

Safety Data Sheet (SDS)

1. Identification: Product and Company Identity

Supplier details: Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP)
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Catalogue Number	Product Name
13010102	ALK Translocation in NSCLC - FISH
13020102	ALK Translocation in NSCLC - IHC
13030102	ALK Translocation in NSCLC - Molecular
13310102	Fluorescence in-situ hybridisation (FISH) Diagnostic
13250102	HER2 BRISH Breast Technical
13260102	HER2 BRISH Gastric Technical
13150102	Immunohistochemistry Breast Markers
13170102	Immunohistochemistry General
13180102	Immunohistochemistry Lymphoma Markers
13140102	Neuropathology Immunohistochemistry
13400102	Neuropathology Technical
13360102	ROS1 Translocation in NSCLC - FISH
13370102	ROS1 Translocation in NSCLC - IHC
13380102	ROS1 Translocation in NSCLC - Molecular
13240102	Technical General
13270102	Immunohistochemistry PD-L1
16010105	Gynaecological Conventional- Lab does not report
16010106	Gynaecological Conventional- Lab routinely reports
16020105	Gynaecological Liquid based SurePath - Lab does not report
16020106	Gynaecological Liquid based SurePath - Lab routinely reports
16030105	Gynaecological Liquid based ThinPrep - Lab does not report
16030106	Gynaecological Liquid based ThinPrep - Lab routinely reports
16090101	Individual Competency - SurePath Cytopathologist

16090104	Individual Competency - SurePath Cytoscientist
16100101	Individual Competency - ThinPrep Cytopathologist
16100104	Individual Competency - ThinPrep Cytoscientist
16080102	Technical

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	Exposure Limit
Not Applicable	Human fluids and tissue	100%	None established

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

Urine: straw colour and odourless, pH neutral

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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