1. PURPOSE

This Standard Operating Procedure (SOP) describes the health monitoring program for macaques.

2. RESPONSIBILITY

Veterinary care staff.

3. MATERIALS

3.1. Ketamine
3.2. Old Mammalian Tuberculin
3.3. Blood collection materials
3.4. Fecal collection containers
3.5. Dry swabs, cotton-tip or synthetic tip
3.6. Amies swabs
3.7. Zip-top biohazard specimen bags
3.8. Styrofoam shipping box and cardboard box

4. PROCEDURES

4.1. Monitor populations that are housed for more than 8 weeks.
4.2. Every 6 months, under ketamine (10 mg/kg IM) anesthesia:
   4.2.1. Examination:
      4.2.1.1. Record body weight.
      4.2.1.2. Perform a complete physical examination.
      4.2.1.3. Examine the animal for oral or genital lesions (e.g. vesicles, ulcerations, etc.) and any clinical evidence of viral shedding.
      4.2.1.4. Trim the nails.
   4.2.2. TB testing:
      4.2.2.1. Inject 0.1 ml of Old Mammalian Tuberculin in the upper eyelid near the edge.
      4.2.2.2. Reaction will be read at 24h, 48h, and 72h.
      4.2.2.3. The description of the reaction or corresponding reaction grade (as per table below) must be entered into the animal’s record.

<table>
<thead>
<tr>
<th>REACTION GRADE</th>
<th>DESCRIPTION OF CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No reaction</td>
</tr>
<tr>
<td>1</td>
<td>Bruise – extravasation of blood in the eyelid associated with the injection of tuberculin.</td>
</tr>
<tr>
<td>2</td>
<td>Varying degrees of erythema of the palpebrum with minimal swelling.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate swelling with or without erythema.</td>
</tr>
<tr>
<td>4</td>
<td>Obvious swelling of the palpebrum with drooping and varying degrees of erythema.</td>
</tr>
<tr>
<td>5</td>
<td>Marked swelling with necrosis and eyelid closure or partially closed.</td>
</tr>
</tbody>
</table>
4.2.4. Grades 0, 1 and 2 are considered negative. Grade 3 is suspect and grades 4 and 5 are considered positive.

4.2.3. Inject ivermectin 0.2mg/kg subcutaneously.

4.2.4. Fecal samples:
   4.2.4.5. Collect fresh feces from cage trays for parasitology (flotation).
   4.2.4.1. Collect fresh feces in Cary-Blair transport medium for culture.

4.2.5. Blood collection, if required:
   4.2.5.2. Take 2 mL of blood from the femoral vein: 0.5 mL in EDTA for hematology and 1.5 mL in SST tube for serology.

4.2.6. Herpes B testing:
   4.2.6.1. PCR:
      4.2.6.1.1. Obtain a mucosal swab using plain dry cotton or synthetic-tip swabs. Refrigerate until shipment.
      4.2.6.1.2. Alternatively collect 0.2 ml cerebrospinal fluid, or 0.2 ml fresh, frozen or fixed central nervous system tissue or 0.2ml of whole blood in EDTA.
      4.2.6.1.3. Dry cards can also be used for sample collection.
   4.2.6.2. Serology (ELISA):
      4.2.6.2.1. Collect 0.5ml whole blood in EDTA.
      4.2.6.2.2. Complete a Zoologix requisition form for test code A0003 http://www.zoologix.com/primate/Orderform.htm
   4.2.6.3. Complete a Declaration Letter (Annex 1) with the information on the content of the shipment. Save an electronic version of the form.

4.2.6.4. Sample shipment:
   4.2.6.4.1. Include a copy of the following documents:
      - Declaration letter
      - Zoologix import permit (Annex 2)
      - Zoologix CDC permit (Annex 3)
      - Zoologix requisition form
   4.2.6.4.2. Enclose all primary sample containers, e.g., tubes, together inside a secondary leakproof ziplock bag or other leakproof container. Enclose absorbent material (batting, paper toweling or similar) inside the secondary bag or container to fully absorb the total volume of all samples should a spill occur in transit.
   4.2.6.4.3. Use labels in Annex 4.
   4.2.6.4.4. Ship via overnight service, at room temperature to:

   **Zoologix, Inc.**
   9811 Owensmouth Ave
   Suite 4
   Chatsworth CA 91311
   USA
   Phone: 818-717-8880

4.3. Health status reports:
   4.3.1. The facility veterinarian reviews all health monitoring reports.
### SOP REVISION HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>PREVIOUS VERSION</th>
<th>NEW VERSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017.12.22</td>
<td>(NO TEXT)</td>
<td>Added section 4.2.5 Herpes B testing information.</td>
</tr>
</tbody>
</table>


To Whom It May Concern,

The package with [Courier Name] [Waybill number] is being sent to Zoologix in Chatsworth, California, USA.

