## Permit to import conditionally non-prohibited goods

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

### Permit: 0004620123

#### Valid for: multiple consignments between 3 December 2020 and 3 December 2022

This permit is issued to: The Walter and Eliza Hall Institute of Medical Research
1G Royal Parade
PARKVILLE VIC 3052
Australia

Attention: Ms Wendy Carter

This permit is issued for the import of Biological products (Non-standard goods).

<table>
<thead>
<tr>
<th>Exporter details:</th>
<th>Various exporters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country of export:</td>
<td>Various countries</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>1. Microorganisms (including viruses)</th>
<th>In vitro use or in vivo use in laboratory organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>End use:</td>
<td>In vitro use or in vivo use in laboratory organisms</td>
</tr>
<tr>
<td>Country of export:</td>
<td>Various countries</td>
</tr>
<tr>
<td>Country of origin:</td>
<td>Various countries</td>
</tr>
<tr>
<td>Permit Conditions:</td>
<td>Microorganisms including viruses and derivatives thereof Page 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Human fluids and tissues</th>
<th>In vitro use or in vivo use in laboratory organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>End use:</td>
<td>In vitro use or in vivo use in laboratory organisms</td>
</tr>
<tr>
<td>Country of export:</td>
<td>Various countries</td>
</tr>
<tr>
<td>Country of origin:</td>
<td>Various countries</td>
</tr>
<tr>
<td>Permit Conditions:</td>
<td>Human fluids and tissues infected with microorganisms and viruses (PC required) Page 7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Genetic material (including viable genetic expression systems)</th>
<th>In vitro use and/or in vivo use in laboratory organisms only</th>
</tr>
</thead>
<tbody>
<tr>
<td>End use:</td>
<td>In vitro use and/or in vivo use in laboratory organisms only</td>
</tr>
<tr>
<td>Country of export:</td>
<td>Various countries</td>
</tr>
<tr>
<td>Country of origin:</td>
<td>Various countries</td>
</tr>
<tr>
<td>Permit Conditions:</td>
<td>Genetic material, purified and derived from microorganisms and viruses (excluding listed species) Page 9</td>
</tr>
</tbody>
</table>

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

Rachel Rathjen
Delegate of the Director of Biosecurity Date: 03 December 2020
### 4. Human fluids and tissues

<table>
<thead>
<tr>
<th>End use</th>
<th>In-vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country of export</td>
<td>Various countries</td>
</tr>
<tr>
<td>Country of origin</td>
<td>Various countries</td>
</tr>
<tr>
<td>Permit Conditions</td>
<td>Laboratory materials for in vitro use only</td>
</tr>
</tbody>
</table>

**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 -----------------------------------------
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 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.

Delegate of the Director of Biosecurity
Rachel Rathjen

Date: 03 December 2020
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. Microorganisms including viruses and derivatives thereof

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

| 1. | Microorganisms (including viruses) |

1.1. Biosecurity Pathway

a. These conditions allow for the import of the following products only:
   - Dengue virus
   - Plasmodium falciparum
   - Plasmodium knowlesi
   - Plasmodium vivax

b. Derivatives must be primary derivatives i.e. components that have been directly isolated and purified from a pure culture of the microorganism. Secondary derivatives i.e. components of the microorganism that have undergone passage or inoculation into a second organism e.g. antibodies, are not permitted under these import conditions.
   Derivatives must be imported in quantities of no greater than 20ml or 20g for each individually packaged unit.

c. Each culture, derivative, sequence or vector must be clearly identified.
   To demonstrate compliance with this requirement you must present the following on a Product label, Invoice, Manufacturer's declaration, Exporter's declaration or Supplier's declaration:
   - The scientific name of the microorganism or the source microorganism of derivatives, sequences and vectors.
   - Cultures must be pure cultures and labelled with the scientific name of the organism as it appears on the import permit including genus, species and any other criteria e.g. subspecies, strain, biotype, serotype, pathovar, variety etc.
   - Derivatives of microorganisms must be primary derivatives only and labelled with the scientific name of the source organism as it appears on the import permit including genus, species and any other criteria e.g. subspecies, strain, biotype, serotype, pathovar, variety etc.
   - Product numbers or codes matching an invoice or inventory list are acceptable for goods in small vials.

d. Post Entry Requirements

   Approved end uses:
   1. *in vitro* laboratory studies,
   2. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.

