



Permit to Import Quarantine Material

Permit: IP15012681 Valid From: 9 Oct 2014 Valid To: 9 Oct 2016 Page 1 of 4

Importer	Exporter
Dr Serguei Kovalenko Specialist Diagnostic Services Pty Ltd trading as Genomic Diagnostics 460 Lower Heidelberg Road Heidelberg VIC 3084 Attn: Mrs Janet Fletcher	Various Suppliers Exporters Various Addresses In All countries

You are authorised to import the following material under the listed conditions
Note: This permit covers the Department of Agriculture quarantine requirement only.
All imports may be subject to quarantine 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 seizure, treatment, re-export or destruction at the importer's expense.
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 to ensure it has complied with, all requirements of any other regulatory organisations and advisory bodies prior to and after importation including The Australian Customs and Border Protection Service, The Department of Health and Ageing, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, Department of Sustainability, Environment, Water, Population and Communities, 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.

This permit is granted for the purposes of the *Quarantine Act 1908* and *Quarantine Proclamation 1998* of the Commonwealth of Australia. The laws of Australian States and Territories may also impose restrictions on the import of animals, plants and other goods into those States and Territories. This import permit does not prevent the application of those State and Territory laws. The importer should seek its own advice on any restrictions that may apply in any State or Territory into which it is proposed to import the animals, plants or other goods to which this permit relates.



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

Notification of the import must be provided to the Department of Agriculture 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 *Quarantine Regulations 2000* (examples include a Quarantine Entry or a Quarantine declaration).

Commodity Name	Condition Number(s)	Country	End Use
Human fluids & tissues - free from listed diseases	PC4206	All countries	In-vitro use or in-vivo use in laboratory organisms only

Condition	Condition Text
PC4206	Human fluids & tissues

1. A valid copy of this Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation must accompany each consignment. Alternatively, necessary documentation will need to be presented to DAFF at the time of clearance.

This permit is granted subject to the condition that fees determined under Section 86E are paid	
 Delegate of Director of Quarantine Printed Name Tran Tang	Stamp: 
Date 9 Oct 2014	

Condition	Condition Text
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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 Quarantine". Documentation may include Import Permit (or Import Permit number), and invoice.

2. Each consignment must be clearly identified and linked to the relevant item(s) on the Import Permit. Identifying documentation must be available to the quarantine officer at the time of clearance. This documentation may include:

- a) an accompanying invoice or airway bill; or
- b) the physical labelling of the goods; or
- c) a manufacturers declaration describing the goods.

3. 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 quarantine officer that the Import Permit covers the products in the consignment.

Manufacturer's declaration

4. The consignment must be accompanied by a declaration from the manufacturer stating that, to the best of my knowledge, the specimens were only taken from persons with no signs or symptoms of the following diseases:

- Cholera
- Highly pathogenic avian influenza in humans (HPAIH)
- Human swine influenza with pandemic potential
- Plague
- Rabies
- Severe acute respiratory syndrome (SARS)
- Small pox
- Viral haemorrhagic fever in humans
- Yellow fever
- Any disease that is exotic to Australia

5. If the consignment is not accompanied by the above declaration or the specimens are known to be infected, or are potentially infected with a human quarantinable or exotic disease, the material must be subjected to gamma irradiation at 50 kGy (5 Mrad), prior to release from Quarantine. Irradiation at 50 kGy at an DAFF approved facility is mandatory even if the product has been irradiated prior to import into Australia.

Condition	Condition Text
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6. Providing all documentation is in order at the time of clearance, the consignment can be released from quarantine.

The manufacturer's declaration must be:

- . issued by the individual manufacturing site or by the manufacturer's head office within the country of export.
- . on manufacturer's letterhead including company address and country.
- . written in English.
- . signed by a designated representative whose name, position and title also appear.
- . identify the date of issue.
- . issued and dated within the last 6 months (unless otherwise specified in this import permit).
- . free from erasures and non certified alterations (all erasures and alterations must be endorsed by the issuer of the document. The only acceptable endorsement is a company stamp or seal and the signature of the company officer responsible for signing the declaration applied adjacent to the alteration).
- . contain the correct statement/s as required by the import conditions (all prescribed information on the certification must be legible and appear above the signature).
- . specific to the product(s) listed on this permit.
- . have a unique identifiable link to the consignment such as one of the following: container number, bill number, commercial invoice number, preferential tariff certificate number, health certificate number, packing list number or letter of credit number, batch/serial number or date of manufacture.

All documentation must meet the requirements of the Minimum Documentary Requirements Policy. For full details of the DAFF minimum documentary requirements, please refer to <http://www.daff.gov.au/biosecurity/import/general-info/documentary-requirements>.

Post entry conditions

- 7.** This Import Permit allows for the importation of goods for in vitro laboratory studies (or in vivo use in laboratory organisms only), unless approved by DAFF for specific in vivo use in non-laboratory organisms.
- 8.** Laboratory organisms include those defined in the following list and must be contained under laboratory or animal house conditions (or equivalent): guinea pigs, hamsters, mice, rabbits, rats, rodents or micro-organisms. Work in all other animals and plants is not permitted.
- 9.** For in vivo use in non-laboratory organisms (eg. chickens, sheep, cattle, etc.) or plants a separate application for in vivo use must be lodged with, and approved by DAFF. This also applies if the product is to be used in veterinary vaccine or veterinary therapeutic manufacture.
- 10.** This Import Permit does not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.
- 11.** 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.
- 12.** It is the importer's responsibility to ensure compliance with all international (eg IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.
- 13.** It is the end user's responsibility to ensure that all laboratory products are used in accordance

Condition	Condition Text
	with the current AS/NZS 2243 Safety in Laboratory standards and Office of the Gene Technology Regulator (OGTR) requirements.

End of Condition Text