RCPAQAP
The Royal College of Pathologists of Australasia
Quality Assurance Programs

Safety Data Sheet (SDS)

1. Identification: Product and Company Identity

Supplier details: The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP)
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Catalogue Number	Product Name
11010102	Automated Differential - Option 1
11020102	Automated Differential - Option 2
11030102	Automated Differential - Option 3
11040102	Automated Differential - Option 4
11050102	Automated Differential - Option 7
11060102	Bone Marrow Morphology
11070102	CD34 program
11080102	Coagulation Factors II, V, VII, X, XI, and XII
11090102	Coagulation Factors VIII and IX
11110102	Compact Full Blood Count
11180102	Condensed Full Blood Count
11250102	Condensed Haemostasis
11130102	D-Dimer Automated
11140102	D-Dimer Semi-quantitative
11150102	ESR - Option 1
11160102	ESR - Option 2 StaRRsed only
11190102	Full Blood Count
11200102	G6PD
11210102	Haematology Immunophenotyping
11220102	Paroxysmal Nocturnal Haemoglobinuria
11230102	Haemoglobinopathy
11240102	Haemostasis
11260102	Malarial Parasite

11270102	Malarial Parasite Rapid Diagnostic Test
23130102	Acute Myeloid Leukaemia NGS Panel testing
23140102	BCR-ABL Qualitative Testing
23150102	Chimerism Analysis
23160102	FLT-3 ITD and TKD
23170102	Hereditary Haemochromatosis (HFE)
23180102	IDH Mutation Analysis in AML (IDH1, IDH2)
23190102	Immunogenotyping (IgH,TCR)
23200102	Myeloproliferative Neoplasms (JAK2, CALR, MPL)
23210102	NPM1
23220102	PML-RARα
23230102	Thalassaemia (alpha, beta)
23240102	Thrombosis (F5, F2)
23250102	TP53 Deletions at 17p13.1 in CLL (FISH)
11280102	Blood Film Differential Count
11290102	Morphology
11300102	Paediatric Morphology
11310102	Point of Care - Condensed Full Blood Count
11330102	Point of Care - HemoCue WBC Automated Differential
11340102	Point of Care - INR
11350102	Reticulocyte - Option 1 Manual
11360102	Reticulocyte - Option 2 Automated
11370102	Reticulocyte - Option 3 Beckman Coulter
11380102	Activated Protein C resistance
11390102	Apixaban (Anti Xa)
11400102	Dabigatran (direct Thrombin Inhibitor)
11410102	Factor VIII Inhibitor
11420102	Factor XIII
11430102	Low Molecular Weight Heparin monitoring
11440102	Lupus Anticoagulant
11450102	PFA-100/200
11460102	Thrombophilia
11470102	Rivaroxaban (Anti Xa)
11480102	Unfractionated Heparin monitoring
11490102	von Willebrand Factor
11500102	Thromboelastography: TEG-5000
11510102	Thromboelastography: TEG-6s

11520102	Thromboelastometry: ROTEM-Delta
11530102	Thromboelastometry: ROTEM-Sigma

Recommended use: Quality Assurance/Proficiency Testing programs. Not to be used in the treatment and diagnosis of patients.

2. Hazard Identification

Chemical hazard: Not applicable

Environmental hazard: Not applicable

Health hazard: **Exempt human specimens**

No known test method can offer complete assurance that products derived from inactivated microorganisms and/or human sources will not transmit infection. All proficiency testing materials supplied by RCPAQAP must be handled appropriately and with care. The participant is responsible for the safe handling, storage and disposal of RCPAQAP proficiency testing materials in such a way that ensures that the proficiency testing materials will not cause any harm to any person.

The participant understands and acknowledges that, given the nature and characteristics of RCPAQAP proficiency testing materials;

- laboratory staff should be trained in the handling of infectious materials.
- proficiency testing materials should be processed in a laboratory environment as identified by the relevant legislative requirements.
- they are aware of all matters that concern the safe handling, storage and disposal of proficiency testing materials.
- they have the facilities and processes required for the safe handling, storage and disposal of proficiency testing materials.
- that they follow Standard Safety Precautions when handling potentially infectious materials.
- they utilise Personal Protective Equipment (PPE) as identified by the relevant legislative requirements for the routine handling of potentially infectious materials.

3. Composition and Information on Ingredients

Products contain the below components:

CAS#	Component	Percentage
Not Applicable	Human fluids and tissue	0-100%
Not Applicable	Stabiliser/Diluent	0-100%

4. First-aid Measures

If accidental contact with material occurs laboratory staff should follow appropriate first aid procedures for exposure to an equivalent clinical specimen. Following exposure, medical advice should be sought. If accidental spillage occurs, follow routine procedures for clean-up of potentially biohazardous materials.

5. Firefighting Measures

Not applicable, not flammable.

6. Accidental Release Measures

Personal protective equipment such as gloves, gown and protective eyewear should be used before cleaning any spills. Dispose any sharps in a safe disposal system. Clean the area with absorbent paper and clean excess with suitable disinfectant (such as bleach or 70% alcohol).

7. Handling and Storage

On arrival, samples should be stored as per instructions on each sample kit. Samples have been shown to be stable when transported at ambient temperature.

Samples should be re-constituted or prepared according to Survey Instructions provided.

8. Exposure Controls and Personal Protection

Samples are generally intended for processing in a clinical laboratory facility and should be handled in the same manner as routine patient samples using universal precautions and appropriate personal protective equipment. Biosafety Level 2 precautions at a minimum should be used in laboratory settings. In point of care (non-laboratory) settings Biosafety Level 1 precautions at a minimum should be used.

9. Physical and Chemical Properties

Stabilised whole blood: red and odourless, pH neutral

Serum/plasma: straw colour and odourless, pH neutral

Urine: straw colour and odourless, pH neutral

Lyophilised plasma/serum/urine – straw colour powder, pH neutral

Medical Glass microscope slides of human origin: odourless

Purified Deoxyribonucleic Acid (DNA) / Purified Ribonucleic Acid (RNA) – clear liquid, pH 8.0

10. Stability and Reactivity

This material is stable under normal temperatures and pressures, is non-corrosive, and polymerization will not occur.

Conditions to avoid: Avoid excess heat.

11. Toxicological Information

Tested and found non-reactive for the presence of Hepatitis B surface antigen (HbsAg), antibodies to Hepatitis C virus (anti-HCV), and antibodies to Human Immunodeficiency Virus (anti-HIV-1/HIV-2).

12. Ecological Information

Same biodegradability as human blood, urine and other bodily fluids.

13. Disposal Information

Dispose as clinical waste in suitably identified containers using a registered clinical waste disposal contractor (same as for patient samples).

14. Transport Information

Proper Shipping Name: Exempt Human Specimens

UN Number: Not Applicable

Hazard Class/Packing Group: Category C

Labels Required: Exempt human specimens

IATA Packaging Requirements: Sample is not subject to the IATA Dangerous Goods Regulations as long as the specimen is transported in triple packaging that prevents leakage

15. Regulatory Information

Not Applicable.

16. Other Information

Reviewed annually as part of the RCPAQAP compliance with ISO/IEC 17043.

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