   Additional written approvals are required prior to direct or indirect use of the imported goods (including their derivatives):
1. in plants,
2. in non-laboratory organisms e.g. chickens, sheep, cattle,
3. as veterinary vaccines and therapeutics.

For information on how to obtain additional written approvals contact imports@agriculture.gov.au or call 1800 900 090.

It is the importers responsibility to ensure that the goods are labelled “in-vitro or in-vivo use in laboratory organisms only” on the smallest packaged unit, prior to distribution. The products may be labelled post entry.

e. **Additional post entry requirements – Department of Health**

Department of Health - Import Conditions:

1. The in vitro work must be conducted in Physical containment level 2 (PC2), or higher. The facility must use PC2 work practices as recommended under the Australian/New Zealand Standard Safety in laboratories Part 3: Microbiological safety and containment (AS/NZS 2243.3:2010).

Department of Health – Advice to importers and end-users:

1. A risk assessment must be conducted and documented to ensure that any specific hazards, depending on the activity, are identified and managed.

2. Personnel must be monitored for any symptoms of infection and provided with prompt first aid and evaluation by a medical professional following any potential exposure incident.

For Dengue Fever: If personnel do become infected it is recommended that they do not travel to North Queensland or other areas where vectors are present.

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.

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, Water and the Environment 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. Human fluids and tissues infected with microorganisms and viruses (PC required)

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

| 2. | Human fluids and tissues |

### 2.1. Biosecurity Pathway

#### a. Biosecurity Pathway

- This import permit allows for the importation of human fluids and tissues, infected with, or potentially infected with, the following organisms only:
  - Dengue virus
  - Plasmodium falciparum
  - Plasmodium knowlesi
  - Plasmodium vivax

#### b. Post Entry/End Use Conditions

1. The human fluids and tissues are for *in vitro* laboratory studies (or *in vivo* use in laboratory organisms) only.
2. Laboratory organisms are those defined in the following list and must be contained under laboratory or animal house conditions: guinea pigs, hamsters, mice, rats, rabbits or micro-organisms. Work in all other animals and plants is not permitted.
3. This import permit does not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.
4. It is the end user’s responsibility to ensure that the goods adhere to any [Therapeutics Goods Administration (TGA)](https://www.tga.gov.au) regulatory requirements.
5. It is the importer’s responsibility to ensure that the goods are labelled "*In vitro* use or *in vivo* use in laboratory organisms only" or equivalent on the smallest packaged unit prior to distribution.
6. It is the end user’s responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243.3:2010 Safety in Laboratory standards.
7. The importer must undertake a risk assessment to ensure any specific hazards associated with *in vitro* use or *in vivo* use in laboratory animals are managed using appropriate work practices including use of any standard precautions as outlined in the Australian Guidelines for the prevention and Control of Infection in Healthcare.
8. It is the end user’s responsibility to ensure that all products are used in accordance with the [Office of the Gene Technology Regulator (OGTR)](https://www.ogtr.gov.au) and Therapeutic Goods Administration (TGA) requirements.
9. It is the importer’s responsibility to ensure compliance with all international (e.g. [International Air Transport Association (IATA)](https://www.iata.org)) and domestic requirements concerning the safe handling, transport and labelling of biological material.

#### c. Additional post entry requirements – Department of Health

- Department of Health - Import Conditions:

  1. The in vitro work must be conducted in Physical containment level 2 (PC2), or higher. The facility must use PC2 work practices as recommended under the Australian/New Zealand Standard Safety in laboratories Part 3: Microbiological safety and containment (AS/NZS 2243.3:2010).
Department of Health – Advice to importers and end-users:

1. A risk assessment must be conducted and documented to ensure that any specific hazards, depending on the activity, are identified and managed.

2. Personnel must be monitored for any symptoms of infection and provided with prompt first aid and evaluation by a medical professional following any potential exposure incident.

For Dengue Fever: If personnel do become infected it is recommended that they do not travel to North Queensland or other areas where vectors are present.

