Australian Government
Department of Agriculture

Quarantine Act 1908 Section 13(2AA)

Phone: 02 6272 4454
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File Ref:

Permit to Import Quarantine Material

Permit: IP15012678 **Valid From:** 9 Oct 2014 **Valid To:** 9 Oct 2016

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
Diagnostic Kits (as listed in PC0010)	PC0010 AND PC0017 AND PC0766	All countries	In-vitro

Condition	Condition Text
PC0010	**This permit allows for the import of the following products only:** Oragene DNA (OG-250, OG-500, OG-575, OG-510) Oragene ONE (ON-500) ORAcollect DNA (OCR-100).

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 **Date** 9 Oct 2014

Stamp: DEPARTMENT OF AGRICULTURE, FISHERIES & FORESTRY QUARANTINE AUSTRALIA Q950

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Condition	Condition Text

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

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

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

PC0766 **Laboratory material for in vitro use only**

Post entry / end use conditions

1. This Import Permit allows for the importation of goods for in vitro laboratory studies only.

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

3. This Import Permit does not permit the direct or indirect exposure of the imported materials or derivatives to animals (including laboratory animals) or plants.

4. For in vivo use in animals (including laboratory animals) or plants a separate application for in

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Condition	Condition Text

vivo use must be lodged with, and approved, by the Department of Agriculture.

5. It is the importer’s responsibility to ensure that the goods are labelled "In vitro use only" on the smallest packaged unit prior to distribution.

6. 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.

7. 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.

End of Condition Text

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