Australian Government
Department of Agriculture, Water and the Environment

Permit to import conditionally non-prohibited goods

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

Permit: 0004023777

Valid for: multiple consignments between 11 February 2020 and 11 February 2024

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. Diagnostic test kits		
End use:	In-vitro	
Country of export:	Various countries	
Country of origin:	Various countries	
Diagnostic kit description:	Diagnostic test kits not testing for disease agents	
Permit Conditions:	Diagnostic test kits not testing for disease agents	Page 4

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

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

Tristan Dewick
Delegate of the Director of Biosecurity

Date: 11 February 2020

T +61 2 6272 3933
F +61 2 6272 5161
18 Marcus Clarke Street
Canberra City ACT 2601
GPO Box 858
Canberra ACT 2601
agriculture.gov.au
ABN 34 190 894 983

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

Important information about this permit and the import of goods

Note: This permit covers Department of Agriculture, Water and the Environment biosecurity requirements. It is your responsibility to ensure all legal requirements relating to the goods described in this import permit are met. While you should rely on your own inquiries, the following information is provided to assist you in meeting your legal obligations in relation to the importation of the goods described in this import permit.

Authority to import

You are authorised to import the goods described in this import permit under the listed conditions.

Compliance with permit conditions and freedom from contamination

All imports may be subject to biosecurity inspection on arrival to determine compliance with the listed permit conditions and freedom from contamination. Imports not in compliance or not appropriately identified or packaged and labelled in accordance with the import conditions they represent may be subject to treatment, export or destruction at the importer's expense, or forfeited to the Commonwealth.

Compliance with other regulatory provisions

Additionally, all foods imported into Australia must comply with the provisions of the *Imported Food Control Act 1992*, and may be inspected and/or analysed against the requirements of the Australia New Zealand Food Standards Code.

All imports containing or derived from genetically modified material must comply with the *Gene Technology Act 2000*.

It is the importer's responsibility to identify and ensure they have complied with all requirements of any other regulatory organisations and advisory bodies prior to and after importation. Organisations include the Department of Home Affairs, the Department of Health, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, Food Standards Australia New Zealand and any state agencies such as Departments of Agriculture and Health and Environmental Protection authorities. Importers should note that this list is not exhaustive.

Change of import conditions

Import conditions are subject to change at the discretion of the Director of Biosecurity. This permit may be suspended or revoked without notice.

Notification of import

Notification of the import must be provided to the Department of Agriculture, Water and the Environment 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*. Notification must be consistent with the Biosecurity Regulation 2016.

Valid import permit

The importer must hold a valid import permit at the time when the goods are brought or imported into Australian Territory.

The importer must verify that they hold a valid import permit in relation to the consignment by providing positive identification to the Department of Agriculture, Water and the Environment, by either:

i. Submitting (or providing) the permit for biosecurity clearance.

OR

ii. Providing any physical, digital or verbal information that allows the permit to be identified at the time of biosecurity clearance.

Provision of required documentation

All required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to the Department of Agriculture, Water and the Environment at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked "Attention Department of Agriculture, Water and the Environment". Documentation may include the import permit (or import permit number), government certification and invoice.

If the product description on the import permit varies from the identifying documentation provided for clearance, the importer is responsible for providing evidence to the biosecurity officer that the import permit covers the goods in the consignment.

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

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. Diagnostic test kits not testing for disease agents

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

1.	Diagnostic test kits

1.1. Biosecurity Pathway

These conditions allow for the import of diagnostic 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 diagnostic 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 diagnostic test kit) or in a separate consignment.

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 diagnostic 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 diagnostic 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.

b. The goods must be commercially manufactured and packaged.

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

The goods are for:

1. *in vitro* use, or
2. allergy testing for external use on humans only (e.g. skin prick tests).

The following end uses are not permitted:

1. The isolation of disease agents from the imported material.
2. The synthesis of replication-competent disease agents or homologues from the imported material.
3. Direct or indirect exposure to animals (excluding allergy testing of humans) or plants.

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.

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.

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, Water and the Environment 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.

2. Nucleic Acid Amplification (NAA) diagnostic test kits

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

2.	Diagnostic test kits

2.1. Biosecurity Pathway

These conditions allow for the import of:

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

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

1. when specifically designed for use with diagnostic 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 diagnostic test kit) or in a separate consignment.

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) diagnostic 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.

b. The goods must be commercially manufactured and packaged.

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

The goods are for *in vitro* use only.

The following end uses are not permitted:

1. Culturing or isolating disease agents.
2. The synthesis of replication-competent disease agents or homologues.
3. Direct or indirect exposure to animals (including laboratory animals) or plants.

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.

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