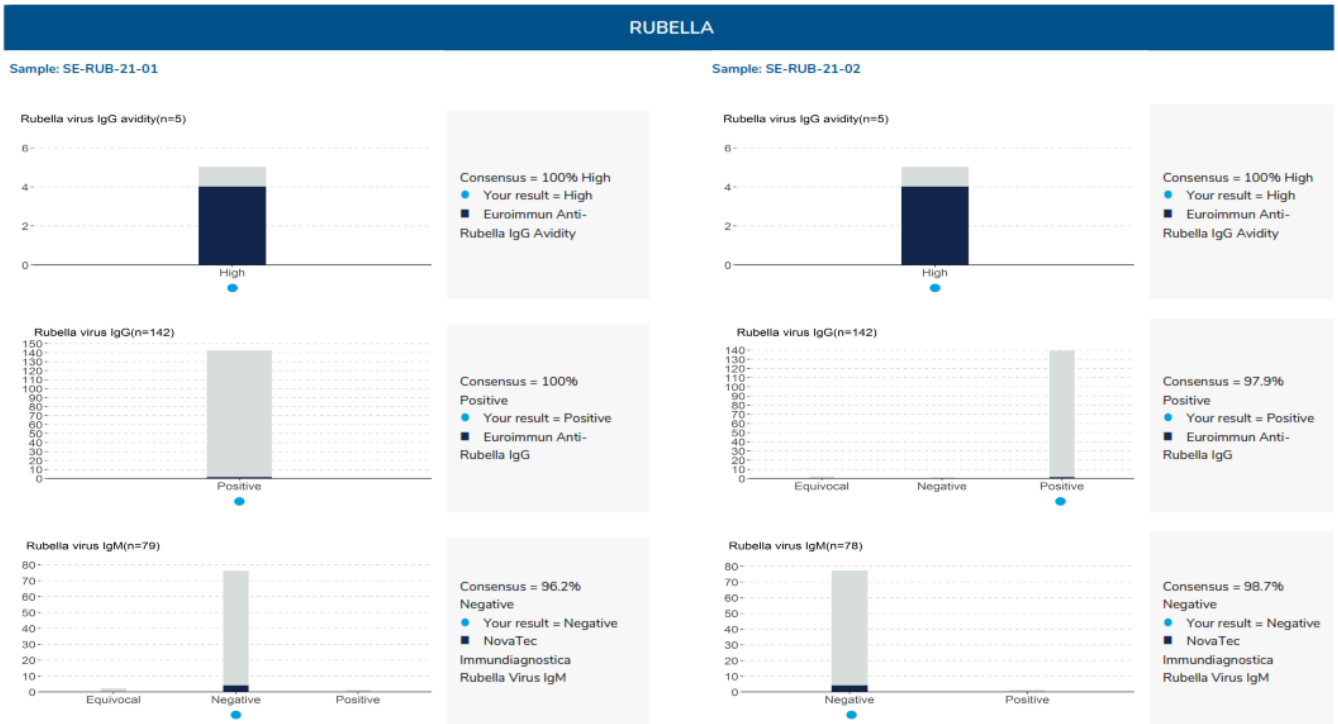
Measurement system used by your laboratory: Lists the measurement system returned by you at result entry in the myQAP portal.

Performance assessment: Provides the assessment of your results against consensus of 80% of all participants returning the same qualitative value for the measurand. Only qualitative results are assessed. Quantitative results are currently not assessed, although statistical analysis will be provided for user groups of 6 or more quantitative data.

Consensus result: The consensus result represents the qualitative result returned by the majority of laboratories for a sample. 80% consensus must be reached by more than 6 laboratories to assess performance.

Overall Performance: Provides a comment on the overall performance for this survey.

Section 2: Result Review



- **Result histograms:** Includes all qualitative results returned for each sample. The report lists your result, the consensus result and the percent consensus achieved. Highlights the number of results for your method group.

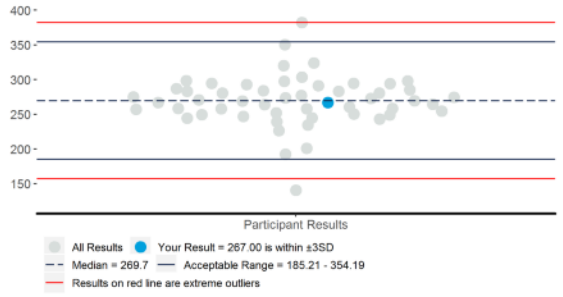
Rubella virus IgG Interpretation - KIT PERFORMANCE (Method consensus not provided if less than 6 users within the method group)

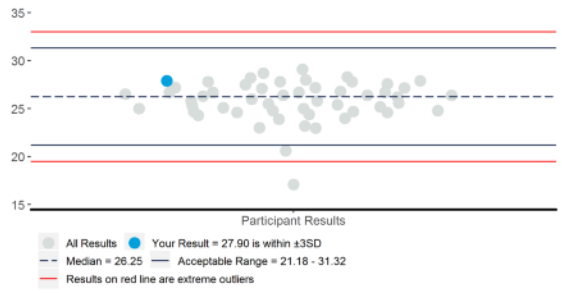
	Sample SE-RUB-21-01 (Consensus = Positive)					Sample SE-RUB-21-02 (Consensus = Positive)				
Kit Name	Negative	Positive	Equivocal	Method Consensus (%)	n Part.	Negative	Positive	Equivocal	Method Consensus (%)	n Part.
Abbott Alinity Rubella IgG	0	19	0	100	19	1	18	0	94.7	19
Abbott Architect Rubella IgG	0	53	0	100	53	0	52	1	98.1	53
Beckman Coulter Rubella IgG	0	2	0	Insufficient data	2	0	2	0	Insufficient data	2
bioMerieux VIDAS Rubella IgG II	0	8	0	100	8	0	8	0	100	8
Bio-Rad Platelia Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
DiaSorin Liaison Rubella IgG II	0	10	0	100	10	0	10	0	100	10
Euroimmun Anti-Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Ortho-Clinical Diagnostics Vitros Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Roche Diagnostics Rubella IgG	0	29	0	100	29	0	28	1	96.6	29
Siemens Advia Rub G II	0	5	0	Insufficient data	5	0	5	0	Insufficient data	5
Siemens Anti-Rubella IgG	0	2	0	Insufficient data	2	0	2	0	Insufficient data	2
Siemens Atellica Rubella IgG Quant	0	6	0	100	6	0	6	0	100	6
Siemens Immulite Rubella IgG Quant	0	2	0	Insufficient data	2	0	2	0	Insufficient data	2
Trinity Biotech Captia Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Vircell Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Virion Serion Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1

- **Kit Performance:** Provides a breakdown of the results returned from participants based on the 'kits' used to perform the assigned tests. Lists the number of participants returning a qualitative result along with the method consensus.

Rubella virus IgG Interpretation - KIT PERFORMANCE (Method consensus not provided if less than 6 users within the method group)

	Sample SE-RUB-21-01 (Consensus = Positive)					Sample SE-RUB-21-02 (Consensus = Positive)				
Kit Name	Negative	Positive	Equivocal	Method Consensus (%)	n Part.	Negative	Positive	Equivocal	Method Consensus (%)	n Part.
Abbott Alinity Rubella IgG	0	19	0	100	19	1	18	0	94.7	19
Abbott Architect Rubella IgG	0	53	0	100	53	0	52	1	98.1	53
Beckman Coulter Rubella IgG	0	2	0	Insufficient data	2	0	2	0	Insufficient data	2
bioMerieux VIDAS Rubella IgG II	0	8	0	100	8	0	8	0	100	8
Bio-Rad Platelia Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
DiaSorin Liaison Rubella IgG II	0	10	0	100	10	0	10	0	100	10
Euroimmun Anti-Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Ortho-Clinical Diagnostics Vitros Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Roche Diagnostics Rubella IgG	0	29	0	100	29	0	28	1	96.6	29
Siemens Advia Rub G II	0	5	0	Insufficient data	5	0	5	0	Insufficient data	5
Siemens Anti-Rubella IgG	0	2	0	Insufficient data	2	0	2	0	Insufficient data	2
Siemens Atellica Rubella IgG Quant	0	6	0	100	6	0	6	0	100	6
Siemens Immulite Rubella IgG Quant	0	2	0	Insufficient data	2	0	2	0	Insufficient data	2
Trinity Biotech Captia Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Vircell Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1
Virion Serion Rubella IgG	0	1	0	Insufficient data	1	0	1	0	Insufficient data	1





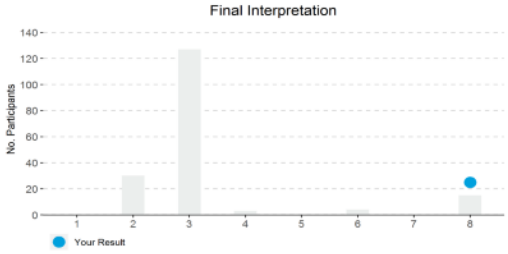
Rubella virus IgG	Sample SE-RUB-21-01					Sample SE-RUB-21-02				
Your Quantitative Value			267.0					27.9		
Kit Name	Unit	n Results	Mean	Median	SD	CV %	n Results	Mean	Median	SD	CV %
Abbott Alinity Rubella IgG	IU/mL	19	263.21	261.8	18.65	7.1	19	25.92	25.7	1.19	4.6

Quantitative results are illustrated in a scatterplot in your specific method group (participants using the same kit). Exclusion of outlier results from your method group may result in differences in the qualitative and quantitative number of results.
Results highlighted in blue within the table of results indicate the method used within your laboratory.

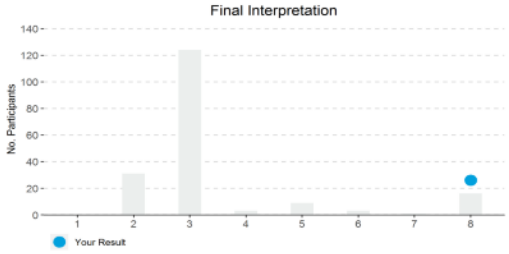
A red line above or below the scatter plot represents 4SD (4 standard deviations) from the mean. Results that lie on or outside the red line represent results that are equal to, or greater than 4SD).

Rubella Interpretation

SE-RUB-21-01



SE-RUB-21-02



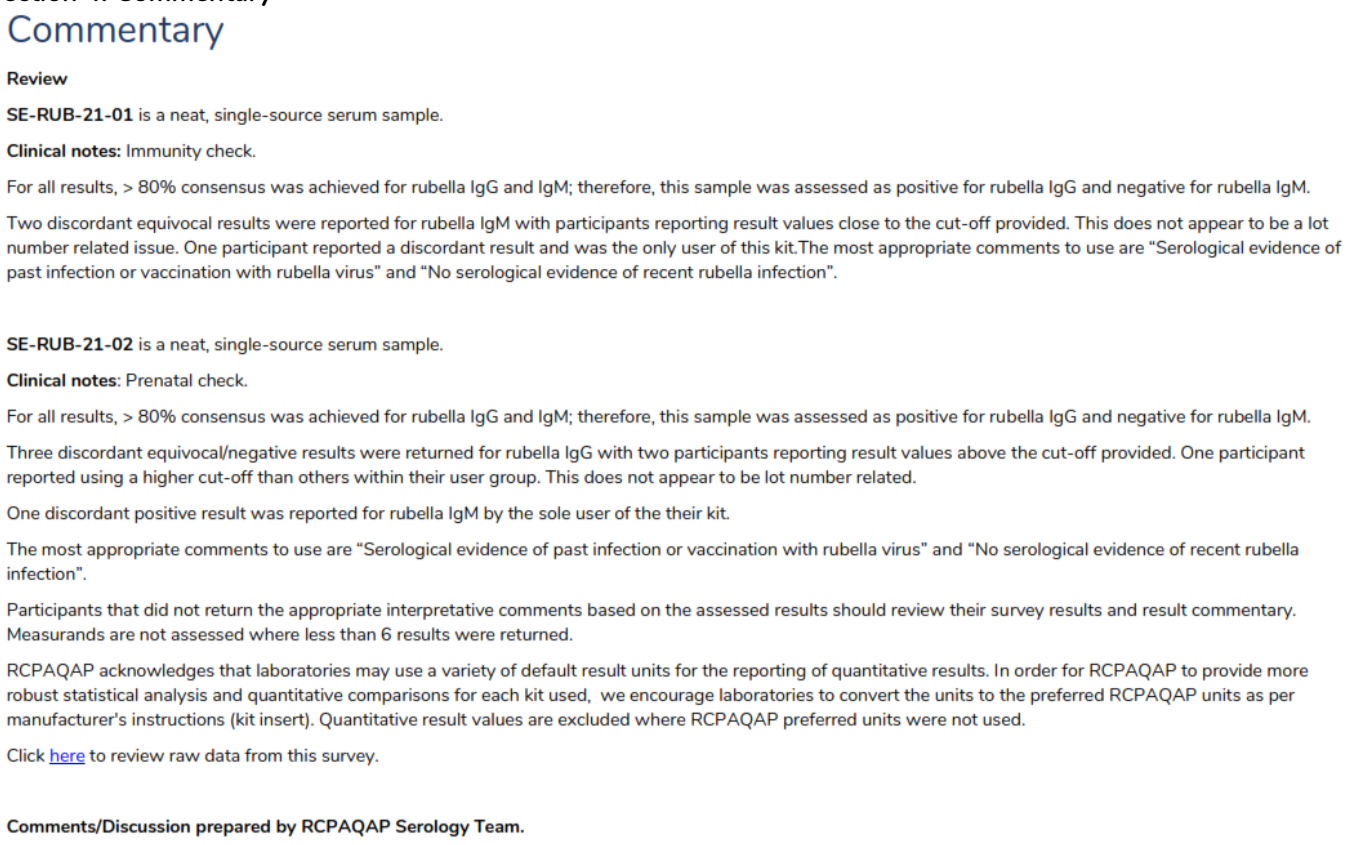
		SE-RUB-21-01		SE-RUB-21-02	
No.	Interpretation	No. Part	%	No. Part	%
1	No serological evidence of past infection or vaccination with rubella virus				
2	No serological evidence of recent rubella infection	30	19	31	20
3	Serological evidence of past infection or vaccination with rubella virus	127	82	124	80
4	Serological evidence of recent rubella infection	3	1	3	1
5	Antibody level is low and may not be protective			9	5
6	In order to confirm or exclude recent infection, please send a second specimen in 10-14 days if clinically indicated	4	2	3	1
7	Refer to a reference laboratory for further testing			1	0
8	No comment	15	9	16	10

Section 3: Interpretation

- Provides a breakdown of all the responses received for the result interpretation. This provides the total number of laboratories that returned each response and as a percentage of the total, for that response. The percentage is based on the total number of participants and not the total number of comments.

  The blue dots above the histogram represents the responses that you have returned.

Section 4: Commentary



Commentary

Review

SE-RUB-21-01 is a neat, single-source serum sample.

Clinical notes: Immunity check.

For all results, > 80% consensus was achieved for rubella IgG and IgM; therefore, this sample was assessed as positive for rubella IgG and negative for rubella IgM.

Two discordant equivocal results were reported for rubella IgM with participants reporting result values close to the cut-off provided. This does not appear to be a lot number related issue. One participant reported a discordant result and was the only user of this kit.The most appropriate comments to use are "Serological evidence of past infection or vaccination with rubella virus" and "No serological evidence of recent rubella infection".

SE-RUB-21-02 is a neat, single-source serum sample.

Clinical notes: Prenatal check.

For all results, > 80% consensus was achieved for rubella IgG and IgM; therefore, this sample was assessed as positive for rubella IgG and negative for rubella IgM.

Three discordant equivocal/negative results were returned for rubella IgG with two participants reporting result values above the cut-off provided. One participant reported using a higher cut-off than others within their user group. This does not appear to be lot number related.

