Australian Government
Department of Agriculture, Fisheries and Forestry

Phone: 02 6272 4578
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File Ref:

Quarantine Act 1908 Section 13(2AA)

Permit to Import Quarantine Material

Permit: IP14016350 **Valid From:** 18 Mar 2014 **Valid To:** 18 Mar 2016

Importer	Exporter
Dr Serguei Kovalenko Specialist Diagnostic Services Pty Ltd trading as Genomic Diagnostics 60-66 Hanover Street Fitzroy VIC 3065 Attn: Ms Lorraine Skalicka	Various Suppliers Exporters Various Addresses In All countries

You are authorised to import the following material under the listed conditions

Note: This permit covers DAFF 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 DAFF 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
Genetic material and vectors - low risk	PC0017 AND PC6797 AND PC5887	All countries	In-vitro use or in-vivo use in laboratory organisms only
Animal fluids and tissues (excluding reproductive material) - sourced from low risk species	PC0017 AND PC6798 AND PC0992	All countries	In-vitro use or in-vivo use in laboratory organisms only

Condition	Condition Text
PC0017	**Biological Imports Program (BIP) - Administrative conditions**

1. This import permit (or number) and all required documentation must accompany each

This permit is granted subject to the condition that fees determined under Section 86E are paid

Delegate of Director of Quarantine

Printed Name Sandra Cuthbert **Date** 18 Mar 2014

Stamp:

Condition	Condition Text

consignment and must be valid at the time the cargo is landed.

2. In order to facilitate clearance of mail shipments, the import permit (or number) and all documentation should be securely attached to the outside of the package and marked 'Attention Quarantine'.

3. The importer must meet all costs associated with the import of this product.

4. The importer (or agent) must lodge a quarantine entry for each consignment.

5. Documents must be provided with each consignment which:
a) identify the consignment e.g. entry number: and
b) identify all goods being imported as part of this consignment e.g. invoice or waybill or importers manifest; and
c) describe the goods being imported (where not clear) Example 1: Product XRab = Purified protein derived from rabbits. Example 2: Product AX = Synthetic antibiotic. Example 3: Comte = Cheese.
Note: It is the importer's responsibility to provide any additional information which is requested in order to demonstrate that the import permit covers all goods being imported.

6. Consignments that do not meet the import conditions will remain under the Department's control pending export or destruction at the importers expense.

7. For further information please contact:

Regional - Clearance assistance: http://www.daff.gov.au/biosecurity/about/contact/regional

Canberra - Biological Import Program - Administrative assistance: bioadmin@daff.gov.au

Canberra - Biological Import Program – Technical assistance: biologicals@daff.gov.au

PC0992 **POST ENTRY / END USE CONDITIONS**

1. This Import Permit allows for the importation of goods 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. For all uses in non-laboratory organisms (e.g. chickens, sheep, cattle, etc.) or plants a separate application for in vivo use must be lodged with, and approved by the Department of Agriculture. This also applies if the product is to be used in veterinary vaccine or veterinary therapeutic manufacture.

4. This Import Permit does not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.

5. This Import Permit does not permit the use of the samples for microbiological cultures or viral isolation.

Condition	Condition Text

6. It is the importer's responsibility to ensure that the goods are labelled "In vitro use or in vivo use in laboratory organisms only" on the smallest packaged unit prior to distribution.

7. It is the importer's responsibility to ensure compliance with all international (e.g. IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.

8. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243 Safety in Laboratory standards and Office of Gene Technology Regulator (OGTR) requirements.

PC5887 POST ENTRY / END USE CONDITIONS

1. This Import Permit allows for the importation of goods 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. For all uses in non-laboratory organisms (e.g. chickens, sheep, cattle, etc.) or plants a separate application for in vivo use must be lodged with, and approved by the Department of Agriculture. This also applies if the product is to be used in veterinary vaccine or veterinary therapeutic manufacture.

4. These goods may be used for use in human therapeutic and/or human vaccine production without any further approval.

5. This Import Permit does not permit the direct or indirect exposure of the imported materials or derivatives to non-laboratory organisms or plants.

6. It is the importer's responsibility to ensure that the goods are labelled "In vitro use or in vivo use in laboratory organisms only" on the smallest packaged unit prior to distribution.

7. It is the importer's responsibility to ensure compliance with all international (e.g. IATA) and domestic requirements concerning the safe handling, transport and labelling of biological material.

8. It is the end user's responsibility to ensure that all laboratory products are used in accordance with the current AS/NZS 2243 Safety in Laboratory standards and Office of Gene Technology Regulator (OGTR) requirements.

PC6797 **Low risk genetic material**

1. This permit allows for the importation of:

a. Purified genetic material from multicellular organisms (excluding plants and fungi); and/or

Condition	Condition Text

b. Purified cloning vectors and expression vectors i.e. bacterial plasmids, cosmid vectors, yeast artificial chromosomes, bacterial artificial chromosomes and bacteriophages may be imported "empty" or may contain transgenes (the specific gene of interest) from multicellular organisms (excluding plants or fungi) only.

Note:

· This case does not allow for cloning vectors that contain transgenes (the specific gene of interest) derived from microorganisms (including viruses). For purified cloning vectors and/or live low risk microbes carrying cloning vectors containing transgenes (the specific gene of interest) derived from microorganisms (including viruses) please see ICON.

· For genetic material derived from plants please refer to ICON.

· For genetic material derived from fungi please contact Plant Programs

PC6798 **Animal fluids, tissues (excluding reproductive material) and anti-sera as listed below.**

1. This permit allows for the importation of:

a. Animal fluids and tissues sourced from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids); if imported in quantities of no greater than **20ml or 20g** per smallest packaged unit

b. Anti-sera derived from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids); if imported in quantities of no greater than **20ml or 20g** per smallest packaged unit. The anti-sera must only be raised against synthetic material or against antigens derived from multicellular organisms.

c. Urine sourced from all species (excluding salmonid fish, non-human primates, humans, avians, ovines, caprines, bovines, cervines, equines, porcines, camelids or giraffids); if imported in quantities of no greater than **500ml or 500g** per smallest packaged unit.

d. Animal fluids and tissues sourced from all species and dried onto filter paper, dip sticks or swabs.

Notes:

· Fluids and tissues include all fluids produced by and all tissues derived from the animals specified above e.g. blood (and blood products including sera), milk, urine, faeces, mucus etc; with the exception of reproductive material.

· Reproductive material is specifically excluded from this case.

· Anti-sera raised against microorganisms (including viruses) and prions is not permitted under this case.

Condition	Condition Text

· For fixed tissues please refer to ICON

End of Condition Text

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