1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for testing of Cercopithecine herpesvirus 1 (herpesvirus simiae, herpes B or monkey B virus) in macaques.

2. RESPONSIBILITY

Veterinary Care staff.

3. MATERIALS

3.1. Dry swabs, cotton-tip or synthetic tip
3.2. Blood collection materials: syringes, needles, blood collection tubes, dry cards
3.3. Sterile 1.5-2ml sample collection tubes, e.g., Eppendorf
3.4. Plastic paraffin film (Parafilm®)
3.5. 50ml conical tubes
3.6. Zip-top biohazard specimen bags
3.7. Insulated shipping container, e.g., Styrofoam box, and cardboard box
3.8. Bubble wrap
3.9. Packing tape
3.10. Dry ice, wet ice or ice packs

4. PROCEDURES

4.1. Testing by PCR at the National Microbiology Laboratory (NML) of the Public Health Agency of Canada (PHAC):

4.1.1. Sample collection:

4.1.1.1. Collect a minimum of 0.5ml whole blood, cerebrospinal fluid or saliva in sterile sample collection tubes.

4.1.1.2. Alternatively, collect swabs from the sites listed below. Place swabs in sterile conical tubes.

- Oral cavity
- Right eye
- Left eye
- Genitalia

4.1.2. Sample preparation:

4.1.2.1. Ensure that all specimen tubes are clearly labeled.

4.1.2.2. Liquid samples should be placed in 1.5-2ml tubes, securely sealed with plastic paraffin film and placed in a 50ml conical tube to avoid spilling during shipment.

4.1.2.3. Swabs in conical tubes or conical tubes with liquid samples are placed in a zip-top plastic biohazard specimen bag.

4.1.2.4. Store samples in refrigerator or frozen until being shipped for testing.

4.1.3. Sample submission:

4.1.3.1. Fill the Special Pathogens Requisition Form (https://rcrsp.canada.ca/gts/reference-diagnostic-test/4781?labId=1021). Print one copy to send with the shipment, keep a copy.
4.1.3.2. Complete a Declaration Letter (Annex 1) with the information on the content of the shipment. Save a copy of the completed form.

4.1.3.3. Advise the National Microbiology Laboratory 24 hours prior to shipment by sending a copy of the Requisition form to NML.Special.Pathogens@phac-aspc.gc.ca.

4.1.4. Sample Shipment:

4.1.4.1. Arrange a courier for next day delivery to:

**Special Pathogens**
National Microbiology Laboratory
1015 Arlington Street,
Winnipeg, MB R3E 3R2
Telephone: (204) 789-6019/7032

4.1.4.2. Ship frozen specimens on dry ice and refrigerated samples on wet ice.

4.1.4.3. Biohazard specimen bags should be placed in bubble wrap over wet or dry ice an insulated shipping container. Seal container with packing tape.

4.1.4.4. Place the sealed Styrofoam box with the samples into a cardboard box.

4.1.4.5. Insert documents listed below in a plastic folder and affix to the cardboard box:
   4.1.4.5.1. Special Pathogens Requisition Form
   4.1.4.5.2. Declaration Letter

4.2. Testing by PCR at Zoologix:

4.2.1. Sample collection:

4.2.1.1. Collect 0.2 ml cerebrospinal fluid, whole blood in EDTA or fresh, frozen or fixed central nervous system tissue in sterile sample collection tubes. Refrigerate or freeze samples until shipment.

4.2.1.2. Liquid samples cerebrospinal fluid or blood can be shipped on dry cards. Spot the liquid on the card and allow to dry as per the instructions printed on the card. Dry cards must be ordered from Zoologix by emailing info@zoologix.com.

4.2.1.3. Alternatively obtain swabs from the sites listed below. Place swabs in sterile conical tubes and refrigerate or freeze until shipment.
   - Oral cavity
   - Right eye
   - Left eye
   - Genitalia

4.2.2. Sample preparation:

4.2.2.1. Ensure that all specimen tubes or cards are clearly labeled.

4.2.2.2. Securely seal tubes with liquid samples with plastic paraffin film and place in 50ml conical tubes to avoid spilling during shipment.