One discordant positive result was reported for rubella IgM by the sole user of the their kit.

The most appropriate comments to use are "Serological evidence of past infection or vaccination with rubella virus" and "No serological evidence of recent rubella infection".

Participants that did not return the appropriate interpretative comments based on the assessed results should review their survey results and result commentary. Measurands are not assessed where less than 6 results were returned.

RCPAQAP acknowledges that laboratories may use a variety of default result units for the reporting of quantitative results. In order for RCPAQAP to provide more robust statistical analysis and quantitative comparisons for each kit used, we encourage laboratories to convert the units to the preferred RCPAQAP units as per manufacturer's instructions (kit insert). Quantitative result values are excluded where RCPAQAP preferred units were not used.

Click here to review raw data from this survey.

Comments/Discussion prepared by RCPAQAP Serology Team.

- Provides comments based on the overall survey performance. These are prepared by the Serology discipline scientists after reviewing all participant data. The commentary may include a link to the survey raw data.

Section 5: Cumulative Performance

- Provides the assessment of performance for each qualitative test performed by the laboratory for the past 4 - 6 surveys. The number of surveys displayed are determined by the program manager.

Section 6: Z-scores

- The z-score is an integer that represents the number of standard deviations your result is from the mean result. This has been included as a guide, so that participants can monitor their performance against their peer group for the quantitative results returned.

Assessment Criteria of survey results

- Results are assessed as Concordant, Discordant and Not Assessed
- When ≥ 6 results achieve 80% consensus, the sample will be assessed
- When < 6 results are received or <80% consensus is achieved, the sample will be reported as “Not assessed”
- Provided that the consensus result is ≥ 80% - A laboratory obtaining the same result as the consensus will be reported as – Concordant
- Provided that the consensus result is ≥ 80% - A laboratory that is inconsistent with the consensus results – Discordant
- Quantitative Data – does not get assessed but statistical analysis (Median, SD, CV) is provided were ≥ 6 data points per user group are received. Mean and median values are provided where there is more than three quantitative values returned within the method group

If there are any queries regarding the new report format, please contact the RCPAQAP by logging a request through the myQAP portal.

Anatomical Pathology

Assessment of Diagnostic Proficiency Programs

The RCPAQAP Diagnostic Proficiency modules include: General, Breast, Oral and Maxillofacial, Dermatopathology, Mohs, Forensic, Gynaecology, Paediatric, Urology, Neuropathology, Gastrointestinal, Electron Microscopy, Head and Neck and Haematopathology.

A Preliminary Report comprising participant submitted preferred diagnosis and preliminary target diagnosis for each case is available within 2 days after the survey close date. Following analysis of all responses (6-8 weeks after survey closing date), participants are provided with a Survey Report comprising assessment results, case performance analysis and discussion.

In the event of a preliminary case target diagnosis being subsequently considered by a program convenor as being erroneous, the target diagnosis will be amended, responses reassessed and participants notified. Alternatively, in such an instance a case may be declared invalid (VOID) for purpose of diagnostic proficiency testing, participants will be notified and this decision will be subsequently recorded in the Survey Report.

All reports are available in myQAP on the Reports tab.

Assessments are assigned according to the preferred diagnosis for each case against the “target” diagnosis as follows:

Concordant	The preferred diagnosis is essentially identical with the target diagnosis
Minor discordance	The preferred diagnosis has one or more minor differences from the target
Differential diagnosis	The preferred diagnosis is a differential diagnosis
Discordant	The preferred diagnosis is substantially different from the target diagnosis
Unable to be assessed	The submission was late, unable to be interpreted or without a preferred diagnosis
No submission received	No result entered

Assessment of HER2 Brightfield ISH (BRISH) Breast Diagnostic Program

Dual ISH Probe:

Assessment of the participant’s response for the HER2 BRISH mean cell count and final HER2/Cep17 ISH status for each case will be classified against a “target” as:

Concordant:	The submitted HER2 IHC status, HER2 BRISH mean cell count, Chromosome (CEP)17 mean count per cell and HER2/CEP17 ISH ratio as being within the target range, and the final HER2 amplification status and subgroup as being the expected interpretation according to the updated 2018 guidelines.
Minor discordance:	A response which has contradicting HER2 IHC status, HER2 gene mean count per cell, Chromosome (CEP)17 mean count per cell, HER2/CEP17 ISH ratio enumeration to the final interpretation (HER2/CEP17 ISH status or subgroup).
Discordant:	The submitted HER2 IHC status, HER2 BRISH mean cell, HER2/Cep17 ISH ratio and the final HER2 amplification status are substantially different from the target response.
Unable to be assessed:	Uninterpretable comment is submitted.
No submission:	No result is entered

Assessment criteria for this survey is based upon the HER2 IHC status, mean HER2 count per cell, mean CEP17 count per cell, HER2/CEP17 ratio, the final target answer of HER2 amplification status and the final subgroup. The response is based on both the interpretation of the HER2 immunohistochemistry and HER2 ISH findings according to the updated 2018 ASCO CAP HER2 and RCPA HER2 testing guidelines to reach the final HER2 amplification status and subgroup.

ASCO CAP 2018 HER2 Testing for Breast Cancer Guidelines – Recommendations for Practice in Australasia. Accessed July 2019 (Sub-grouping table shown below).

Group	Biology	HER2/CEP17 Ratio	Mean HER2 copy number	2018 ASCO CAP Recommendation
1	Classic HER2 amplified cancer	≥2.0	≥4.0	Positive
2	Monosomy 17	≥2.0	<4.0	Negative, unless concurrent IHC3+
3	Co-amplification, previously polysomy 17	<2.0	≥6.0	Negative, unless concurrent IHC 2+ or 3+
4	Borderline/Λequivocal	<2.0	≥4.0 and <6.0	Negative, unless concurrent IHC 3+
5	Classic HER2 non-amplified cancer	<2.0	<4.0	Negative

Single ISH Probe:

Assessment of interpretation of the Single HER2 ISH tests performed as follows**:**

Assessment criteria

Assessment of the participant's response for the HER2 IHC status, HER2 ISH mean cell count and final HER2 ISH status for each case will be classified against a "target" as:

Concordant:	The submitted HER2 IHC status, HER2 ISH mean cell count and HER2 ISH status being consistent with the target.
Minor discordance:	A response which has contradicting HER2 IHC status, HER2 ISH enumeration to the final interpretation (HER2 ISH status).
Discordant:	The submitted HER2 IHC status, HER2 ISH mean cell count and HER2 ISH status being substantially different from the target.
Unable to be assessed:	Uninterpretable comment submitted.
No submission:	No result entered

Assessment criteria for this survey is based upon the HER2 IHC status, mean HER2 count per cell and the final target answer of HER2 amplification status. The response is based on both the interpretation of the HER2 immunohistochemistry and HER2 ISH findings according to the updated 2018 ASCO CAP HER2 and RCPA HER2 testing guidelines to reach the final HER2 amplification status.

http://ascopubs.org/doi/full/10.1200/JCO.2018.77.8738

Please note concordance for this survey includes concordant and minor discordant responses.

Assessment of HER2 Brightfield ISH (BRISH) Gastric Module Diagnostic Program

The HER2 BRISH Gastric Diagnostic Program is a Diagnostic Proficiency exercise comprising virtual images for interpretation.

Diagnostic Interpretive Assessment criteria

Assessment of the interpretation of the HER2 IHC and HER2 BRISH Gastric adenocarcinoma cases is as per the updated 2016 HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline from the College of American Pathologists, American Society for Clinical Pathology, and the American Society of Clinical Oncology.

HER2 IHC status

Data entry responses are required to be submitted for assessment and this includes the intensity of the positive tumour cells as either 0 to 1+ (Negative), 2+ or 3+ (Positive).

HER2 ISH Probe

Data entry responses are required to be submitted for assessment and this includes: HER2 gene mean count per cell, Chromosome (CEP17) count per cell, HER2/CEP17 ratio and HER2/CEP17 ISH status, for e.g. Amplified, Non-amplified or Uninterpretable, i.e. for all 6 cases**.**

Where there are technical problems, such as tissue floating off during staining, or a case missing, please enter the response as stated in the data entry lay out.

Assessment criteria

Assessment of the participant's response for the HER2 IHC, final HER2/CEP17 ratio and overall HER2 ISH status for each case will be classified against a "target" as:

Concordant	The submitted HER2 IHC, HER2/CEP17 ratio and overall HER2 ISH status being identical to the target.
Discordant	The submitted HER2 IHC, HER2/CEP17 ratio and overall HER2 ISH status is substantially different from the target.
Minor Discordance	A response which has contradicting HER2 IHC, HER2/CEP17 ratio enumeration and overall HER2 ISH status.
Unable to be assessed	Uninterpretable comment is submitted.
No submission	No result is entered

References:

HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology

Immunohistochemistry Breast Marker Audit

The Breast Marker Audit is offered as a separate program. The audit is open for 6 months to allow participants adequate time to submit data. There is no technical component to this survey, but it comprises online submission of the hormone receptor and HER2 status for each case of early invasive primary (not stage 4 disease) breast carcinoma. It is recommended that 100 cases from the preceding year are submitted.

The aim of this exercise is to review the reporting of immunohistochemistry (IHC) and in-situ hybridization (ISH) breast markers through an audit of clinical results. The exercise is designed to assist participants in assessing the quality of oestrogen, progesterone and HER2 receptor reporting within their laboratories. This is an important quality assurance activity, established in response to ongoing difficulties experienced by laboratories in this area of testing.

The RCPAQAP will assess performance in the breast marker audit according to the following criteria:

Concordant	Proportion of ER positive, ER-PR+ and HER2 ISH results are within the ranges specified. No comment is given where results are close to the expected ranges for ER+ and HER2+ results
Minor discordance	Proportion of ER positive, ER-PR+ or HER2 ISH results are marginally outside the ranges specified. One or more "Review recommended" comments are obtained for ER, ER-PR+ results.

Discordant results	Proportion of ER positive, ER-PR+ or HER2 ISH results are well outside the ranges specified. One or more "Review required" comments are obtained for ER, ER-PR+ results
Unable to be assessed	Sample size too small: 50 or fewer cases reported are submitted, submissions are received late
No Submission received	Participants did not submit any results

***Note**: HER2 IHC results are NOT included in the assessment of concordance due to the availability of HER2 ISH to confirm or clarify the IHC results.*

Assessment Criteria

The guidelines have changed in Australia towards the end of 2018, which may correspond to a change of reporting practice by participants. As from 2020, the collection of the 2019 breast marker data will reflect the revised ASCO/CAP (RCPA approved) guidelines.

References for your information:

1. ASCO CAP 2018 HER2 Testing for Breast Cancer Guidelines – Recommendations for Practice in Australasia.
2. ASCO-CAP - HER2 Testing in breast Cancer – 2018 Focused Update, accessed at January 2020

Assessment of Technical Proficiency Programs

The RCPAQAP Technical Proficiency programs include: General, Frozen Section and Neuropathology.

Following assessment of submissions (8-10 weeks after the survey closing date), participants are provided with a Survey Report comprising assessment results and a Generic Report comprising the exercise analysis and discussion.

Criteria for assessment may vary for each survey depending on the type of exercise or stain and are included in the survey instructions. As a guide an example of the criteria for H&E staining is provided below:

Staining quality

- The effectiveness in demonstrating nuclear membranes, nucleoli, chromatin of vesicular and hyperchromatic nuclei
- Definition of fine and coarse chromatin
- Absence of carryover of haematoxylin into the cytoplasm
- The effectiveness in demonstrating all non-nuclear material e.g. cytoplasm, fine and dense connective tissue fibres, skeletal and smooth muscle and red blood cells (where present)
- Definition of muscle fibres of blood vessels
- Definition of kidney basement membrane
- Uniformity of staining across slide
- Absence of contaminants

Section presentation

- Coverslip placed centrally over entire section and within boundaries of slide
- Absence of excess mountant
- Absence of bubbles
- Absence of artefacts from dehydration, clearing and mounting

Four members of the Technical Advisory Committee will independently score each slide out of 5. Where there is a discrepancy of ≥2 marks between assessors, the submitted slide is reviewed. The assessor marks are then reported as an average.

Scoring of slides

0	No staining/ incorrect antibody applied to slide.

1 Un-diagnosable, very poor staining and none of the assessment criteria met.
2 Unsatisfactory staining - criteria has not been met, diagnosis may be impacted upon.
3 Criteria has been met at a basic level
4 Above average
5 Reflects a perfect fulfilment of the criteria

Assessment Classification Marks

Satisfactory	A mark equal to or greater than 3.0
Borderline	A mark greater than or equal to 2.5 and less than 3.0
Unsatisfactory	A mark of less than 2.5
Unable to be assessed	The participant indicated that the exercise was not relevant; OR the submission was late or unable to be assessed (e.g. broken slide)

For the special staining exercise, participants are required to mark the area of interest on the control slide before submission. Participants are required to submit their routine control slides, these will be assessed by the Advisory Committee as either 'Satisfactory' or 'Unsatisfactory' however a numerical result will not be reported. Failure to submit a control will be recorded as 'No submission received'. *Please note that the assessment result of the control section (IQC) is not an indication of your EQA on the provided test section.*

Assessment of Immunohistochemistry Programs

The RCPAQAP Immunohistochemistry programs include: General Markers, Breast Markers, HER2 BRISH for Gastric and Breast cancers Lymphoma Markers, and Neuropathology.

Following assessment of submissions (8-10 weeks after the survey closing date), participants are provided with a Survey Report comprising assessment results and a Generic Report comprising the exercise analysis and discussion.

Criteria for assessment of immunohistochemistry staining may vary for each survey depending on the type of exercise and are included in the survey instructions.

The RCPAQAP will assess the immunohistochemical labelling according to the following criteria:

- Intensity of true positivity is of reasonable strength
- Absence of background staining (good signal to noise ratio)
- Sensitivity – all target tissues labelled
- Localisation – only target antigenic sites labelled
- Chromogen character – crisp and distinct
- Counterstain quality – complementary not obscuring
- Absence of artefacts

Four members of the Immunohistochemistry Advisory Committee will independently score each slide out of 5. Where there is a discrepancy of ≥2 marks between assessors, the submitted slide is reviewed. The assessor marks are then reported as an average.

Scoring of slides

0 No staining/ incorrect antibody applied to slide.
1 Un-diagnosable, very poor staining and none of the assessment criteria met.
2 Unsatisfactory staining - criteria has not been met, diagnosis may be impacted upon.
3 Criteria has been met at a basic level
4 Above average
5 Reflects a perfect fulfilment of the criteria

Assessment Classification Marks

Satisfactory	A mark equal to or greater than 3.0
Borderline	A mark greater than or equal to 2.5 and less than 3.0
Unsatisfactory	A mark of less than 2.5

Unable to be assessed The participant indicated that the exercise was not relevant; OR the submission was late or unable to be assessed (e.g. broken slide)

For technical assessment, participants are required to return the stained slide together with their in-house controls to RCPAQAP. Controls will be reviewed if the test slide is assessed as unsatisfactory. Comments will be provided.

Assessment of ALK Translocation in non-small cell lung carcinoma (NSCLC) program

This program consists of multiple proficiency testing:

1. **Immunohistochemistry ALK staining for technical and interpretation proficiency**. The assessment criteria for the IHC technical proficiency will be the same as stated above (Assessment of Immunohistochemistry Programs) and the interpretation proficiency where the assessment will be classified against the "target" result as concordant, minor discordance, discordant or unable to be assessed and "No Submission" if no result has been entered.