- It contains [number] serum specimens and [number] dry swabs (oral, ocular, genital and anal) from a [species] macaque used in biomedical research.
- The specimens are for 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]
FEDERAL FISH AND WILDLIFE PERMIT

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

2. AUTHORITY-STATUTES
16 USC 1538(d)
REGULATIONS
50 CFR PART 13
50 CFR PART 14

3. NUMBER
LE108468-0

4. RENEWABLE
YES
5. MAY COPY
YES

6. EFFECTIVE
07/01/2016
7. EXPIRES
06/30/2017

8. NAME AND TITLE OF PRINCIPAL OFFICER: (If #3 is 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 CONTAINED IN FEDERAL REGULATIONS CITED IN BLOCK #2 ABOVE, ARE HEREBY MADE A PART OF THIS PERMIT. ALL ACTIVITIES AUTHORIZED HEREIN MUST BE CARRIED OUT IN ACCORD WITH AND FOR THE PURPOSES DESCRIBED IN THE APPLICATION SUBMITTED. CONTINUED VALIDITY, OR RENEWAL, OF THIS PERMIT IS SUBJECT TO COMPLETE AND TIMELY COMPLIANCE WITH ALL APPLICABLE CONDITIONS, INCLUDING THE FILING OF ALL REQUIRED INFORMATION AND REPORTS.
B. THE VALIDITY OF THIS PERMIT IS ALSO CONDITIONED UPON STRICT OBEDIENCE OF ALL APPLICABLE FEDERAL, STATE, LOCAL, TRIBAL, OR OTHER FEDERAL LAW.
C. VALID FOR USE BY PERMITTEE NAMED ABOVE.
D. Licensee is responsible for requesting 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. ADDITIONAL CONDITIONS AND AUTHORIZATIONS ALSO APPLY

13. 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
PH: 916-414-6660

DATE
05/24/2016
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**PUBLIC HEALTH SERVICE**

Centers for Disease Control and Prevention  
Office of Health and Safety, M3 A-46  
Atlanta, Georgia 30333  
TEL: 404-718-2077, FAX: 404-718-2093; Email: importpermit@cdc.gov

**SAFER • HEALTHIER • PEOPLE**

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**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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. DESCRIPTION OF MATERIAL</th>
</tr>
</thead>
<tbody>
<tr>
<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, LYMHOCRYPTOVIRUS, GIARDIA LAMBLIA, ESCHERICHIA COLI, CLOSTRIDIUM DIFFICILE, TOXOPLASMA GONDII, BORRELIA BURGDORFERI, CRYPTOCOCCUS NEOFORMANS, CAMPYLOBACTER JEJUNI, AND CYTOMEGALOVIRUS.</td>
</tr>
</tbody>
</table>

| 2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION) |
| STEVEN LLOYD  
ZOLOGIX, INC.  
9811 OWEINSMOUTH AVE, SUITE 4  
CHATSWORTH, CA, 91311 |

| 3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY) |
| WORLDWIDE |

| 4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE |
| As the permittee, your facility will be subject to inspection at some time in the future to confirm that the importer's biosafety measures are commensurate with the hazard posed by the items to be imported and the level of risk given its intended use. |
| A. Record of each importation shall be maintained on permanent file by permittee. |
| B. Enclosed label(s) must be forwarded to the shipper(s). |
| C. One label shall be affixed to shipping container. Enclosed labels may be photocopied. |

| 5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED |
| A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service. |
| B. All material is for laboratory use only - Not for use in the production of biologicals for humans or animals. |
| C. All material is free of tissues, serum and plasma of domestic and wild ruminants, primates, and equines. |
| D. Additional Requirements: |
| IATA Packaged to preclude escape. |
| USDA permit may be required (Telephone: 301-851-3300). |
| E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIAID publication "Biosafety in Microbiological and Biomedical Laboratories." |
| F. Packaging must conform to 42 CFR Sections 171-190. |

| 6. Signature of Issuing Officer |
| Daniel Sosin, MD, MPH, FACPs Acting Director, Division of Select Agents and Toxins |

**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.