4.2.2.3. Swabs in conical tubes or conical tubes with liquid samples are placed in a zip-top plastic bags.

4.2.2.4. Dry cards are sealed inside their plastic pouch.

4.2.3. Sample submission:

4.2.3.1. Complete a Zoologix requisition form for test code S0078
   [http://www.zoologix.com/primate/Orderform.htm](http://www.zoologix.com/primate/Orderform.htm)

4.2.3.2. Complete a Declaration Letter (Annex 1) with the information on the content of the shipment. Save a copy of the completed form.
4.2.4. Sample shipment:
4.2.4.1. Ship samples the same day as collected if possible.
4.2.4.2. Arrange a courier for next day delivery to:
   **Zoologix, Inc.**  
   9811 Owensmouth Ave  
   Suite 4  
   Chatsworth CA 91311  
   USA  
   Phone: 818-717-8880

4.2.4.3. Most swab samples may be shipped at normal room temperature if less than 3-4 days' transit time is expected.
4.2.4.4. Fixed tissues and dry cards may be shipped at ambient temperature.
4.2.4.5. Ship frozen specimens on dry ice and refrigerated samples on wet ice in an insulated shipping container.
4.2.4.6. When shipping liquid samples enclose enough absorbent material (batting, paper toweling or similar) inside the secondary bag to fully absorb the total volume of all samples should a catastrophic spill occur in transit. Use dunnage if necessary to prevent movement of contents.
4.2.4.7. Seal insulated container with packing tape. Place the sealed insulated container with the samples into a cardboard box. Use labels in Annex 4.
4.2.4.8. Insert documents listed below in a plastic folder and affix to the cardboard box:  
   4.2.4.8.1. Declaration letter  
   4.2.4.8.2. Zoologix import permit (example in Annex 2)  
   4.2.4.8.3. Zoologix CDC permit (example in Annex 3)  
   4.2.4.8.4. Zoologix requisition form

4.3. Testing by serology (ELISA) at Zoologix:
   4.3.1. Collect 0.5ml whole blood in EDTA. Refrigerate until shipment.
   4.3.2. Place tubes in a zip-top plastic bag.
   4.3.3. Follow sample shipping instructions in section 4.2.4.

**SOP REVISION HISTORY**

<table>
<thead>
<tr>
<th>DATE</th>
<th>PREVIOUS VERSION</th>
<th>NEW VERSION</th>
</tr>
</thead>
</table>
| 18.03.21 | 4.2.4.8.2. Zoologix import permit (Annex 2)  
   4.2.4.8.3. Zoologix CDC permit (Annex 3) | 4.2.4.8.2. Zoologix import permit *(example in Annex 2)*  
   4.2.4.8.3. Zoologix CDC permit *(example in Annex 3)* |
[DATE]

To Whom It May Concern,

The package with [Courier Name] [Waybill number] is being sent to the [Testing Laboratory] in [Province/State and Country].

- It contains [number and type] specimens from a [species] macaque used in biomedical research.
- The specimens are for \textit{in vitro} diagnostic use only.
- The specimens do not come from a laboratory that works with exotic viruses affecting avian species or livestock.
- The specimens are not recombinant.
- The samples are for research purposes only, not for trade or sale.

[Veterinarian Full Signature and address]
FEDERAL FISH AND WILDLIFE PERMIT

1. PERMITTEE
ZOOLOGIX, INC.
9811 OWENSMOUTH AVENUE, SUITE 4
CHATSWORTH, CA 91311
U.S.A.

2. AUTHORITY STATUTES
16 USC 1368 (g)

3. NUMBER
LE10468-0

4. RENEWABLE
YES

5. MAY COPY
NO

6. EFFECTIVE
07/01/2016

7. EXPIRES
06/30/2017

8. NAME AND TITLE OF PRINCIPAL OFFICER (if not a business)
STEVEN LLOYD
CEO

9. TYPE OF PERMIT
IMPORT/EXPORT LICENSE

10. LOCATION WHERE AUTHORIZED ACTIVITY MAY BE CONDUCTED
ANY DESIGNATED PORT PER 50 CFR 14

11. CONDITIONS AND AUTHORIZATIONS:
A. GENERAL CONDITIONS SET OUT IN SUBPART D OF 50 CFR 13. AND SPECIFIC CONDITIONS OF THIS PERMIT. ALL ACTIVITIES AUTHORIZED HEREUNDER MUST CONFORM TO THE REQUIREMENTS DESCRIBED IN THE APPLICATION AND FOR THE PURPOSES DESCRIBED IN THE APPLICATION SUBMITTED. CONTINUANCE OR RENEWAL OF THIS PERMIT IS SUBJECT TO COMPLIANCE WITH ALL APPLICABLE CONDITIONS, INCLUDING THE FILING OF ALL REQUIRED INFORMATION AND REPORTS.

B. THE VALIDITY OF THIS PERMIT IS ALSO CONDITIONED UPON THE LICENSEE'S WRITTEN AGREEMENT TO COMPLY WITH APPLICABLE FOREIGN, STATE, LOCAL, TRIBAL, OR OTHER FEDERAL LAW.