2. **ALK FISH and ALK Molecular techniques interpretation proficiency.** Participating laboratories are required to provide method details including limits of detection, which will be used to determine the final assessment of genotyping results. This information may also be used to assist participating laboratories in troubleshooting where applicable.

   i) Genotyping: detection of an ALK fusion variant i.e. present or absent

   (ii) Interpretation: comment on the therapeutic implication of genotyping result based on the mock clinical scenario provided

   The standardized terms used to assess the performance are:

   - Concordant – Meets the expected response
   - Minor discordance – Deemed acceptable, however has one or more minor differences from the target.
   - Discordant – Deemed unacceptable or does meet the expected response
   - Unable to be assessed – Used when the submission was unable to be interpreted
   - Non-participation – Did not participate

Assessment of Transmission Electron Microscopy (TEM) Technical Program

The RCPAQAP will assess the images submitted required for the Technical exercise according to the following criteria:

Assessment criteria

The submitted material is assessed in a two-tiered approach according to the following criteria:

Diagnostic suitability

- The presence of the appropriate diagnostic feature(s), enabling an accurate diagnosis by a third party.
- Submission of a sufficient number of images to fully document the diagnostic features.
- Use of an adequate range of magnification to visualise diagnostic features.

Technical quality:

- Images of sufficient number and quality to allow the case to be reviewed and reported accurately by a third party.
- Image presentation and quality: magnification, image size, contrast and overall density and evenness. Diagnostic features should be clearly visible and easily identifiable.
- Images should not show substantial or consistent artefacts due to processing, sectioning or staining, or imaging (microscope) or camera artefacts.

NB: The Advisory Committee understands that in some circumstances no specific diagnosis can be made, or that all diagnostic features may not be contained in the sample received for EM. In such a case the committee will assess the submission on the basis of a suitable number of images to represent the findings present, rather than expect specific diagnostic features to be present.

Assessment classification marks

Four members of the Electron Microscopy Advisory Committee assess each set of micrographs submitted individually and grade the submission separately for diagnostic suitability and for technical quality, where:

Score:	**Assessment:**
< 2.5	Unsatisfactory
≥ 2.5 and < 3.0	Borderline
≥ 3.0	Satisfactory

The marks are then collated between members of the panel, and the submission is assessed by consensus, on diagnostic and on technical grounds, as either satisfactory or unsatisfactory.

Satisfactory vs unsatisfactory assessment

Submissions are assessed as either satisfactory or unsatisfactory on their diagnostic and technical merits (separately) and are reported as such to the participating laboratory. The numerical score allocated to a submission remains confidential and is not given. A submission may be rated as unsatisfactory or borderline due to the following reasons:

- The number of images submitted was deemed insufficient to reach a diagnosis.
- The quality of the images was very poor overall, impairing their interpretation.
- Artefacts and contaminants were present in the majority of images, interfering with the examination of the diagnostic images.

Following assessment of submissions (8-10 weeks after the survey closing date), participants are provided with a Survey Report comprising assessment results and a Generic Report comprising the exercise analysis and discussion.

Cytopathology

Gynaecological Programs

The RCPAQAP gynaecological programs include Conventional, Liquid based ThinPrep and Liquid based SurePath.

A Preliminary Report is emailed directly to the laboratory primary contact within two days of receipt of survey submissions and this contains a set of coordinates for conventional slides when applicable. The coordinates, when used with the Cell Finder provided, allow easy location of diagnostic features. Laboratories are therefore able to review their performance **prior to** returning the slide sets. Please note that the Cell Finder is available in the myQAP portal in the Documents tab.

The expected response is the target diagnosis as defined by the Cytopathology Advisory Committee. The committee has agreed that there may be a range of acceptable responses for each slide. A final Survey Report containing a diagnostic classification is then uploaded to myQAP within 6 weeks of the survey close date.

Diagnostic classifications are as follows:

1. *Target response*: an exact match with the expected (panel) diagnosis.
2. *Acceptable response:* not an exact match, but a diagnosis that would not result in an adverse patient outcome.
3. *Unacceptable response*: a response which is considered to be a significant deviation from the panel diagnosis but not a major error.
4. *Major error:* A significant deviation from the panel diagnosis that may have a significant adverse effect on patient management.

The classifications 'target' and 'acceptable' may be considered together for statistical purposes.

A table outlining how responses are categorised is available in the myQAP portal in the Documents tab. This table is reviewed annually by the RCPAQAP Cytopathology Advisory committee.

The report viewing and management system in myQAP can be used to document appropriate follow-up if required. An Action Sheet is also provided with the final survey report. If all results are target or acceptable the action sheet will indicate no further action is required. If a participant records a 'major error' or unacceptable response classification this will be noted on the Action Sheet and a list of possible actions provided e.g. case reviewed, references read, teaching material reviewed. All actions taken to address the potential source of error should be documented in the myQAP portal management system or alternatively on the Action Sheet, and be made available for accreditation purposes.

An Annual Summary Report provides a summary of performance and includes diagnostic classification of responses for all twenty cases.

Non-Gynaecological Programs

The RCPAQAP non-gynaecological programs include General, Fine Needle Aspiration (FNA) and an anatomical site specific Specialty Program.

A Preliminary Report comprising participant submitted preferred diagnosis and preliminary target diagnosis for each case is available within 2 days after the survey close date. Following analysis of all responses (6-8 weeks after survey closing date), participants are provided with a Survey Report comprising assessment results and case performance analysis, photomicrographs and discussion.

In the event of a preliminary case target diagnosis being subsequently considered by a program convenor as being erroneous, the target diagnosis will be amended, responses reassessed and participants notified. Alternatively in such an instance a case may be declared invalid (VOID) for purpose of diagnostic proficiency testing, participants will be notified and this decision will be subsequently recorded in the Survey Report.

Preliminary and Survey Reports are available in myQAP on the Reports tab. All myQAP contacts will be notified via email when reports have been released.

Assessments are provided and are assigned according to the preferred diagnosis for each case against the "target" diagnosis as follows:

Concordant	The diagnosis is essentially identical with the target diagnosis
Minor discordance	The diagnosis has one or more minor differences from the target
Differential diagnosis	The diagnosis is a differential diagnosis
Discordant	The diagnosis is substantially different from the target diagnosis
No submission received	No result entered
Unable to be assessed	The submission was late, unable to be interpreted or without a preferred diagnosis

Technical Program

Criteria for assessment may vary depending on the type of exercise or stain and are included in the survey instructions.

Four members of the Cytopathology Advisory Committee will independently score each slide out of 5. Where there is a discrepancy of ≥2 marks between the assessors, the submitted slide is reviewed. The assessor marks are then reported as an average. Following analysis of all submissions (8-10 weeks after survey closing date), participants are provided with a Survey Report compromising assessment results and case performance analysis, photomicrographs and discussion.

Assessment Classification Marks

Satisfactory	A mark equal to or greater than 3.0
Borderline	A mark greater than or equal to 2.5 and less than 3.0
Unsatisfactory	A mark of less than 2.5
Unable to be assessed	The participant indicated that the exercise was not relevant; OR the submission was late or unable to be assessed

Microbiology

The Microbiology discipline has commenced using the new RCPAQAP software platform to structure survey programs, analyse survey results and assess performance. The report format has also been updated to follow a standard structure used by programs offered by the RCPAQAP.

The following information provides participants with a guide to understand the data analysis system used to assess participant performance.

Participant Performance

The RCPAQAP Microbiology discipline provide programs, allowing participants to monitor the effectiveness of their quality assurance measures and to detect and remedy problems. Distributed specimens cover the main areas of clinical microbiology including general bacteriology, microscopy and culture of mycobacteria, antimicrobial susceptibility testing, mycology. molecular microbiology and parasitology. Scientists prepare simulated clinical samples which are as close to the real specimen as possible. The choice and frequency of organisms distributed depends on a number of factors including the current epidemiology, clinical importance and educational value.

Participants are assessed on the technical and diagnostic skills.

Analysis of results

Criteria used to generate participant performance assessment are approved by the Program Chair using any information relevant to the particular survey supplied by the Program scientists from the analysed data, post-dispatch testing, input from the collaborators and results from referring laboratories

The terms used to grade survey results are listed below:-

- **CONCORDANT** – A result containing the target organism or the expected result
- **MINOR DISCORDANT** - A result that may have partial agreement with the expected or target result
- **DISCORDANT** – A result that is substantially different from the expected or target result.

Preliminary Reports

A Preliminary Report containing the expected results of the items in a survey is available after closing date. Results for mycobacterial culture are not issued at this time because of the extended closing date required for this test. These results are issued with the Survey Report

Survey Reports

The RCPAQAP Microbiology report format follows a standard structure that will be adopted by other programs offered by the RCPAQAP. This single report replaces the previous generic and survey reports.

The structure of the new reports provides participants with a summary of performance, reviews the performance of participant result, providing a method breakdown review with commentary and provides cumulative performance.

An example of the report issued for the Bacteriology – Urine program can be seen below, however the structure of all other Microbiology reports will follow the same structure:

Section 1: Summary of Performance – the summary of performance provides a snapshot of your participation and assessment in the program. It has been split into 2 sections, when antibiotic susceptibility is included in the program structure.

a. Summary of performance - tests marked for assessment

Summary of Performance

Survey: **2** Open Date: **11 June 2019** Report Issue Date: **19 September 2019**

Performance Assessment – Microscopy, bacterial count and identification

		Sample: 2019:4:1A			Sample: 2019:4:1B		
Test	**Measurement System**	**Your Result**	**Target**	**Assessment**	**Your Result**	**Target**	**Assessment**
Urine microscopy							
...White cell count	Manual method	> 100	> 100	Concordant	> 100	> 100	Concordant
...Red cell count	Manual method	> 100	> 100	Concordant	> 100	> 100	Concordant
...Epithelial cell	Manual method	<10	<10	Concordant	<10	<10	Concordant
Bacterial count							
...Bacterial count		10E7-8	> 10E8	Not Assessed	> 10E8	> 10E8	Concordant
...Bacterial growth		Pure	Pure	Concordant	Pure	Pure	Concordant
Species isolated							
...Species Identification		Escherichia coli	Escherichia coli	Concordant	Escherichia coli - refer	Klebsiella pneumoniae	Discordant

Performance – Microscopy, bacterial count and identification

Please review results returned for Sample
2019:4:1B Species Identification

Below is an explanation of what is populated in the table columns provided in the example above.

- **Test:** Is the test performed by the participant, that is assessed.
- **Measurement system:** Will list the measurement system returned by you at result entry in the myQAP portal.
- **Your result:** Is the result submitted by you at result entry in the myQAP portal.
- **Target:** Is the expected result
- **Assessment:** Will provide the assessment of your results based on the target (expected result). If a test does not pass homogeneity testing, the assessment grade of “Not assessed” will be assigned.

Please note: The assessment of performance now uses terminology to grade performance, which replaces the scores that has been used in the past. The terms used to assess performance are

Concordant: Matches the target or expected result

Discordant: Does not match the target response

Not Assessed: Not assessed due to failure in homogeneity or stability testing

b. Summary of performance - Antibiotic susceptibilities (if included in the program structure)

Summary of Performance

Survey: **2** Open Date: **11 June 2019** Close Date: **1 July 2019**

Performance Assessment – Antibiotic susceptibilities

		Sample: 2019:4:1A			
Antibiotic	**Antibiotic Standard**	**Your Primary Test Result**	**Your Reported Test Result**	**Expected Reported Test Result**	**Assessment**
Amoxycillin-clavulanate	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Susceptible	Susceptible	Concordant
Ampicillin/Amoxycillin	Clinical and Laboratory Standards Institute (CLSI)	Resistant	Resistant	Susceptible	Discordant
Cefazolin	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Susceptible	Susceptible	Concordant
Cefotaxime	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Not Reported		Unable to be Assessed
Cefoxitin	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Not Reported		Unable to be Assessed
Gentamicin	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Susceptible	Susceptible	Concordant
Nitrofurantoin	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Susceptible	Susceptible	Concordant
Norfloxacin	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Susceptible		Concordant
Trimethoprim	Clinical and Laboratory Standards Institute (CLSI)	Susceptible	Susceptible	Susceptible	Concordant
Ceftriaxone				Susceptible	
Cephalexin				Susceptible	
Trimethoprim-sulfamethoxazole				Susceptible	

Overall Performance

Please review results returned for Sample
01 Ampicillin/Amoxycillin

The performance review for the antibiotic susceptibility testing has been split to review the performance based on the sample. Below is an explanation of what is populated in each column in the example provided.

- **Antibiotic:** The antibiotics that are listed in this table are those reported from you as well as antibiotics that have pretested by our reference laboratory.
- **Antibiotic standard:** Will list the antibiotic susceptibility testing guidelines used by you at result entry in the myQAP portal.
- **Your Primary Test Result:** Is the primary test result submitted by you at result entry in the myQAP portal.
- **Your Reported Test Result:** Is the reported test result submitted by you at result entry in the myQAP portal.
- **Expected Reported Test Result:** Is the expected reported result for the antibiotics listed. An expected result will only be displayed if the antibiotic was tested for by our reference laboratory.
- **Assessment:** Will provide the assessment of your results based on “your reported test result”.

Please note: The assessment of performance now uses terminology to grade performance, which replaces the scores that has been used in the past. The terms used to assess performance are

Concordant: Matches the target or expected result

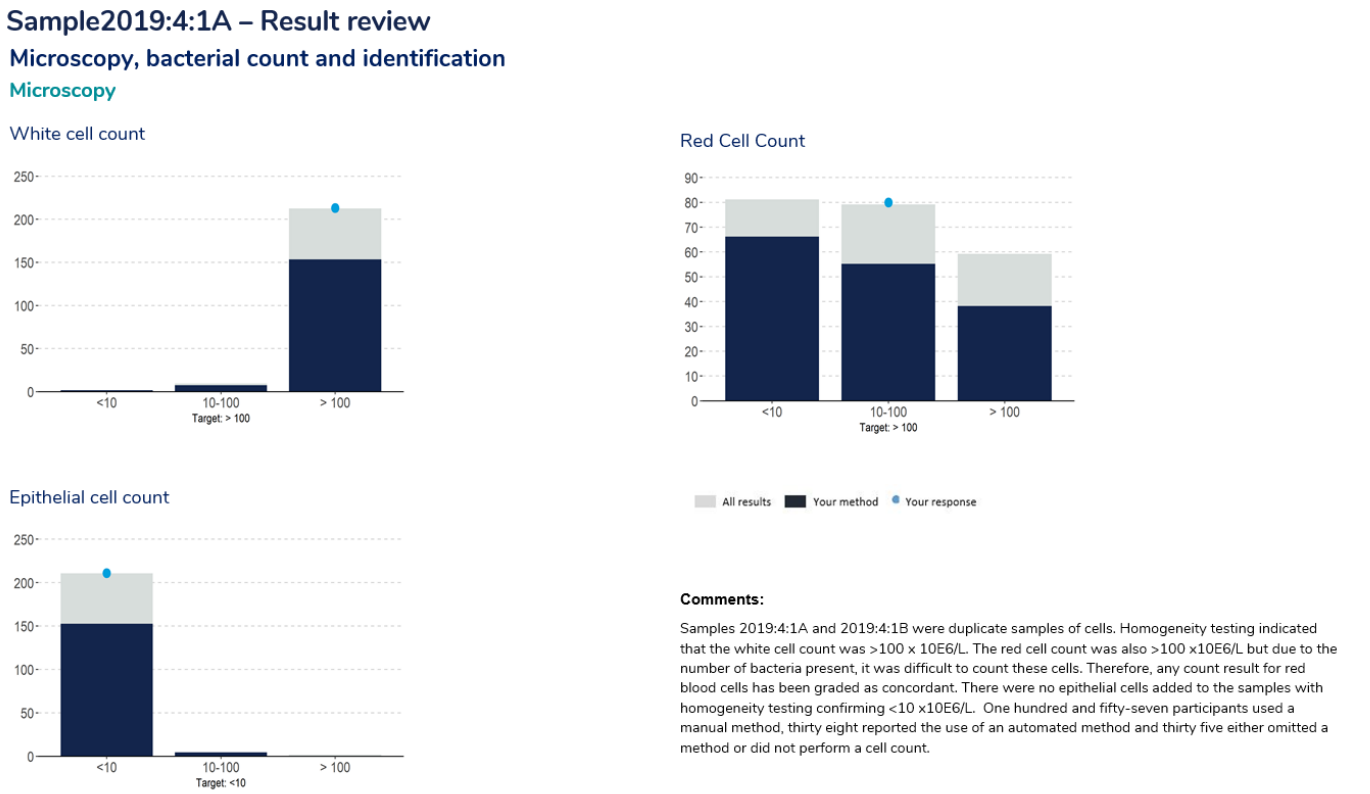
Discordant: Does not match the target response

Not Assessed: Not assessed due to the unavailability of “an expected result”.

