

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
12210102	Molecular Alphavirus and Flavivirus
12220102	Molecular Bordetella pertussis
12230102	Molecular C. trachomatis and N. gonorrhoeae
12430102	Molecular Coronavirus SARS-CoV-2
12240102	Molecular Cytomegalovirus
12250102	Molecular Enterovirus
12260102	Molecular Gastrointestinal Pathogens - Bacteria
12270102	Molecular Gastrointestinal Pathogens - Parasites
12280102	Molecular Gastrointestinal Pathogens - Viral
12290102	Molecular Hepatitis B Virus DNA
12300102	Molecular Hepatitis C Virus RNA
12310102	Molecular Hepatitis C Virus RNA Genotyping
12320102	Molecular Herpes simplex virus type 1 and 2
12330102	Molecular HIV-1 RNA
12340102	Molecular Human Papillomavirus DNA
12350102	Molecular Influenza
12360102	Molecular M. tuberculosis / M. avium complex
12370102	Molecular mec A/nuc gene
12380102	Molecular Neisseria meningitidis
12390102	Molecular Rapid Diagnostics Influenza/RSV
12400102	Molecular Respiratory Pathogens
12410102	Molecular Vaccine Preventable Pathogens
12420102	Molecular Varicella zoster virus

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

2. Hazard Identification

Chemical hazard:	Not applicable
Environmental hazard:	Not applicable
Health hazard:	Biological Substance, Category B

These samples must be considered as potentially biohazard and should 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	Exposure Limit
Not Applicable	Microbial cultures	0-100%	None established
Not Applicable	Human fluids and tissue	0-100%	None established
Not Applicable	Transport medium	0-100%	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, a gown and protective eyewear should be used before cleaning any spills. Dispose of 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 provided. Samples have been shown to be stable at the nominated transport temperature.

Samples should be re-constituted or prepared according to the 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

Human serum/plasma: straw colour and odourless, pH neutral

Lyophilised serum/urine/CSF/respiratory/broth – white/straw colour powder, pH neutral

Lyophilised stimulated stool – brown/black colour powder, pH neutral

Cervical cells in PreservCyt solution - Clear to slightly opaque liquid, colourless, mild odour

Simulated stool: light to dark brown solution and mild to odourless

Inactivated culture materials – clear to pink 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

These samples are potentially infectious and may be positive for hepatitis B, hepatitis C virus, human immunodeficiency virus (anti-HIV-1/HIV-2) or other infectious diseases.

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: Biological Substance, Category B

UN Number: UN3373

Hazard Class/Packing Group: Category B

Labels Required: UN3373

IATA Packaging Requirements: IATA compliant to PI 650 requirements.

15. Regulatory information

Not Applicable

16. Other information

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

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