Australian Government
Department of Agriculture,
Fisheries and Forestry

Permit to import conditionally non-prohibited goods

This permit is issued under *Biosecurity Act 2015* Section 179 (1)

Permit: 0008383951

Valid for: multiple consignments between 12 February 2024 and 12 February 2029

This permit is issued to: SydPath
Level 6 Xavier Building
St Vincent's Hospital
Victoria Street
DARLINGHURST NSW 2010
AUSTRALIA

Attention: Ms Lilian Milis

This permit is issued for the import of Biological products (Standard goods).

Exporter details:	Various exporters

This permit includes the following good(s). Refer to the indicated page for details of the permit conditions:

1. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Test kits not testing for disease agents (Standard)	
Permit Conditions:	Test kits not testing for disease agents	Page 4

2. Test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Test kit description:	Nucleic acid amplification (e.g. PCR) test kits (Standard)	
Permit Conditions:	Nucleic Acid Amplification (NAA) test kits	Page 7

NOTE: Where a good has more than one set of permit conditions please read each set to determine which set of permit conditions applies to a specific consignment.

---------- End of commodity list ----------

This permit is granted subject to the requirement that fees determined under section 592(1) are paid.

Amy Wythes
Delegate of the Director of Biosecurity Date: 17 November 2023

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Important information about this permit and the import of goods

Note: This permit covers Department of Agriculture, Fisheries and Forestry import conditions. It is the permit holder's responsibility to ensure all legal requirements relating to the goods described in this permit are met. While the permit holder should rely on their own inquiries, the following information is provided to assist the permit holder in meeting legal obligations in relation to the importation of the goods described in this permit.

Information about this permit

Authority to import

The permit holder is authorised to import the goods described in this permit subject to the listed conditions specified in this permit.

Compliance with permit conditions and assessment and management of biosecurity risk

All imports are subject to biosecurity control and may be subject to biosecurity inspection on arrival to determine compliance with the listed permit conditions and to assess the level of biosecurity risk associated with the goods. Imports that do not comply with the import conditions specified in the permit may present an unacceptable level of biosecurity risk and may be subject to biosecurity measures that may include treatment, export or destruction at the permit holder's expense or forfeited to the Commonwealth.

Additionally, non-compliance with import permit conditions may constitute an offence or contravention of a civil penalty provision under section 187 of the *Biosecurity Act 2015*.

Change of import conditions

The Director of Biosecurity may, in accordance with section 180 of the *Biosecurity Act 2015* vary or revoke the conditions on a permit or impose further conditions.

General information about importing goods

Notification of import

Notification of the import must be provided to the Department of Agriculture, Fisheries and Forestry for all imported goods other than goods imported as accompanied baggage or goods imported via the mail and not prescribed under *the Customs Act 1901,* or where other exceptions specified in the *Biosecurity Regulation 2016* apply. Notification must be provided in accordance with section 120 of the *Biosecurity Act 2015* and Part 1 of Chapter 2 of the *Biosecurity Regulation 2016*. Please refer to 'Sending your goods to Australia' on the Department of Agriculture, Fisheries and Forestry website.

Provision of required documentation

It is recommended that all required documentation accompanies each consignment. Required documentation must be presented to the Department of Agriculture, Fisheries and Forestry for assessment. Airfreight or mail shipments should have all required documentation securely attached to the outside of the package, and clearly marked "Attention Department of Agriculture, Fisheries and Forestry" Documentation may include the permit (or permit number), government certification and invoice.

If the product description on the permit varies from the identifying documentation provided, the goods will not be released from biosecurity control unless evidence is provided to the biosecurity officer that the permit covers the goods in the consignment.

Any documentation provided must comply with the Department of Agriculture, Fisheries and Forestry's minimum documentation requirements policy.