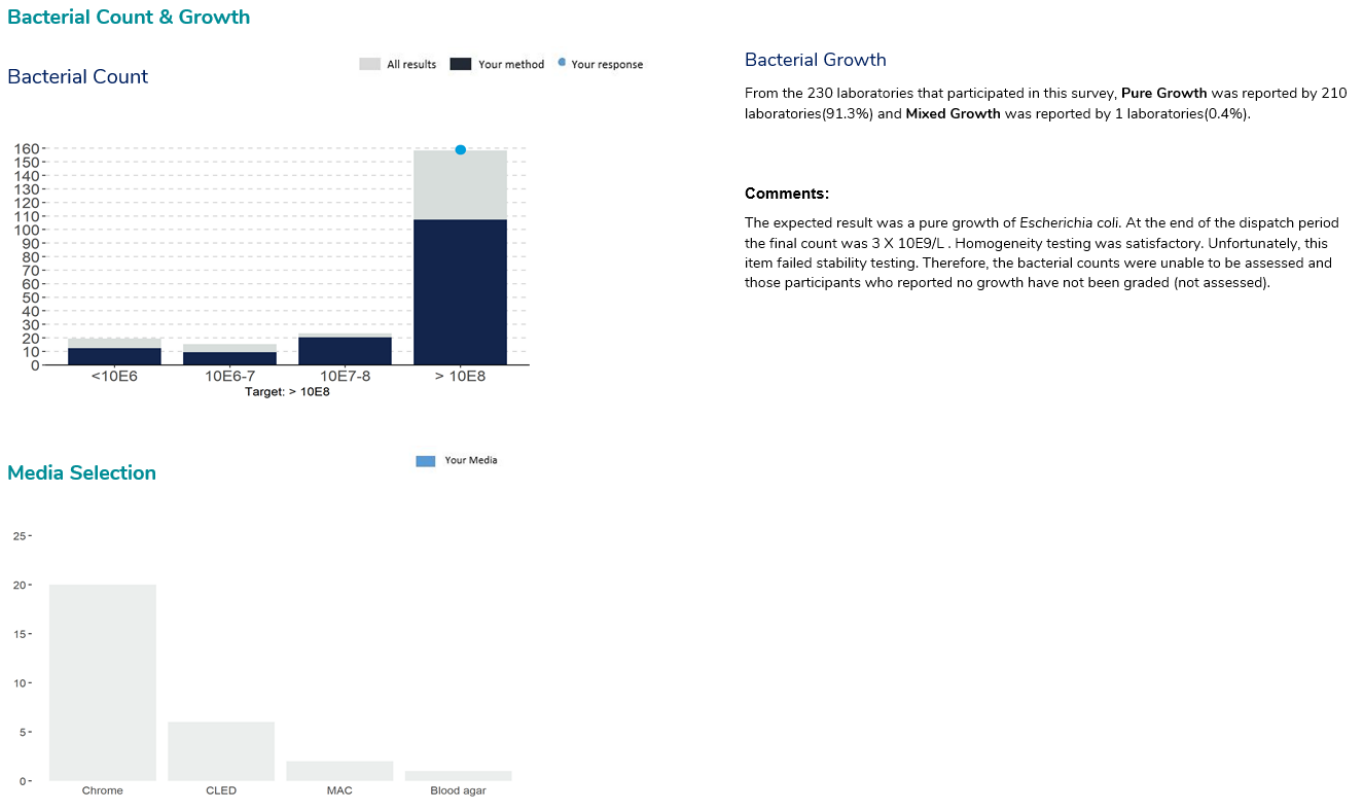
Discordant results will be highlighted in red and the antibiotic that is highlighted as discordant will be listed in the ‘Overall Performance’ summary at the bottom of the page.

Section 2: Result Review

The review of the survey performance has been structured so you are able to see the breakdown of results by the survey case. That is, all results for Sample A will be displayed, followed by results for Sample B.



- **Result review – Microscopy:** Provides you with a breakdown on the responses received for the microscopy, bacterial count and species identification components of the survey. The histograms provide you with a review of the responses received for each test. The dark blue overlay represents the results returned by other participants using your method. The “blue” circle represents the result provided by your laboratory.



- **Result review – Bacterial Count & Growth / Media Selection:** Provides you with a breakdown on the responses received for the bacterial count and growth. The histograms provide you with a review of the responses received for each test, with the same legends used for the bacterial count chart. The "Media Selection" histogram also provides a breakdown in the responses received. The bars in this histogram will be highlighted in blue if the media was chosen by your laboratory as result entry.

- **Result review – Species Identification:** Provides you with a histogram illustrating the responses received from participants for species identification. The responses are ordered by the assessment grade provided.

  Please note: The terms used to assess performance are

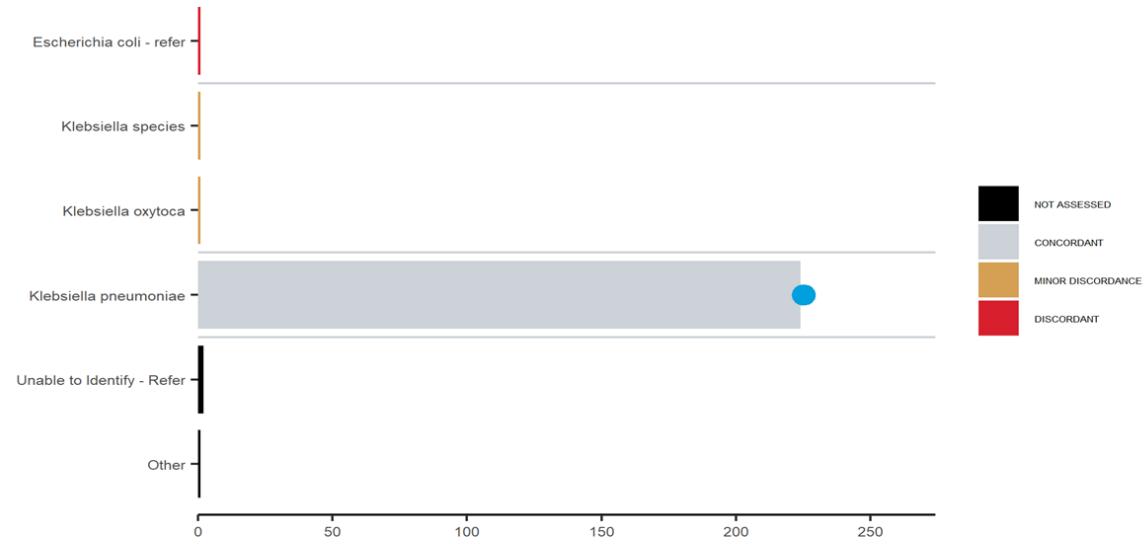
  Concordant: Matches the target or expected result

  Minor Discordance A result that may have partial agreement to the target result

  Discordant: Does not match the target response

  Not Assessed: This assessment grade may be provided to participants unable to grow the pathogen

Species Identification

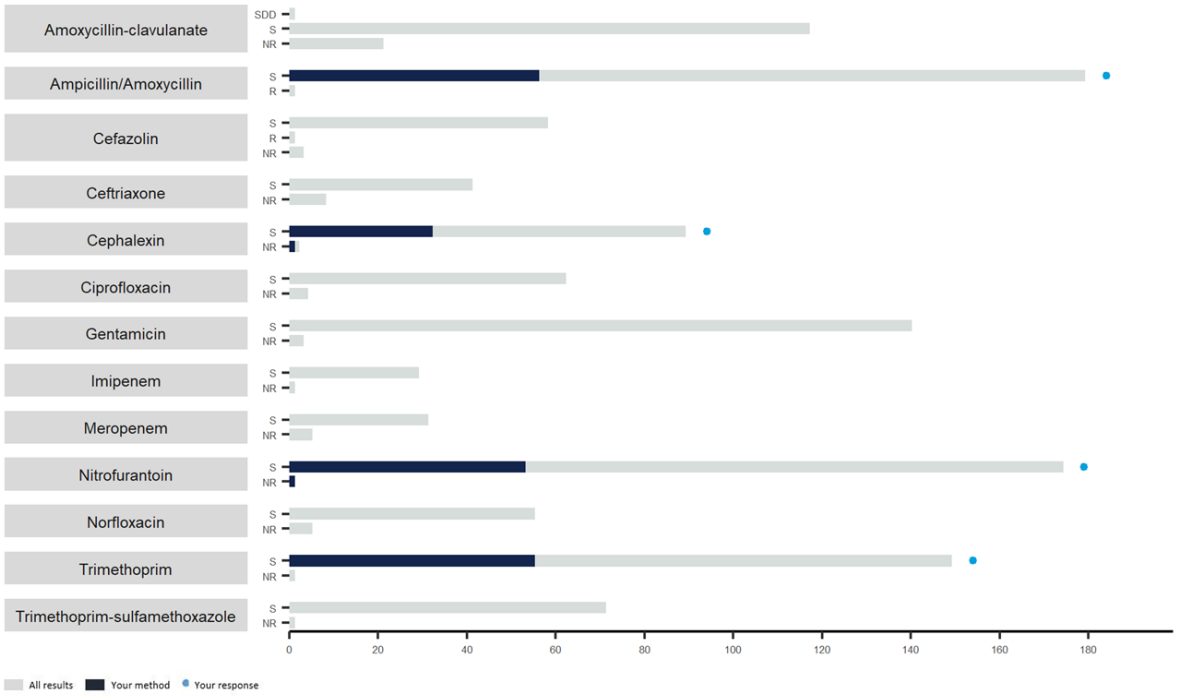


Comments:

Two hundred and twenty-four participants (97%) correctly reported *Klebsiella pneumoniae*. The participant who reported '*Escherichia coli*-refer' also reported '*Escherichia coli*' in 1A so this was not a transposition of results. API 20E was used for both isolates. The other users of this kit reported *K. pneumoniae* in this challenge.

Antibiotic – susceptibility testing: The antibiotics listed in this histogram have been reported by 10 or more participants that have been assessed. The histogram displays the responses received by all laboratories that reported the antibiotic for testing, the results received. The dark blue overlay represents the results returned by other participants using the same antibiotic standard. The "blue" circle represents the result provided by your laboratory.

Antibiotic - susceptibility testing



Section 3: Cumulative Performance

Cumulative Performance

Sample: 2019:4:1A			
Test	**Target**	**Your Result**	**Assessment**
Urine microscopy			
... White cell count	> 100	> 100 cells x 10E6/L	Concordant
... Red cell count	> 100	10-100 cells x 10E6/L	Concordant
... Epithelial cell	<10	<10 cells x 10E6/L	Concordant
Bacterial count			
... Bacterial count	> 10E8	> 10E8 CFU/L	Unable to be Assessed
... Bacterial growth	Pure	Pure	Concordant
Species isolated			
... Species Identification	Escherichia coli	Escherichia coli	Concordant

Sample: 2019:4:1B			
Test	**Target**	**Your Result**	**Assessment**
Urine microscopy			
... White cell count	> 100	> 100 cells x 10E6/L	Concordant
... Red cell count	> 100	<10 cells x 10E6/L	Concordant
... Epithelial cell	<10	<10 cells x 10E6/L	Concordant
Bacterial count			
... Bacterial count	> 10E8	> 10E8 CFU/L	Concordant
... Bacterial growth	Pure	Pure	Concordant
Species isolated			
... Species Identification	Klebsiella pneumoniae	Klebsiella pneumoniae	Concordant

Each survey report will provide a snapshot of your performance for the microscopy, bacterial count and identification components of the program. The cumulative performance will list your performance for each survey sample sent throughout the survey year. Please note, as survey 1 results were assessed using the number scoring system, they will not be included.

Molecular Infectious Disease (MID) survey reports

The Molecular Infectious disease reports will follow the same structure as the Microbiology reports, now combining the Individual survey report with the generic report previously issues to participants. To see a guide to interpret the MID- Gastrointestinal pathogens (Bacteria) program please visit the RCPAQAP website (https://myqaphelp.rcpaqap.com.au/help-article/).

Synovial Fluid

Survey Reports

At present the Survey Reports are presented in the following format:

Section One: This shows the total number and the percentage of participants who correctly identified the target response. Clinical information, comments by the chair and any other information about the specimens are reported.

Section Two: For each specimen; this section reports on the total number of returned surveys and the findings of all the participants in graph form.

Section Three: For each specimen; this section shows the participant's response and the Target Response. The standardised terms used to assess the performance are Concordant, Minor Discordance, Discordant, Unable to be Assessed or Non Participation.

Other issues concerning the survey may also be included on the report.

Participant Performance

The results are determined by a target value as set by the Chair and the Synovial Fluid Referee. The report will indicate the percentage of participants with the correct response and may be commented upon by the Program Chair of RCPAQAP Synovial Fluid.

RCPAQAP advises that participant enquiries relating to information contained in RCPAQAP reports should be forwarded directly to program staff rather than to the report reviewer or committee member.

Educational Component.

The report should be read in conjunction with the second video available in the myQAP portal, which has a commentary with the correct responses. The report will show the target response and the participant's response. The number of participants who correctly identified the target response with the percentage compared to all participants who returned their results.

Molecular Genetics

Reports

Assessment

See table below for the assessment categories of each module.

Module	Target	Qualitative	Quantitative	Genotyping	Interpretation	Technical
Coeliac Disease HLA Genotyping	HLA-DQA1, HLA-DQB1	✓		✓	✓	
Human Leukocyte Antigen B*57	HLA-B57:01	✓		✓	✓	
Molecular Testing in Glioma	IDH1, IDH2, MGMT	✓		✓	✓	
Mutation Detection in Colorectal Cancer	KRAS, NRAS	✓		✓	✓	
Mutation Detection in Lung Cancer	EGFR	✓		✓	✓	
Mutation Detection in Melanoma	BRAF, NRAS	✓		✓	✓	
Maternal Cell Contamination	n/a	✓	✓		✓	✓
Quality Assessment of DNA Extracts	n/a					✓
Quality Assessment of FFPE Extracts	n/a					✓
Sanger DNA Sequencing	n/a	✓		✓		✓
PTEN	PTEN	✓		✓		
Kennedy's Disease	Androgen receptor; CAG trinucleotide repeat expansion	✓		✓		
Acute Myeloid Leukaemia NGS Panel Testing	AML associated variants by next generation sequencing	✓		✓		
BCR-ABL Qualitative Testing	p190, p210, e1a2, e1a3, e13a2, e13a3, e14a2, e14a3	✓		✓		
Chimerism Analysis	n/a		✓			
FLT3 ITD & TKD	Internal tandem duplication, tyrosine kinase domain variants	✓		✓		
Hereditary Haemochromatosis	C282Y, H63D	✓		✓		
IDH Mutation Analysis in AML	IDH1, IDH2	✓		✓		
Immunogenotyping	Gene rearrangement	✓		✓		
Myeloproliferative Neoplasms	JAK2 V617F, CALR exon 9, MPL codon 515	✓		✓		
NPM1	NPM1	✓		✓		
PML RARA	Gene rearrangement	✓		✓		
Thalassaemia	HBA, HBB	✓		✓		
Thrombosis	Prothrombin, factor V leiden	✓		✓		
TP53 Deletions at 17p13.1 in CLL	17p deletion by FISH	✓		✓	✓	✓

Various types of report are issued for the Molecular Genetics programs. See table below for the reports issued for each module. Description of the different report types are provided as well.

