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
20410102	Alphavirus
20350102	Bordetella pertussis
20030102	Brucella
20040102	Chlamydia genus
20460102	Coronavirus SARS-CoV-2 Antibodies
20480102	Coronavirus SARS-CoV-2 Antigen
20220102	Cryptococcal Antigen
20180102	Cytomegalovirus
20420102	Dengue virus
20230102	Entamoeba
20190102	Epstein Barr virus
20430102	Flavivirus
20050102	Helicobacter pylori
20120102	Hepatitis A
20130102	Hepatitis B
20140102	Hepatitis C
20150102	Hepatitis D
20160102	Hepatitis E
20440102	Herpes simplex
20320102	Human Immunodeficiency Virus
20330102	Human T-Lymphotropic Virus
20240102	Hydatid
20170102	Infectious Mononucleosis
20360102	Influenza A and B Antibody

20060102	Legionella Antibody
20070102	Legionella Antigen
20250102	Leptospirosis
20260102	Lyme Disease
20370102	Measles
20380102	Mumps
20080102	Mycoplasma
20450102	Parvovirus
20470102	PoCT COVID-19 serology (IgG/IgM)
20290102	PoCT Human Immunodeficiency Virus
20300102	PoCT Influenza A and B Antigen
20310102	PoCT RSV Antigen
20390102	Q Fever
20090102	QuantiFERON-TB
20100102	Rickettsia
20010102	Rubella
20270102	Schistosomiasis
20110102	Streptococcus
20280102	Strongyloides
20020102	Syphilis
20200102	Toxoplasma
20400102	Varicella zoster

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: **Biological Substance Category B**

These samples must be considered as potential 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
Not Applicable	Human fluids and tissue	0-100%
Not Applicable	Culture material (see section 9)	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 only 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.

9. Physical and Chemical Properties Whole blood:

red and odourless, pH neutral Serum/plasma: straw

colour and odourless, pH neutral Urine: straw colour

and odourless, pH neutral

Lyophilised serum/plasma – straw colour powder, pH neutral

Cerebrospinal Fluid (CSF) – clear to straw colour and odourless, pH neutral

Inactivated culture materials – clear to pink and odourless, pH neutral

Culture materials (not inactivated; legionella antigen and cryptococcus antigen programs only) - 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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