C. VALID FOR USE BY PERMITTEE NAMED ABOVE.

D. Licensee is responsible for applying for renewal of license at least 30 days prior to the expiration date as outlined in 50 CFR 13. Service Law Enforcement Officers will not clear shipments presented for import or export under expired licenses.

E. Licensee is authorized to import/export wildlife and/or wildlife products at the port(s) specified in Block 10.

F. Licensee must comply with all import/export procedures as outlined in 50 CFR 14.

12. REPORTING REQUIREMENTS
LICENSEE IS REQUIRED TO MAINTAIN RECORDS PER 50 CFR 14
ACCEPTANCE OF THIS LICENSE AUTHORIZES INSPECTION PER 50 CFR 13

ISSUED BY

LEGAL INSTRUMENT EXAMINER, REGION 8

TITLE

05/24/2016

DATE

Annex 2
Zoologix Import Permit
**Permit to Import Infectious Biological Agents, Infectious Substances, and Vectors**

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulations, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.

<table>
<thead>
<tr>
<th>PHS PERMIT NO.</th>
<th>2016-05-105</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATES</td>
<td>ISSUED: Tuesday, May 17, 2016 EXPIRES: Wednesday, May 17, 2017</td>
</tr>
<tr>
<td>1. DESCRIPTION OF MATERIAL</td>
<td>BLOOD/BLOOD PRODUCTS, OTHER BODY FLUIDS, AND TISSUES FROM NON-HUMAN PRIMATES AND OTHER ANIMALS (EQUINE, CANINE, FELINE, AND NON-AFRICAN RODENTS) THAT MAY CONTAIN SIMIAN T-CELL LEUKEMIA VIRUS, SIMIAN RETROVIRUS, SIMIAN IMMUNODEFICIENCY VIRUS, CERCOPITHECINE HERPESVIRUS, MYCOBACTERIUM TUBERCULOSIS, MYCOBACTERIUM BOVIS, MEASLES VIRUS, LYMPHOHYPOTHALMIC VIRUS, GIARDIA LAMBLIA, ESCHERICHIA COLI, CLOSTRIDIUM DIFFICILE, TOXOPLASMA GONDII, BORRELLIA BURGDORFERI, CRYPTOCOCCUS NEOFORMANS, CAMPYLOBACTER JEJUNI, AND CRYPTOSPORIDIUM PARVUM.</td>
</tr>
<tr>
<td>2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)</td>
<td>STEVEN LLOYD ZOLOGIX, INC. 9811 OWEWNSMOUTH AVE, SUITE 4 CHATSWORTH, CA 91311</td>
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<tr>
<td>3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)</td>
<td>WORLDWIDE</td>
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<tr>
<td>4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE</td>
<td>As the permittee, your facility will be subject to inspection at some time in the future to confirm that the importer's biosafety measures and containment with the hazard posed by the items to be imported and the level of risk given to the public.</td>
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<tr>
<td></td>
<td>Single Import into U.S. ☐ Multiple Import into U.S. ☐ Single Transfer Within the U.S. ☐ Multiple Transfer Within the U.S. ☐</td>
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<td>A. Records of each shipment shall be maintained on permanent file by the permittee.</td>
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<td>B. Enclosed labels must be forwarded to the shipper(s).</td>
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<td></td>
<td>C. Material shall be affixed to shipping container. Enclosed labels may be photocopied.</td>
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<tr>
<td>5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED</td>
<td>☐ A. Export distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service.</td>
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<tr>
<td>☐ B. The material is for laboratory use only - Not for use in the production of biologics for humans or animals.</td>
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<tr>
<td>☐ C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines.</td>
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<tr>
<td>☐ D. Additional Requirements:</td>
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<tr>
<td>☐ E. Work with the agents described shall be restricted to areas and conditions meeting requirements in the CDC/NHLBI publication, &quot;Biosafety in Microbiological and Biomedical Laboratories.&quot;</td>
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<tr>
<td>☐ F. Packaging must conform to 49 CFR Sections 171-180.</td>
<td></td>
</tr>
<tr>
<td>0. Signature of issuing officer</td>
<td>Daniel Sosin, MD, MPH, FACP Acting Director, Division of Select Agents and Toxins</td>
</tr>
</tbody>
</table>

CDC 0728 (F 13.40) REV. 4-13

42 CFR 71.54. Permit to Import Biological Agents, Infectious Substances, and Vectors

A person may not import into the United States any infectious biological agent, infectious substance, or vector unless: It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC). The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.