Module	Preliminary	Survey	Generic
Coeliac Disease HLA Genotyping	✓	✓	✓
Human Leukocyte Antigen B*57		✓	✓
Molecular Testing in Glioma	✓	✓	✓
Mutation Detection in Colorectal Cancer	✓	✓	✓
Mutation Detection in Lung Cancer	✓	✓	✓
Mutation Detection in Melanoma	✓	✓	✓
Maternal Cell Contamination	✓	✓	✓
Quality Assessment of DNA Extracts		✓	✓
Quality Assessment of FFPE Extracts		✓	✓
Sanger DNA Sequencing	✓	✓	✓
PTEN		✓	
Kennedy's Disease		✓	
Acute Myeloid Leukaemia NGS Panel Testing		✓	
BCR-ABL Qualitative Testing		✓	
Chimerism Analysis		✓	
FLT3 ITD & TKD		✓	
Hereditary Haemochromatosis		✓	
IDH Mutation Analysis in AML (IDH1, IDH2)		✓	
Immunogenotyping		✓	
Myeloproliferative Neoplasms (JAK2, CALR, MPL)		✓	
NPM1		✓	
PML RARA		✓	
Thalassaemia (alpha, beta)		✓	
Thrombosis (F5, F2)		✓	
TP53 Deletions at 17p13.1 in CLL (FISH)		✓	✓

Preliminary Report

Preliminary report provide participants with the expected results and is issued one week after a survey closes. Participants can thereby institute corrective action to their procedures, if required, soon after the submission of their results and completion of the module.

Survey Report

Survey report is an individual report on laboratory performance. This report contains the expected results, results submitted and an assessment of survey results. Detailed assessment criteria are also provided in survey reports. Survey reports are issued within four to six weeks after survey closes.

Generic Report

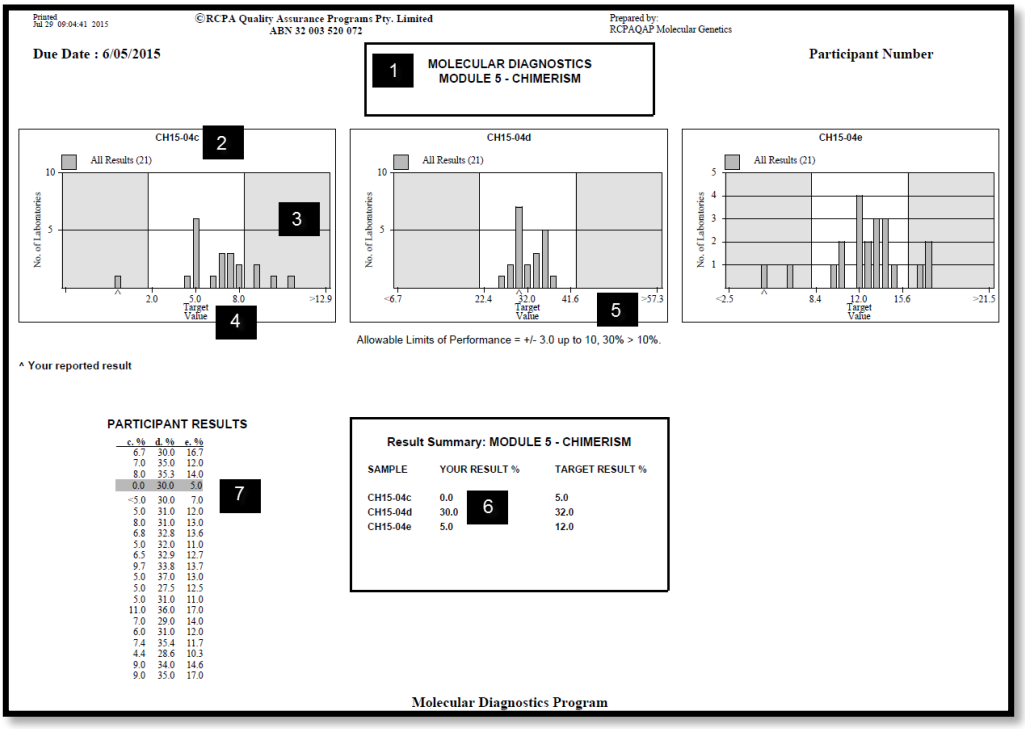
Generic reports are issued to all participants at the end of the survey and represent a final assessment of all participating laboratories. Generic report contains the statistical data used for participant assessment and provides the overall performance of all participating laboratories. Graphical representations provide information on the number of participants enrolled and the methods used by each laboratory for diagnostic analysis. General key recommendations are further provided where necessary to aid improvements for performance. Generic reports are issued within six to ten weeks after survey closes.

Molecular Haematology Reports

The Survey Report examples below are for programs that are hosted on the legacy software. As the Molecular Haematology transition over to the eQuality software (new reporting system), the new standardised report will be introduced. Once the survey report is release, a guide to interpret the new reports will be available on the RCPAQAP myQAP help page.

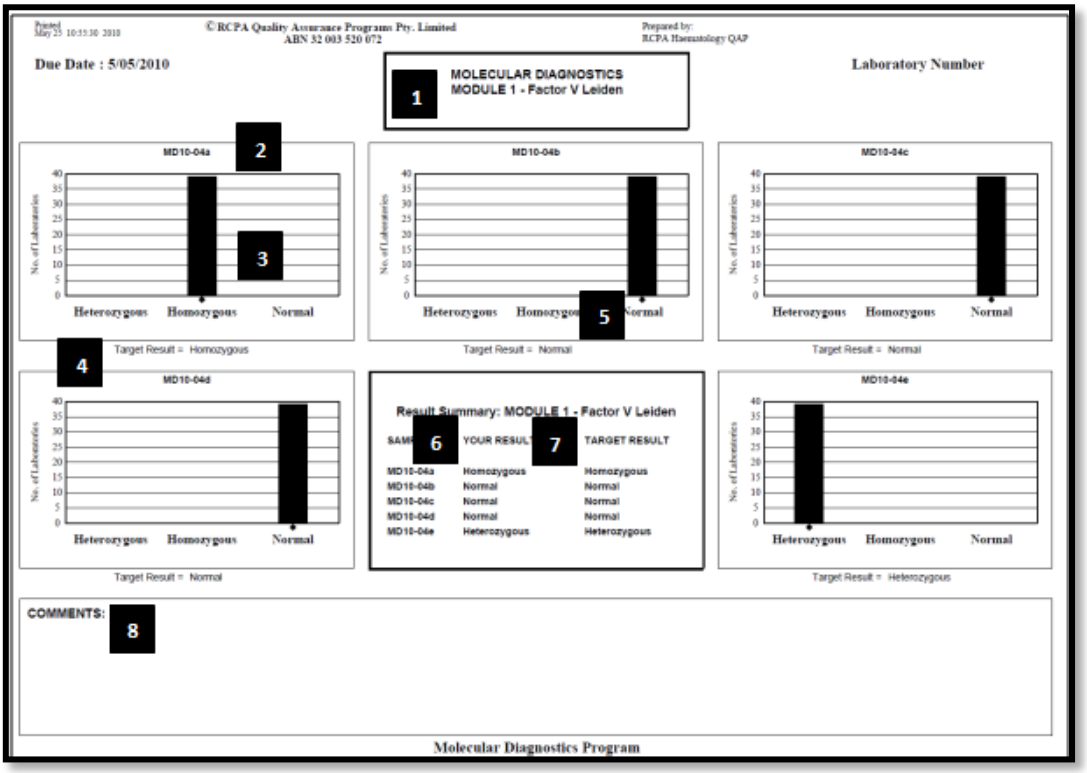
Please find below examples of reports for the Molecular Haematology Program. Please note, methods used by each laboratory have been requested at each survey which is displayed in each report as useful information for all laboratories.

Example: Quantitative Report (Chimerism)



1. Name of test being surveyed
2. Sample ID
3. Histogram showing the distribution of results. The ^ represents where the laboratory's result lies within the distribution
4. The target result for the sample
5. Analytical Performance Specifications
6. ± 3.0 units for target results ≤ 10% of Recipient. Target results > 10% have an Analytical Performance Specification ± 30% of the target result. A summary of the laboratory's results compared to the target value
7. A summary of results submitted by ALL laboratories (% of Recipient). Your laboratory's result is highlighted as per example.

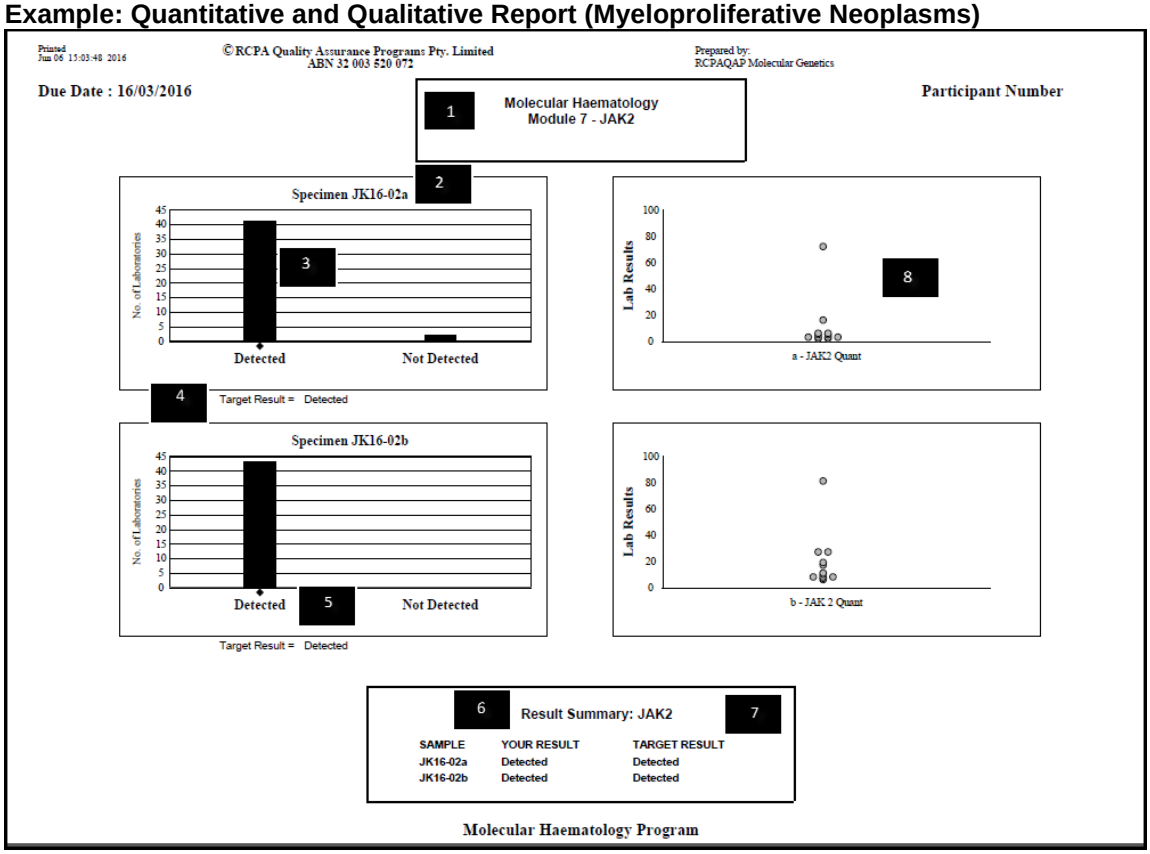
Example: Qualitative Report (Thrombosis)



1. Name of test being surveyed
2. Sample ID
3. Histogram showing the distribution of results
4. The target or expected result for this sample
5. ♦ The diamond represents the laboratory's result
6. Your result: Result submitted by the laboratory
7. The target or expected result for each sample
8. Comments: Area used to provide comments when necessary

Please note this report style is used for tests surveyed in Modules 1 and 2.

Example: Quantitative and Qualitative Report (Myeloproliferative Neoplasms)



1. Name of test being surveyed
2. Sample ID
3. Histogram showing the distribution of results
4. The target or expected result for this sample
5. ♦ The diamond represents the laboratory's result
6. Your result: Result submitted by the laboratory
7. The target or expected result for each sample
8. Your quantitative result if provided.

Biosecurity

The Biosecurity discipline is transitioning to the new RCPAQAP software platform to structure survey programs and analyse survey results. The report formats are being updated to follow a standard structure used by programs offered by the RCPAQAP. An example of the new report format can be found here.

Preliminary Reports

RCPAQAP Biosecurity issues Preliminary Reports which contain collated results for each item in a survey. Preliminary Reports are circulated after the closing date of a survey.

Final Reports

RCPAQAP Biosecurity produces a Final Report for participants after each module is completed. These contain the results of all surveys within the module, an assessment of the results and extensive educational material.

Kit or Method Performance
RCPAQAP Biosecurity participants are encouraged to document all kits and methods used to test survey material. This information is included and assessed in the Final Module Report for any given module.

Participant Performance

Assigned values
Assigned values are those that have been determined by RCPAQAP Biosecurity for any specimen through stability and homogeneity testing and any pre-issue testing that has been performed. An example of an assigned value would be the bacterial species included in a survey specimen. This information is made available by collaborating laboratories who provide material to RCPAQAP Biosecurity and is confirmed by RCPAQAP Biosecurity personnel after they have performed pre-issue testing of the survey material.

Statistical design to evaluate results
At this point in time the program does not use statistical design or analysis to evaluate results but will consider doing so in 2022

Graphical display of results
Results are displayed graphically in Preliminary and Final Reports as is appropriate and useful.

Analysis of Participant results and Analytical Performance Specifications
RCPAQAP Biosecurity offers a range of specialised PTP with a diverse participant base so scoring of results is difficult due to the wide diversity of test methods and kits used. The RCPAQAP Biosecurity Advisory Committee have decided that it is inappropriate for the program to score results as this would act as a deterrent for participation especially for less experienced participants. Another issue of concern was that the Specimen Module participant base is currently about 20 participants, which means that for any survey there may not be sufficient results (data points) to validate the information statistically.

There is a strong element of research in developing specimens for the RCPAQAP Biosecurity and participant access to equipment required for the testing of these specialised specimens varies greatly. Where there is consistency e.g. RAMP kits provided by the Department of Health to specified laboratories, there are many unknowns regarding the capability of this equipment nationally and globally. RCPAQAP Biosecurity surveys are often used to gain insight into how certain tests and equipment perform and what inhibitions to watch out for.