Non-commodity cargo clearance

In addition to the conditions for the goods being imported, non-commodity biosecurity risks are assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

Fees

Fees are payable to the Department of Agriculture, Fisheries and Forestry for certain services (see the *Biosecurity Charges Imposition (General) Regulation 2016*, Part 2 of Chapter 9 of the *Biosecurity Regulation 2016* and Part 3 of Chapter 11 of the *Biosecurity Act 2015*). Detail on how the department applies fees and levies may be found in the Charging guidelines.

Compliance with other regulatory provisions

Goods imported into Australia may be subject to regulatory requirements under other legislation. It is the permit holder's responsibility to identify and ensure they have complied with all requirements of any other regulatory agency or advisory body prior to and after importation.

Permit conditions

It is the importer's responsibility to ensure that the following permit conditions are met in relation to each consignment. Where more than one set of permit conditions is shown for a good please read each set of conditions to determine which applies to a specific consignment.

1. Test kits not testing for disease agents

This section contains permit conditions for the following commodity (or commodities):

1.	Test kits

1.1. Biosecurity Pathway

These conditions allow for the import of test kits testing for human, veterinary and environmental conditions including:

1. haematology tests,
2. hormone tests, including pregnancy tests etc.,
3. drug tests,
4. chemical tests,
5. genetic tests,
6. environmental test kits, including soil test kits,
7. allergy test kits for use on humans only.

Additional reagents, controls, calibrators etc. may also be imported:

1. when specifically designed for use with test kits eligible for import under these conditions.
2. where they can meet all import conditions.
3. whether or not they are imported in the same consignment (separate to the test kit) or in a separate consignment.

Import conditions prior to arrival in Australian territory

a. The goods must only be test kits, which:
   1. do not test for disease agents.
   2. do not contain disease agents (live, live attenuated or inactivated) or their derivatives (e.g. antigens).
   3. do not contain any components raised against disease agents (e.g. antibodies).

b. All animal derived material must be in volumes of no greater than 20ml or 20g per individually packaged unit.

   Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.

c. The goods must be commercially manufactured and packaged.

d. The goods must meet biosecurity requirements.

To demonstrate compliance with this requirement you must present the following on a Manufacturer's declaration:

1. A statement that the goods are test kits (or individual components specifically designed for use with kits eligible for import under these conditions), which:
   1.1. do not test for disease agents.
   1.2. do not contain disease agents (live, live attenuated, or inactivated) or their derivatives (e.g. antigens).
   1.3. do not contain any components raised against disease agents (e.g. antibodies).
2. A statement that all animal derived material contained in these test kit(s) is in volumes of no greater than 20ml or 20g per individually packaged unit.
   Note: The total volume of the individually packaged units may be greater than 20ml or 20g, however the animal derived material contained within must not be greater than 20ml or 20g.

Product name(s) of each kit and each reagent, control, calibrator etc. (if imported separately to the kit) must be included on the manufacturer's declaration.

The manufacturer’s declaration must be supplied by either a legal manufacturer, or the individual manufacturing site.

Note: The manufacturing declaration does not need to be issued from within the country of manufacture.

Import conditions after arrival in Australian territory

e. **Post entry/end use conditions**

1. The goods must not be exposed to or used in animals, plants, cell cultures or the environment, and must not be used in or on humans (except for allergy tests to be applied to the skin).
2. The goods must not be used for culture or isolation of microorganisms and infectious agents.
3. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.
4. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
5. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

f. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer’s manifest
3. describe the goods being imported (where not clear).
   e.g. 1: Product XRab = Purified protein derived from rabbits

e.g. 2: Product AX = Synthetic antibiotic
e.g. 3: Comte = Cheese.