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.
### 3. Genetic material, purified and derived from microorganisms and viruses (excluding listed species)

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

| 3. Genetic material (including viable genetic expression systems) |

#### 3.1. Biosecurity Pathway

a. These conditions allow for the import of genetic material, purified and derived from microorganisms and viruses (excluding listed species) only.

b. The goods must be clearly labelled with the name of the source microorganism or infectious agent.

c. The genetic material must not be derived from microorganisms and infectious agents in the list of microorganisms and infectious agents of significant biosecurity concern (Appendix 1).

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

A declaration stating:

1. that the genetic material has been highly purified and is unable to replicate, and
2. the name (genus and species) of the source microorganism or infectious agent.

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

Approved end uses:

1. *in vitro* laboratory studies, and/or
2. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions.

Additional written approvals* are required prior to direct or indirect use:

1. in plants
2. in non-laboratory organisms e.g. chickens, sheep, cattle
3. as veterinary vaccines and therapeutics
4. in culturing or isolating microorganisms and infectious agents
5. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

*For information on how to obtain additional written approvals contact imports@agriculture.gov.au or call 1800 900 090.

It is the importer’s responsibility to ensure that the goods are labelled “*in vitro or in vivo use in laboratory organisms only*” on the smallest packaged unit, prior to distribution. The products may be labelled post entry.

---

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

1. International (e.g. [International Air Transport Association](https://www.iata.org)) 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. The Security Sensitive Biological Agents (SSBA) regulatory scheme.

e. **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.

f. 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.

g. 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.
4. Laboratory materials for in vitro use only

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

| 4. Human fluids and tissues |

4.1. Biosecurity Pathway

- These conditions allow for the import of the following products only:
  - Human fluids and tissues infected with, or potentially infected with SARS-CoV-2 (CoVID-19) only.

- i. The goods must only be taken from persons with no clinical signs or symptoms of infectious disease other than SARS-CoV-2 (CoVID-19)
  
- ii. The goods must be infected, or potentially infected with SARS-CoV-2 (CoVID-19) only.

- c. The goods are individually packaged in units of no greater than 20mL or 20g

- d. Post entry/end use conditions

  Approved end use:
  
  1. *in vitro* laboratory studies.

  The following end uses are not permitted:
  
  1. in culturing or isolating microorganisms and infectious agents,
  2. in the synthesis of replication-competent microorganisms, infectious agents or homologues.

  It is the importer's responsibility to ensure that the goods are labelled “*in vitro* only” on the smallest packaged unit, prior to distribution. The products may be labelled post entry.

Additional written approvals are required prior to direct or indirect use:

1. *in vivo* in laboratory organisms. Laboratory organisms are guinea pigs, hamsters, mice, rats, rabbits or microorganisms contained under laboratory or animal house conditions

2. *in vivo* in non-laboratory organisms e.g. chickens, sheep, cattle

3. in plants.

For more information on how to obtain additional written approvals contact imports@agriculture.gov.au or call 1800 900 090.

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. The Security Sensitive Biological Agents (SSBA) regulatory scheme.
e. **Additional post entry conditions**

Department of Health - Import Conditions:

1. The in vitro work must be conducted in Physical containment level 2 (PC2), or higher. The facility must use PC2 work practices as recommended under the Australian/New Zealand Standard Safety in laboratories Part 3: Microbiological safety and containment (AS/NZS 2243.3:2010).

Department of Health – Advice to importers and end-users:

1. A risk assessment must be conducted and documented to ensure that any specific hazards, depending on the activity, are identified and managed.

2. Personnel must be monitored for any symptoms of infection and provided with prompt first aid and evaluation by a medical professional following any potential exposure incident.

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.

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.

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.
Appendix 1: Microorganisms and infectious agents of significant biosecurity concern

1. All plant pathogens (viruses, viroids, bacteria, fungi and stramenopiles).

2. Microorganisms and infectious agents associated with Listed Human Diseases. Listed Human Diseases are those that are listed under the Biosecurity (Listed Human Diseases) Determination 2016, which is published on the Federal Register of Legislation (the Listed Human Diseases are also published on the Department of Health’s website).

3. Foot and mouth disease virus

4. African horse sickness virus

5. Peste des petits ruminants virus

6. Ovine and caprine pox virus

7. Pulmonary adenomatosis virus

8. Swine vesicular disease virus

9. African swine fever virus

10. Classical swine fever virus

11. Avian influenza virus

12. Newcastle disease virus

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