KIMMS

KIMMS Risk Matrix

In 2011 the RCPAQAP KIMMS program introduced a Risk Matrix to help laboratories identify the areas of greatest risk in the pre- and post- analytical areas for the Quality Indicators reported. It allows laboratories to compare "Your % Risk" against "Total Pre- and Post- analytical % Risk" for each Quality Indicator reported. The Risk matrix uses the values and calculations below to determine the risk.
Harm and Detection are defined as follows

Harm	Detection
1 = potential	1=immediate
4 = recollect	4 = probably
7 = >recollect	7 = unlikely
10 = sentinel event	10 = almost impossible

PRE-ANALYTICAL (before results released)

IDENTIFICATION INCIDENTS	KIMMS Default Harm	KIMMS Default Detection
Sample suspected to be from wrong patient	10	10
Unlabelled samples	4	1
Minimum labelling requirements not met	4	4
Mismatched samples	4	4
Precious samples	7	4
Transfusion specimen problems	4	1
Transfusion documentation problems	4	1
Sample misidentification not classified	4	1
SAMPLES REJECTED/ACCEPTED	**KIMMS Default Harm**	**KIMMS Default Detection**
Precious samples with ID problems rejected	1	1
Transfusion samples with ID problems accepted	10	4
Other misidentified samples accepted	7	1
SAMPLES REJECTED DUE TO COLLECTION AND TRANSPORT INCIDENTS	**KIMMS Default Harm**	**KIMMS Default Detection**
Sample haemolysed	4	4
Sample Clotted	4	1
Incorrect fill level of sample	4	4
Insufficient sample	4	1
Incorrect sample collection, storage or transport	4	4
Specimen not collected	4	1
Incorrect specimen type	4	1
Contaminated sample	4	4
SAMPLES REJECTED DUE TO LABORATORY INCIDENTS	**KIMMS Default Harm**	**KIMMS Default Detection**
Any within laboratory failure of ID	10	10
Registration error	1	4
Laboratory accident/error	4	4
POST-ANALYTICAL (after results released)	**KIMMS Default Harm**	**KIMMS Default Detection**
Report retracted	7	7
Results released to wrong doctor	4	4

Quality Indicator Definitions

KIMMS Quality Indicators are divided into five Categories – four Pre-Analytical and one Post Analytical. There is also 2 calculated quality indicators

Pre-analytical:
Identification Incidents – incidents relating to the identification of the patient
Transfusion Incidents – incidents relating to patient identification and paperwork relating to transfusion testing
Collection and Transport Incidents – incidents with the collection of samples and transport to the laboratory, including incorrect storage of samples during collection and/or transport.
Laboratory Incidents – incidents that occur once the samples have reached the laboratory i.e. caused by the laboratory in the laboratory. In this context, the laboratory includes specimen reception and registration of the episode

Post-analytical:
Incidents found AFTER results have been released.

Calculated quality indicators
Accepted Identification incidents - because all episodes (other than those with transfusion testing requested) with Identification incidents are not rejected, data is collected on how many are rejected and a calculation is made from this to show how many are accepted.
Accepted transfusion incidents – because all episodes with identification incidents for transfusion samples should be rejected, a calculation is made to if any are accepted. The risk for accepting a transfusion sample with identification errors is higher than for other samples.

LABORATORY DEMOGRAPHICS This information is being collected for benchmarking purposes. Apart from Total Episodes, these need only be submitted once per year, unless large changes occur within the Laboratory(s)	
	Definition / Example
Episodes	This is a compulsory field. The number of episodes that have occurred during the 3 month reporting period to KIMMS (survey). An episode is usually covered by a single request and may consist of one or more samples. It may be covered by more than one request, but the samples are collected at the same time: i.e. samples received together in a bag with a request form.
Number of Sites	The number of individual sites for which data is being submitted. This may be a single site (1) or multiple sites (a value >1).
% Episodes collected by trained phlebotomists within the control of the pathology service	If known, report the number of episodes that are collected by staff employed as phlebotomists by the Pathology Laboratory/Company.
% Episodes collected from Emergency Department	If known and appropriate, report the percentage of episodes that are collected from the Emergency Department (ED).
% Episodes collected from inpatients	If known and appropriate, the percentage of episodes collected from inpatients
% Episodes from other sources	This is a calculation. It is the difference between the Total episodes and (Episodes collected in ED plus Episodes from inpatients).
Disciplines covered by the KIMMS data	Please tick all disciplines which are covered by the scope of practice or site(s) and which are contributing data to KIMMS

PRE ANALYTICAL – Identification incidents All incidents should be counted, whether they lead to rejection or not. Incidents for precious and transfusion samples should be counted separately. Note that in the context of KIMMS, a sample may be a sample or a specimen.	
QI	**Definition / Example**
Sample suspected to be from wrong patient (wrong blood in tube - WBIT)	E.g. Sample and request form from Patient A, all apparently correctly labelled. However, sample is from Patient B i.e. from a completely different patient. This category applies to all types of sample, i.e. urines, swabs, blood cultures, biopsies, etc. The terminology WBIT is used widely in the literature and has been included here.
Unlabelled samples	E.g. Any unlabelled samples for a collection event, including cases where some samples were labelled and some were not E.g. FBC tube OK but chemistry tube unlabelled. Excludes any incidents in precious or transfusion samples, which are recorded separately
Insufficient identifiers initially supplied (<3 identifiers for Australian laboratories)	E.g. full name and Date of Birth but no Medical Record Number / National Health Identifier / Unit Record Number etc. Note that the minimum labelling requirements may vary from Country to Country. Please use whatever requirements are acceptable to your laboratory. Excludes any incidents in precious or transfusion samples, which are recorded separately
Mislabelled samples	Any episode where identification on the sample does not match the information on the request e.g. clearly different name, spelling of name different, DOB different, married vs maiden name used, incorrect MRN or lab number noted on the request and or samples. Excludes any incidents in precious or transfusion samples, which are recorded separately
Other samples accepted	This is a calculation, no data required. The number of identification samples rejected, is subtracted from the total number of ID samples reported. Accepting samples with ID issues adds to your risk.
Other ID samples rejected.	The number of samples rejected due to Identification problems (not including transfusion samples). Note this is not all samples rejected, only those rejected due to identification incidents.

PRE ANALYTICAL – Transfusion Specimens (TS)	
QI	**Definition / Example**
Pre-analytical transfusion errors	Any pre-analytical incidents pertaining to transfusion samples should be reported here. Unlabelled/mislabelled/mismatched for Transfusion samples In Australia and New Zealand, it is expected that all unlabelled blood bank (transfusion) samples would be rejected, in line with ANZSBT and NPAAC guidelines. This should not include samples just for Group and Antibody screen where these are differentiated from Cross-match or Group and Hold samples.
Transfusion samples accepted	This is a calculation, no data required. It is the number of pre-analytical transfusion errors minus the number of transfusion samples rejected. It is expected that most transfusion samples are rejected, so this number should be low. Accepting transfusion samples adds to your risk.
Transfusion samples rejected	The number of transfusion samples rejected. This will generally equal the number of pre-analytical transfusion errors if the 100% rejection policy is in place.

PRE ANALYTICAL – Collection and transport incidents Incidents that lead to rejection due to collection and transport should be reported here (please include storage issues that occur during this time)	
QI	**Definition / Example**
Sample haemolysed	Any sample showing Haemolysis whether accepted or rejected.
Sample clotted	E.g. clotted FBC tubes.
Incorrect fill level of sample	E.g. ESR or other whole blood / plasma tubes or syringes not filled to correct level.
Insufficient sample	Sample provided is not sufficient for the tests requested.
Incorrect patient preparation, sample transport or storage during collection and transport.	The patient has not undergone the correct preparation, or the sample has not been stored or transported correctly. Examples: • Incorrect patient preparation (not fasting, medication taken etc) • samples leaked or lost in transit • cytogenetic specimen pre-culture stored refrigerated causing loss of cell viability • inappropriately adding formalin to fresh tissue specimen • biochemistry or fresh Cytology sample stored overnight at room temp before analysis • sample not frozen, incorrect transport temperature • sample left and not centrifuged on time • delayed transportation resulting in the sample too old to process requested test
Unsuitable specimen	This includes sample not collected, incorrect sample type, contamination of the sample, inappropriate additive, inappropriate patient preparation. Examples: • EDTA instead of Citrate preservative • Mid stream rather than first pass urine • Inappropriate addition of acid to urine • Collection from drip arm • Patient commenced antibiotics before collection for microbiology.

PRE ANALYTICAL – Laboratory Incidents Incidents that lead to rejection due to incidents that occur once the samples are under the control of the laboratory (which includes specimen reception and request registration) are reported here.	
QI	**Definition / Example**
Any within laboratory failure of Identification	Any within laboratory identification error not related to the collection of the sample. Examples include mistakenly swapping laboratory numbers on samples from different patients, aliquoting samples into a wrongly labelled tube or failure to label an aliquot tube.
Laboratory accident/incident	Any sample rejected due a laboratory error e.g. sample broken in the laboratory, sample lost in laboratory, total volume not recorded.
Data entry/registration incidents	Any registration incident that is found after data entry is complete. Examples include missed tests, wrongly entered tests, data entry of incorrect patient demographic information (age, sex, DOB), merging of two different patient's information. It does not include incorrect information due to incorrect information being received.

POST ANALYTICAL – Incidents (after results have been released)	
QI	**Definition / Example**
Report Retracted (Amended report)	Report retracted because of an error after release in any form by the laboratory. Should include any laboratory data entry errors, analytical errors or interpretation errors found after report has been issued. It does not include reports reissued with additional test results or further interpretation (including 2nd opinions).
Results released to wrong Doctor.	Results released to wrong doctor or to wrong 'Copy' doctor or not sent to 'Copy' doctor; may be identified through complaints or registration audit. Causes include wrong doctor codes, locations, email or HL7 message addresses, or as simple as placing reports into the wrong envelope for delivery.
Turn Around Time	This measures the proportion of Haemoglobin's that fail a laboratories stated turn-around time (TAT). Each laboratory should have documented TAT's, so this QI is a calculation: (number of Haemoglobins failing TAT/total number of Haemoglobin's) x 100. Note the TAT may be different for urgent Haemoglobin's compared to routine Haemoglobin's.
TAT quoted	Participants are asked whether the %TAT failure rate is based on Urgent, Haemoglobin or Both.

OTHER STATISTICS	
How the incident was detected	**Definition / Example**
Complaint	These are incidents that are not picked up by staff before a report is issued. It is expected that these are all reported in the Organisations feedback system.
Incidents detected by the lab i.e. Quality System	These are all the incidents reported to KIMMS that have been detected by the Organisation. It is not a measure of all incidents, only those reported to KIMMS
Unknown	This is a calculation. The Complaints and Incidents detected by the quality system are subtracted from the total number of incidents. Where this number is negative, it means that more incidents have been detected and reported in this category than are reported in QI's to KIMMS.

OTHER STATISTICS	
Root source of incident	**Definition / Example**
Outside laboratory control	These are incidents that have been caused by people outside the organisation's control. Examples are samples collected by GPs or nurses, information of request forms being incorrect.
Within Laboratory control	These are incidents that have been caused by people within the organisation's control i.e. samples collected by staff employed by the organisation
Mixed source	These are incidents that have been caused partly by people outside the organisation's control and partly by people within the organisation's control. Example: information of the request form incorrect but should have been corrected by the phlebotomist e.g. sex of patient.
Unknown	This is a calculation. The 3 values above are subtracted from the total number of incidents. Where this number is negative, it means that more incidents have been detected and reported in this category than are reported in QI's to KIMMS.

Data Analysis

For each run, RCPAQAP KIMMS performs data analysis on data submitted by the participant (Your data) and on data from all the participants (All data). Results are tabulated and graphed for each QI for both Frequency (Count, on the left of the graph) and Risk (on the right of the graph)

FREQUENCY:

Your Count - this is the participant's raw data for each quality indicator in the category
ALL Count - is the raw data reported by all participants for each quality indicator in the category
Your % ID - this is the participant's raw data for each QI, reported as a percentage of the total data in the category
ALL % ID - is the raw data reported by all participants for each QI, as a percentage of the total data from all participants in the category
Your % Acc - this is the total count for the category, reported as a percentage of your episodes
ALL % Acc - is the raw data reported by all participants for the category, reported as a percentage of all participants episodes for the category

RISK:

Risk Factor* - this is equal to the “default harm” x “default detection”
Your Risk - this is equal to the “risk factor”* x “your count”.
ALL - this is equal to the “risk factor” x “All count”
Your % Risk - this is “Your Risk” reported as a percentage of “Your Total Risk” for all categories.
All % Risk - this is equal “All Risk” reported as a percentage
results are graphically shown on the graph at the right.
*See Risk Matrix, page 137, for default harm and default detection values.

OTHER STATISTICS

Overall Incident Rate
The Overall Incident rate is the total pre-analytical errors and total post-analytical errors reported together, to provide an overall percentage Incident rate, for the current Survey. The data is shown in tabular and graph form.. Your Incident Rate is also compared to the ALL participant Overall Incident Rate. Participants should find this a relatively good basic way to benchmark their Incident Rate to all their peers.

How was the incident detected
This data reflects the amount of incidents that are not detected by the Laboratories quality system as reported by the participant. The incidents missed by the quality system represent the biggest risk to the organisation. “Unknown” = “Total incidents” – (“Complaints” + “Problems detected by the lab)”.

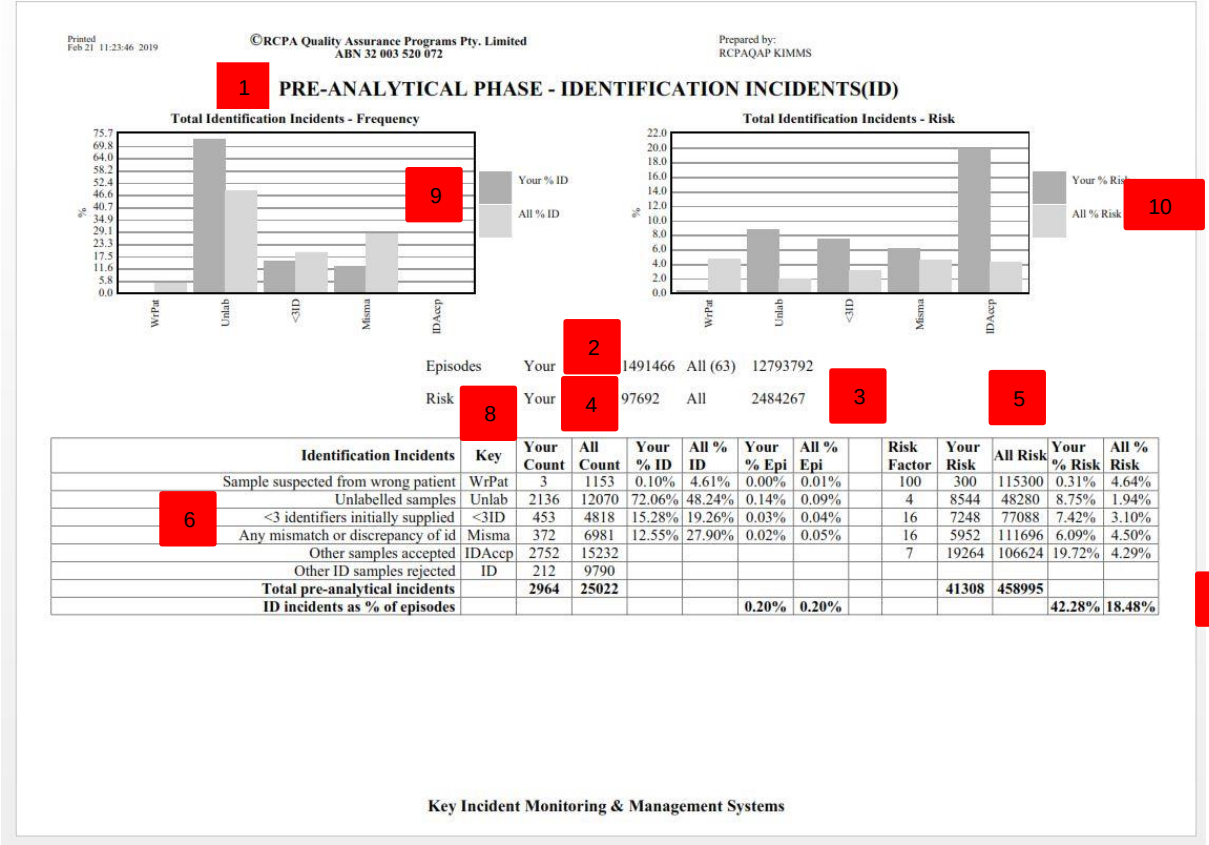
Root source of the incident
Participants are asked to submit data on how many of their incidents were within the pathology service’s control and how many were outside their control and possibly where the source of the incident was mixed. This data can assist the participant to identify the areas to which quality improvements should be focused. “Unknown” = “Total incidents”-(“Outside Lab control” + “Inside Lab control” + “Mixed”).