Where applicable, the importer or end user must comply with:

1. International (e.g. International Air Transport Association) and domestic requirements concerning the safe handling, transport and labelling of biological material.
2. AS/NZS 2243 Safety in Laboratories standards.
3. Office of the Gene Technology Regulator (OGTR) requirements.
4. Any regulatory requirements of the Therapeutic Goods Administration (TGA).
5. Any regulatory requirements of the Australian Pesticide and Veterinary Medicines Authority (APVMA).
6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

g. Under the Biosecurity Charges Imposition (General) Regulation 2016 and Chapter 9, Part 2 of the Biosecurity Regulation 2016, fees are payable to the Department of Agriculture, Fisheries and Forestry for all services. Detail on how the department applies fees and levies may be found in the Charging guidelines.

h. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

2. Nucleic Acid Amplification (NAA) test kits

This section contains permit conditions for the following commodity (or commodities):

2.	Test kits

2.1. Biosecurity Pathway

These conditions allow for the import of:

1. Polymerase Chain Reaction (PCR) test kits.
2. Real-Time PCR or Quantitative PCR (qPCR) test kits.
3. Reverse Transcriptase PCR (RT-PCR) test kits.
4. Loop-Mediated Isothermal Amplification (LAMP) test kits.

Additional reagents, controls, calibrators etc. may also be imported:

1. when specifically designed for use with test kits eligible for import under these conditions.
2. where they can meet all import conditions.
3. whether or not they are imported in the same consignment (separate to the test kit) or in a separate consignment.

Import conditions prior to arrival in Australian territory

a. The goods must meet biosecurity requirements.

To demonstrate compliance with this requirement you must present the following on a Manufacturer's declaration:

1. A statement that the goods are Nucleic Acid Amplification (NAA) test kits only (or individual components specifically designed for use with kits eligible for import under these conditions).
2. A statement that the goods contain nucleic acid up to 1000 nucleotides, enzymes and chemical buffers only.

Product name(s) of each kit and each reagent, control, calibrator etc. (if imported separately to the kit) must be included on the manufacturer's declaration.

The manufacturer’s declaration must be supplied by either a legal manufacturer, or the individual manufacturing site.

Note: The manufacturing declaration does not need to be issued from within the country of manufacture.

b. The goods must be commercially manufactured and packaged.

Import conditions after arrival in Australian territory

c. **Post entry/end use conditions**

1. The goods must not be exposed to or used in animals, plants, or the environment, and must not be used in or on humans.
2. Microorganisms or infectious agents must not be cultured or isolated from the materials imported under this permit.

3. Any microorganisms or infectious agents (including derivatives) within the goods must not be used for the synthesis of replication-competent microorganisms or infectious agents.
4. The goods must be labelled with the end use conditions on the smallest individually packaged unit.

   OR

   The smallest individually packaged unit must be accompanied by documentation stating the end use conditions. This documentation must be provided to the end user of the goods.

Additional information

d. **Commercial administrative conditions**

Documents must be provided with each consignment which:

1. identify the consignment (if non-personal) e.g. entry number
2. identify all goods being imported as part of this consignment e.g. invoice or waybill or importer's manifest
3. describe the goods being imported (where not clear).
   e.g. 1: Product XRab = Purified protein derived from rabbits
   e.g. 2: Product AX = Synthetic antibiotic
   e.g. 3: Comte = Cheese.

Where applicable, the importer or end user must comply with:

1. International (e.g. International Air Transport Association) and domestic requirements concerning the safe handling, transport and labelling of biological material.
2. AS/NZS 2243 Safety in Laboratories standards.
3. Office of the Gene Technology Regulator (OGTR) requirements.
4. Any regulatory requirements of the Therapeutic Goods Administration (TGA).
5. Any regulatory requirements of the Australian Pesticide and Veterinary Medicines Authority (APVMA).
6. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

e. Under the Biosecurity Charges Imposition (General) Regulation 2016 and Chapter 9, Part 2 of the Biosecurity Regulation 2016, fees are payable to the Department of Agriculture, Fisheries and Forestry for all services. Detail on how the department applies fees and levies may be found in the Charging guidelines.

f. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the Non-Commodity Cargo Clearance BICON case for further information.

---------- **End of permit conditions** ----------