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)
Suite 201, Level 2, 8 Herbert Street
St Leonards NSW 2065, Australia

Tel: +61 2 9045 6000

Emergency Tel: +61 418 996 351

Email: Customer.service@rcpaqap.com.au

Website: www.rcpaqap.com.au

Catalogue Number	Product Name
23010102	Coeliac Disease HLA Genotyping
23020102	Human Leukocyte Antigen B*57
23030102	Molecular Testing in in Glioma (IDH1/2, MGMT)
23040102	Mutation Detection in Colorectal Cancer
23050102	Mutation Detection in Lung Cancer (NSCLC)
23060102	Mutation Detection in Melanoma
23070102	Kennedy's Disease
23080102	PTEN
23090102	Maternal Cell Contamination
23100102	Quality Assessment of DNA Extracts
23110102	Quality Assessment of FFPE DNA Extracts
23120102	Sanger DNA Sequencing

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 may contain the below components:

CAS#	Component	Percentage
Not Applicable	Human fluids and tissue	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

Medical Glass microscope slides of human origin: odourless

Purified Deoxyribonucleic Acid (DNA) / Purified Ribonucleic Acid (RNA) / Polymerase Chain Reaction (PCR) amplified product from purified DNA / Oligonucleotide – 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.

The information provided in this document is believed to be accurate and represents the best information currently available to us. The RCPAQAP make no warranty or merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no event shall the RCPAQAP be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages arising from the use of this product or the information contained in this Material Safety Data Sheet.