CUMULATIVE DATA

“Your %Total” Counts for each category, “Your %Risk” for each category, “Your Overall Incident Rate”, “Your %Risk/Episodes” and “Your %Incident Detection” are cumulatively reported and graphed for the previous four surveys, along with the corresponding results for “All” data.
This will provide an overview of how your Organisation/Laboratory is performing over time. It should be especially useful to monitor the effects of any quality improvement initiatives introduced in the area of pre- and post-analytical performance.

PEER REVIEW

This is a dot plot graph that shows a grey dot for the result for each participant for each Quality Indicator, with your result marked as a black dot. The results are expressed as count per 100 or 1000 episodes. Unlab, <3ID, Misma, Haem, Clot, Insuff, SpNC, IncSP are per 100 episodeswhile wrPat, TransID, TransSP, PrecID, Fill, Contam, LabIDF, LabACC, Reg, ZrepRet and WrngDR are per 1000 episodes. TAT is plotted as analyte failures/total analyte (i.e. this is not a %and is a different analyte over time.



Identification Incidents	Key	Your Count	All Count	Your % ID	All % ID	Your % Epi	All % Epi		Risk Factor	Your Risk	All Risk	Your % Risk	All % Risk
Sample suspected from wrong patient	WrPat	3	1153	0.10%	4.61%	0.00%	0.01%		100	300	115300	0.31%	4.64%
Unlabelled samples	Unlab	2136	12070	72.06%	48.24%	0.14%	0.09%		4	8544	48280	8.75%	1.94%
<3 identifiers initially supplied	<3ID	453	4818	15.28%	19.26%	0.03%	0.04%		16	7248	77088	7.42%	3.10%
Any mismatch or discrepancy of id	Misma	372	6981	12.55%	27.90%	0.02%	0.05%		16	5952	111696	6.09%	4.50%
Other samples accepted	IDAccp	2752	15232						7	19264	106624	19.72%	4.29%
Other ID samples rejected	ID	212	9790										
Total pre-analytical incidents		**2964**	**25022**							**41308**	**458995**		
ID incidents as % of episodes						**0.20%**	**0.20%**					**42.28%**	**18.48%**

6

7

Category

1 KIMMS has 5 categories. Each Category has multiple Quality Indicators (QI's)

Your Episodes

2 The number of episodes you have reported to KIMMS. The result is used in the calculations for "Your" % of episodes

All Episodes

3 This is the Total episodes reported by all Participants for this run. This result is used in the calculations for "All" % episodes. The number in brackets is the number of Participants who reported data for this run.

Your Risk

4 The Total risk calculated for your results for this survey. This result is used in the calculations for "Your" % Risk

Total Risk

5 This is the Total Risk for all Participants for this survey. This result is used in the calculations for "all" % Risk.

Quality Indicators

6 This is the list of Quality Indicators for this Category.

Calculations

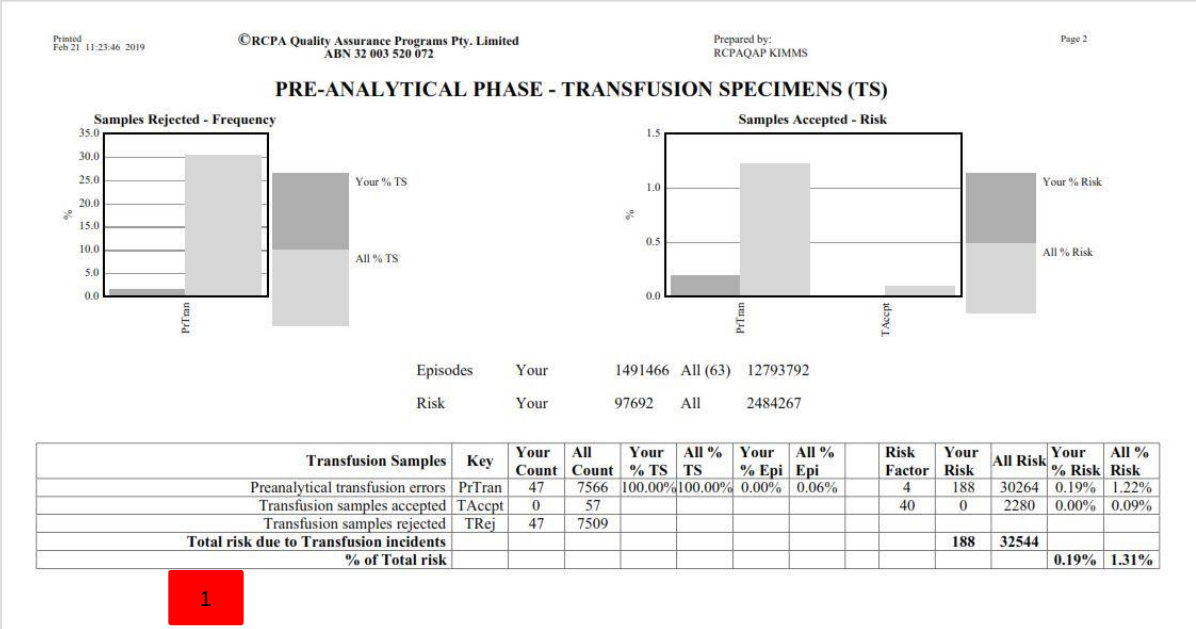
7 This table contains your results and All results for each of the Quality Indicators, and the results for the calculations performed on these results.

8 This is the key for each of the Quality Indicators used as the descriptions for the graphs above.

9 **Identification Problem – Frequency**
This is a graphical representation for Your %ID vs All % ID for each of the Quality Indicators in the category.

10 **Identification Problems – Risk**
This is a graphical representation of Your % Risk vs All % Risk for each on the Quality Indicators in the category.

Identification samples accepted



Transfusion Samples	Key	Your Count	All Count	Your % TS	All % TS	Your % Epi	All % Epi		Risk Factor	Your Risk	All Risk	Your % Risk	All % Risk
Preanalytical transfusion errors	PrTran	47	7566	100.00%	100.00%	0.00%	0.06%		4	188	30264	0.19%	1.22%
Transfusion samples accepted	TAccpt	0	57						40	0	2280	0.00%	0.09%
Transfusion samples rejected	TRej	47	7509										
Total risk due to Transfusion incidents										**188**	**32544**		
% of Total risk												**0.19%**	**1.31%**

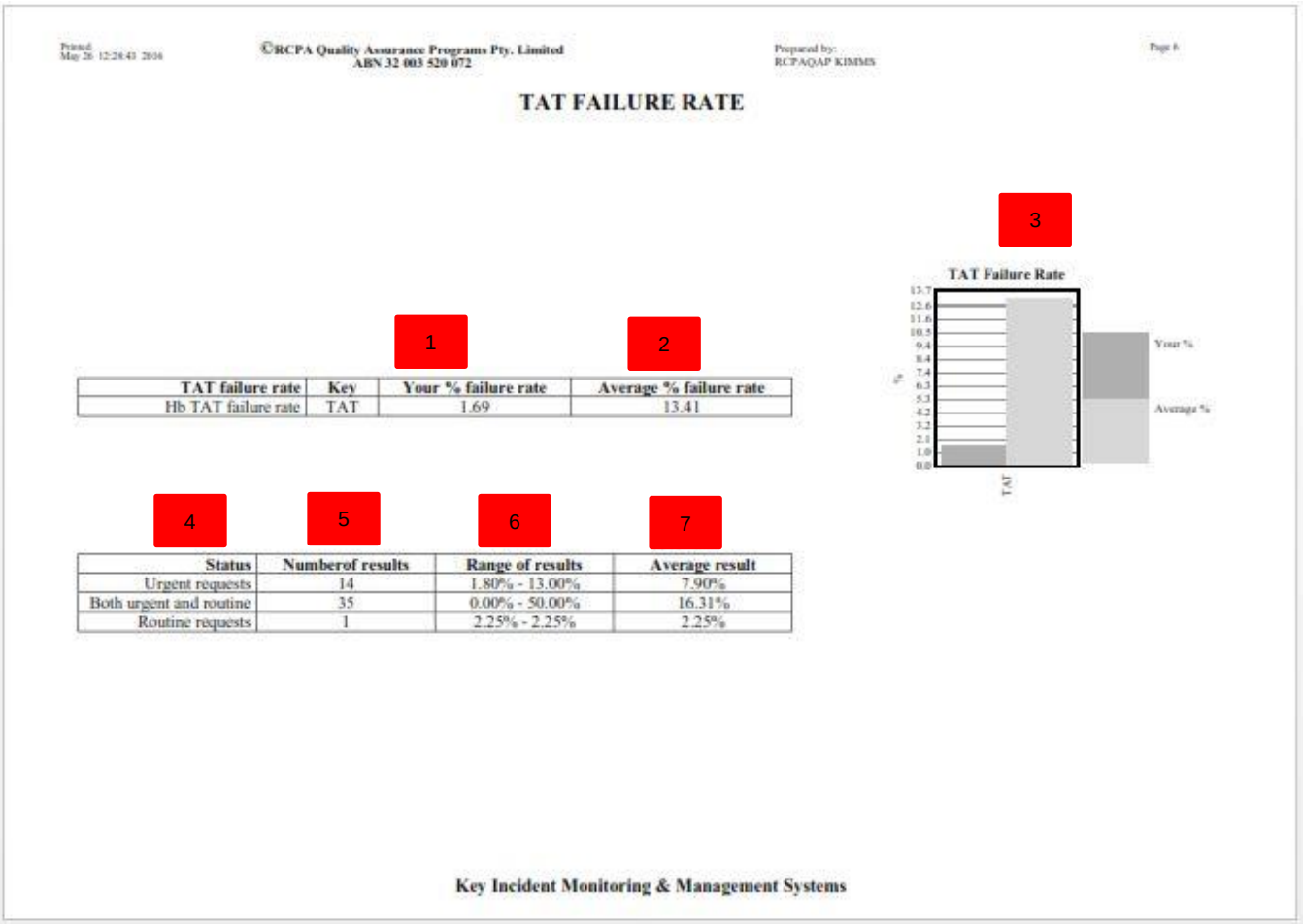
1

2

1 Preanalytical transfusion errors – this QI is reported alone, so is always 100% of the errors in this category.

2 Transfusion samples accepted are deemed to be of higher risk that other samples being accepted.

TAT Failure Rate



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TAT FAILURE RATE

3

1 2

TAT failure rate	Key	Your % failure rate	Average % failure rate
Hb TAT failure rate	TAT	1.69	13.41

4 5 6 7

Status	Numberof results	Range of results	Average result
Urgent requests	14	1.80% - 13.00%	7.90%
Both urgent and routine	35	0.00% - 50.00%	16.31%
Routine requests	1	2.25% - 2.25%	2.25%

Key Incident Monitoring & Management Systems

1 Your % failure rate is the rate reported to KIMMS

2 Average % failure rate is the average rate calculated from all participants who entered data for this QI

3 A graphical representation of Your result and the Average result.

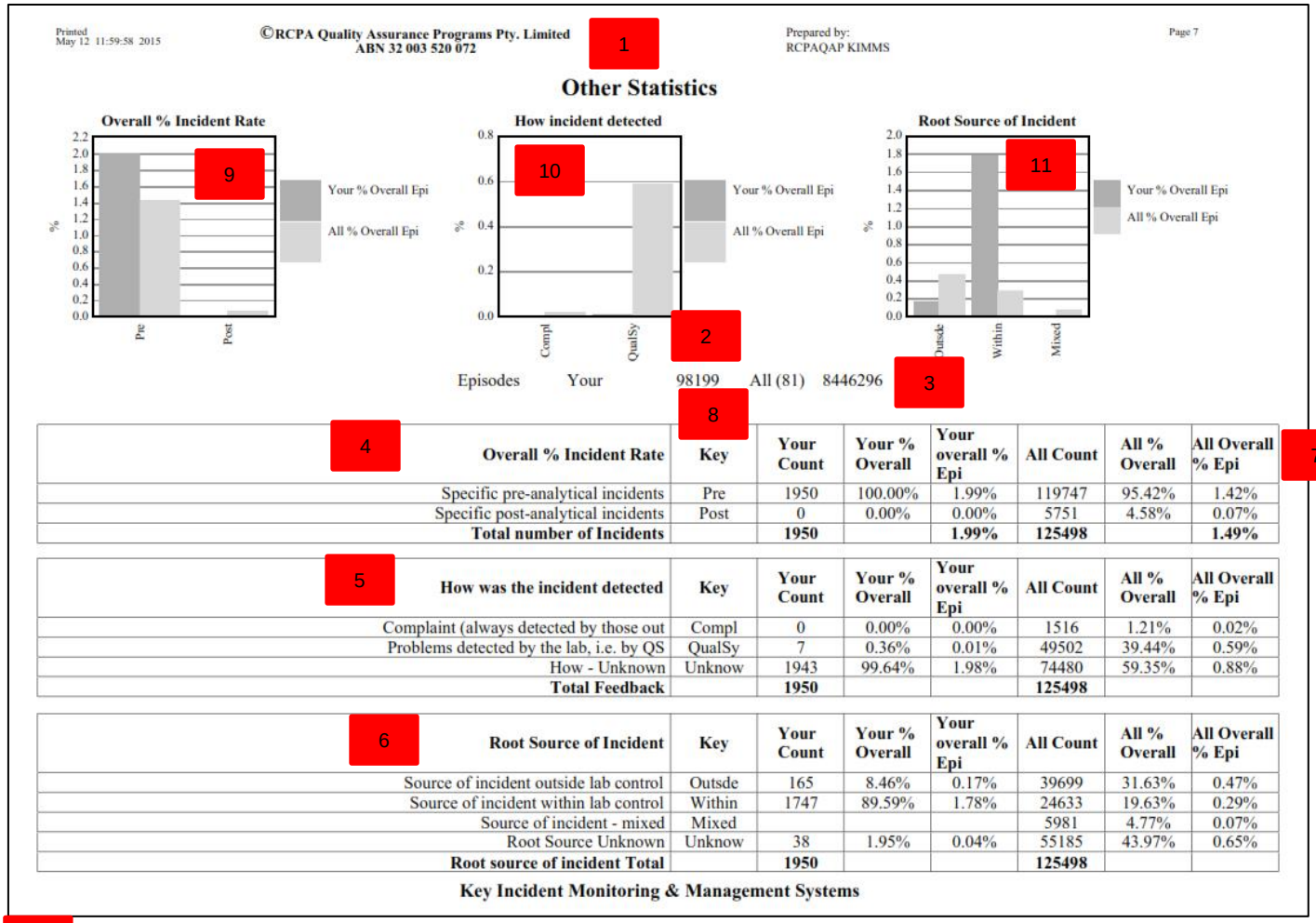
4 Table showing differences between %TAT failure rates depending on Urgent or Routine Status

5 The number of participants returning results for each status

6 The range of results for each status

7 The average result for each status

Other statistics



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Other Statistics

2

Episodes Your 98199 All (81) 8446296

3

8

4 Overall % Incident Rate	Key	Your Count	Your % Overall	Your overall % Epi	All Count	All % Overall	All Overall % Epi
Specific pre-analytical incidents	Pre	1950	100.00%	1.99%	119747	95.42%	1.42%
Specific post-analytical incidents	Post	0	0.00%	0.00%	5751	4.58%	0.07%
Total number of Incidents		**1950**		**1.99%**	**125498**		**1.49%**

7

5 How was the incident detected	Key	Your Count	Your % Overall	Your overall % Epi	All Count	All % Overall	All Overall % Epi
Complaint (always detected by those out	Compl	0	0.00%	0.00%	1516	1.21%	0.02%
Problems detected by the lab, i.e. by QS	QualSy	7	0.36%	0.01%	49502	39.44%	0.59%
How - Unknown	Unknow	1943	99.64%	1.98%	74480	59.35%	0.88%
Total Feedback		**1950**			**125498**		

6 Root Source of Incident	Key	Your Count	Your % Overall	Your overall % Epi	All Count	All % Overall	All Overall % Epi
Source of incident outside lab control	Outsde	165	8.46%	0.17%	39699	31.63%	0.47%
Source of incident within lab control	Within	1747	89.59%	1.78%	24633	19.63%	0.29%
Source of incident - mixed	Mixed				5981	4.77%	0.07%
Root Source Unknown	Unknow	38	1.95%	0.04%	55185	43.97%	0.65%
Root source of incident Total		**1950**			**125498**		

Key Incident Monitoring & Management Systems

1 **Other Statistics**
This summarizes “Your” and “All” incidents, as well as reporting “How the incidents were detected” and “The Root Source of incident”

2 **Your Episodes**
The number of episodes you have reported to KIMMS. This result is used in the calculations for “Your” % of episodes

3 **All Episodes**
This is the total episodes reported by all Participants for this survey. This result is used in the calculations for “All” % episodes. The number in brackets is the number of Participants who reported data for this survey.

4 **Overall % Incident rate**
This shows your total Pre-analytical, total Post-analytical and total Incidents

5 **How was the incident detected**
This separates the incidents depending on how the organisation found out about them – whether they were detected in house via the Quality System, or by being alerted to the incident from outside the organisation i.e. via the complaints system. Where these two do not add up to the total incidents reported, the difference is calculated and reported as “unknown”. Where “unknown” is a negative answer, it indicates that the participant is counting more incidents in this category than has been reported to KIMMS.

6 **Root source of incident**

Incidents are separated depending on who caused the error – whether an employee or someone outside the Participant's organization. It may be harder to solve issues that occur outside the organistion. Where these two do not add up to the total incidents reported, the difference is calculated and reported as "unknown". Where "unknown" is a negative answer, it indicates that the participant is counting more incidents in this category than has been reported to KIMMS.

7 **Calculations**
This table contains "Your" results and "All" results for each of the Quality Indicators described above, as well as the results calculated as per section 6 of this handbook.

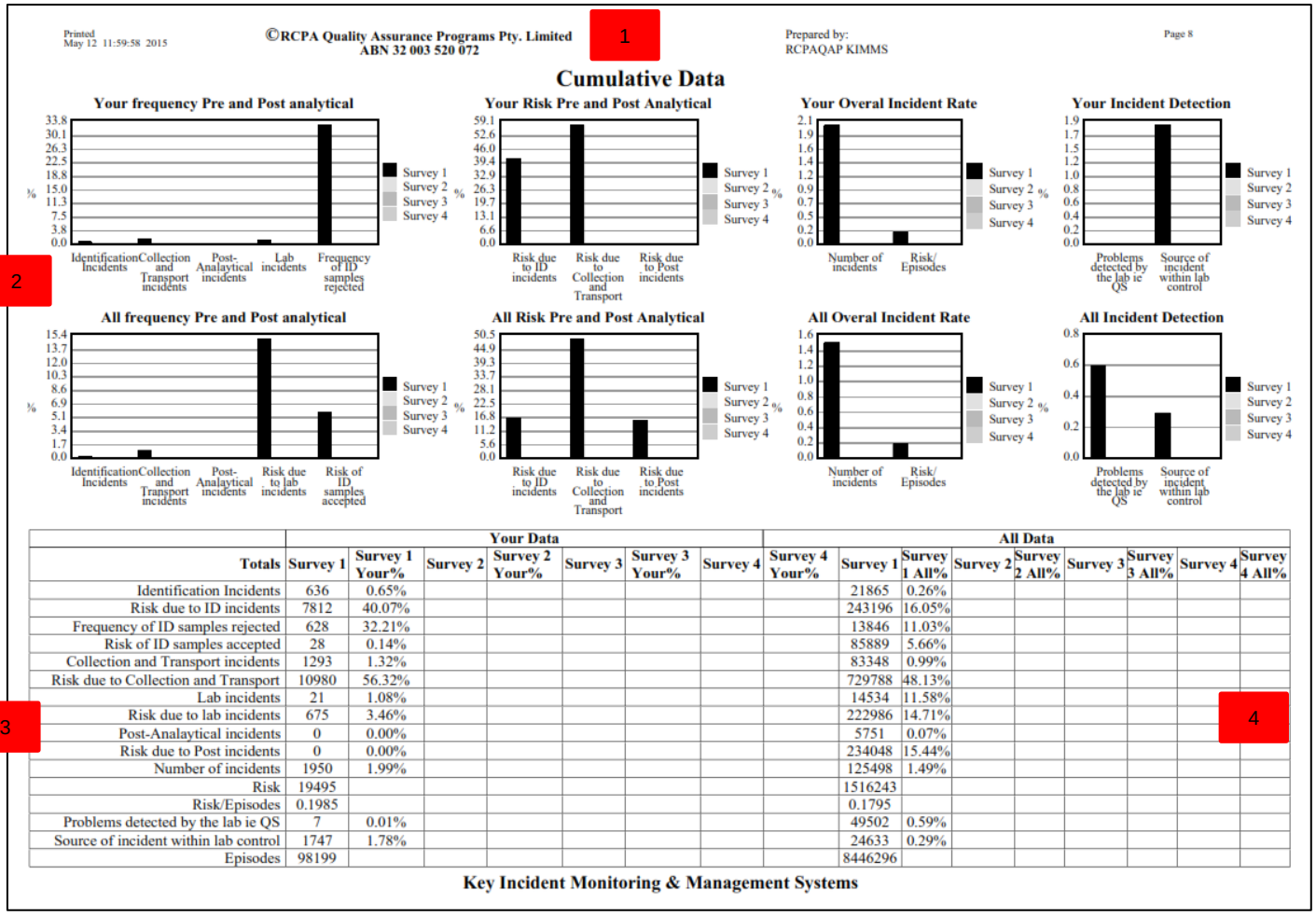
8 **Key**
This is the key for each of the Quality Indicators used as descriptions for the graphs above.

9 This is a graphical representation of "Your overall % of episodes" vs "All overall % of episodes" for the Total incidents

10 This is a graphical representation of "Your overall % of accessions vs "All overall % of episodes" for How incident was detected.

11 This is a graphical representation of "Your overall % of accessions vs "All overall % of episodes" for Root source of incident.

Cumulative Data



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Cumulative Data

Your frequency Pre and Post analytical

Your Risk Pre and Post Analytical

Your Overal Incident Rate

Your Incident Detection

2

All frequency Pre and Post analytical

All Risk Pre and Post Analytical

All Overal Incident Rate

All Incident Detection

	Your Data							All Data							
Totals	Survey 1	Survey 1 Your%	Survey 2	Survey 2 Your%	Survey 3	Survey 3 Your%	Survey 4	Survey 4 Your%	Survey 1	Survey 1 All%	Survey 2	Survey 2 All%	Survey 3	Survey 3 All%	Survey 4	Survey 4 All%
Identification Incidents	636	0.65%							21865	0.26%						
Risk due to ID incidents	7812	40.07%							243196	16.05%						
Frequency of ID samples rejected	628	32.21%							13846	11.03%						
Risk of ID samples accepted	28	0.14%							85889	5.66%						
Collection and Transport incidents	1293	1.32%							83348	0.99%						
Risk due to Collection and Transport	10980	56.32%							729788	48.13%						
Lab incidents	21	1.08%							14534	11.58%						
Risk due to lab incidents	675	3.46%							222986	14.71%						
Post-Analaytical incidents	0	0.00%							5751	0.07%						
Risk due to Post incidents	0	0.00%							234048	15.44%						
Number of incidents	1950	1.99%							125498	1.49%						
Risk	19495								1516243							
Risk/Episodes	0.1985								0.1795							
Problems detected by the lab ie QS	7	0.01%							49502	0.59%						
Source of incident within lab control	1747	1.78%							24633	0.29%						
Episodes	98199								8446296							

3

4

Key Incident Monitoring & Management Systems

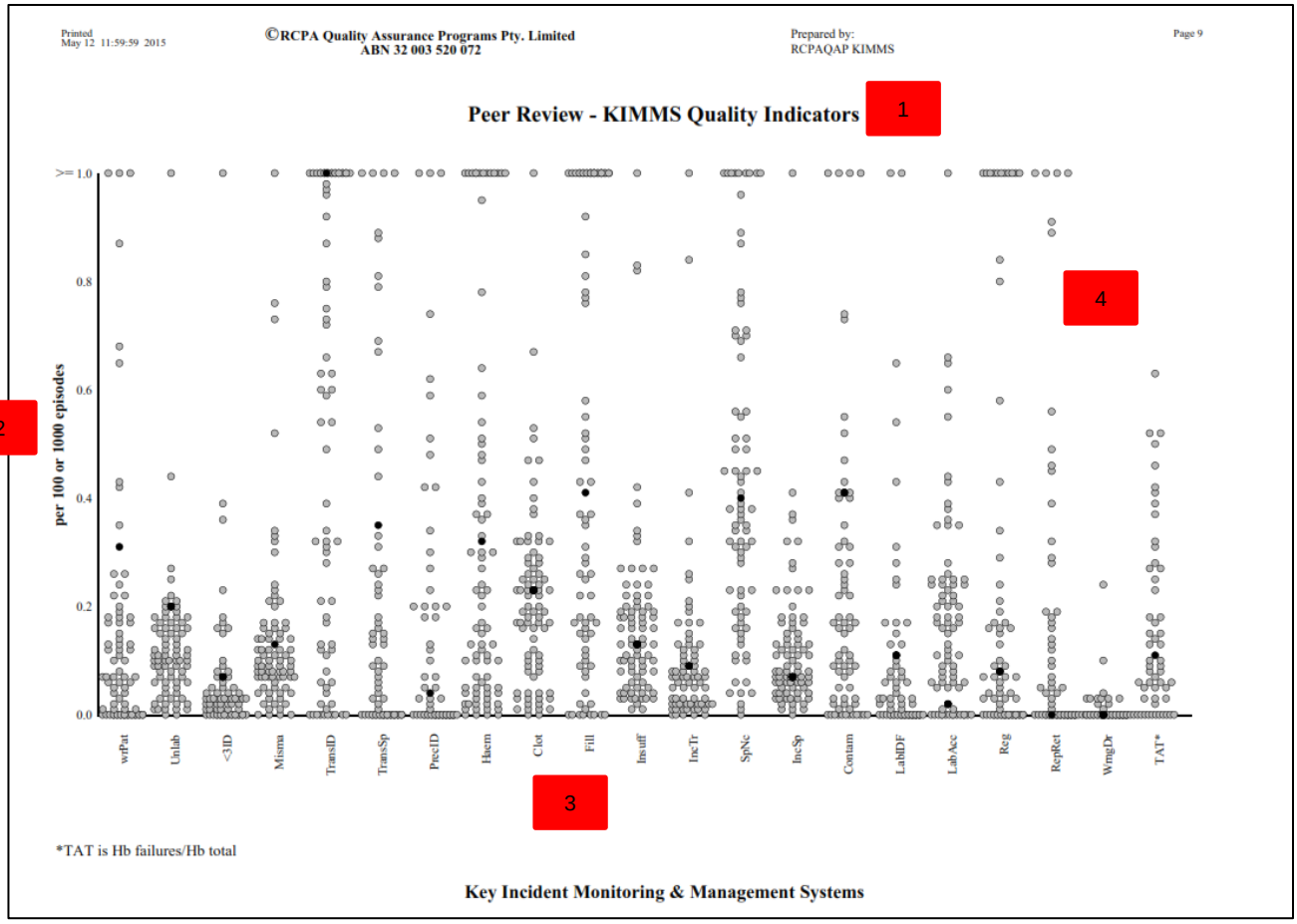
1 **Cumulative Data**
This summarizes the data for the previous 4 surveys. It is designed to quickly identify any changes that occurred in the overall data between runs.

32 **Graphs**
These are a graphical representation of the data for each of the Categories

3 **Categories**
These are a summary of the categories form the previous pages. There is one new calculation introduced which== is Total Risk/Episode. Each category is summarized by frequency and risk, shown as “Your %” and “All %”

4 **Results**
The table contains the results for “your %” and All %”.

Peer Review



1 **Peer Review – KIMMS Quality Indicators**
This is a graphical representation of all participants results entered for the current survey.

2 **X-axis**
The labels are taken from the “key” for each of the Quality Indicators

3 **Y-Axis**
The results are expressed as count per 100 or 1000 episodes. Unlab, <3ID, Misma, Haem, Clot, Insuff, SpNC, IncSP are per 100 episodes, while wrPat, TransID, TransSP, PrecID, Fill, Contam, LabIDF, LabACC, Reg, ZrepRet and WrngDR are per 1000 episodes. TAT is Hb failures/Hb total (i.e. this is not a %).

4 **Graph**
Each point represents a Participant’s result. Your result is the black point. Note that the 0 answers may be that a result was not submitted for this QI. The top points represent a result >1.0 i.e. >1 incident per 100 or 1000 episodes, depending on the Quality Indicator as above.

General Comment

The General comment page allows the program Manager and Advisory Committee to point out certain aspects of the report, to discuss any Participant Feedback, to present any case studies and links to articles of interest.

KIMMS Report interpretation

KIMMS data can vary quite considerably between participants. There is no correct result and, to date, benchmarking between "like laboratories" is not ideal as no two laboratories are the same.

Possible reasons QI's may vary between participants are:

- Size / type of the laboratory / Type of institution (teaching hospital or stat lab)
- Demographics of patient base (inpatient or outpatient)
- Large or small Emergency Department
- Who collects the sample – trained phlebotomist, nursing staff, Doctors?
- Compliance level of staff
- Whether data manually or automatically collected by the Laboratory Information System
- Equipment and method differences e.g. Haemolysis index cut off's.
- Laboratory's policies regarding recollections of samples e.g. with regards to Blood group and antibodies vs Transfusion samples, haemolysed samples.

Factors that can affect Your %

Your % is calculated for each QI as a % of the total for the category. This means that any changes to the QI's count within a category will change the Your % for each QI in the category.

When comparing yourself to other Participants, you may have higher % rates if you report less QI'S within a category e.g. Lab A reports total of 10 errors, 1 for each QI. Each QI will have Your % equal to 10%. Lab B reports total of 10 errors, 5 for Unlabelled and 5 for <3 Identifiers. These 2 QI's would have Your % equal to 50%. It is thus not recommended that you attempt to compare Your% for each QI to other participants.

Factors that can affect Your % Episodes

This should remain fairly constant and only change when there is a change to company policies or methods. This is the value that should be monitored when improvements are introduced.

Factors that can affect Your % Risk

Your % Risk is calculated for each QI as % of the total Risk for all QI's in all categories. Thus changes to any QI will change the % Your Risk for all the other QI's in the program.

A small change to the count of a QI with a large Risk Factor, will lead to a much larger change in Your % risk for that QI, with a corresponding reduction in Your % risk for all the other QI's. The size of the reductions will be governed by how many QI's you are entering data on.

Factors that affect the All % and All % Risk

These can be affected anytime a new Participant joins the program. This is especially seen if a laboratory with large numbers of episodes joins. As each Participant see's different counts depending on its demographics, it can lead to quite large changes in the percentages for the "All" QI's for both frequency and risk.

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