



**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.

<b>PHS PERMIT NO.</b>	<b>2018-01-104</b>	
<b>DATES</b>	<b>ISSUED: Monday, January 22, 2018</b>	<b>EXPIRES: Tuesday, January 22, 2019</b>
<b>1. DESCRIPTION OF MATERIAL</b>	<b>HUMAN BLOOD/BLOOD PRODUCTS THAT MAY CONTAIN HEPATITIS B VIRUS, HUMAN IMMUNODEFICIENCY VIRUS, AND HEPATITIS C VIRUS.</b>	
<b>2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)</b>	<b>DWIGHT DUBOIS CENETRON DIAGNOSTICS, LLC 2111 WEST BRAKER LANE, SUITE 300 AUSTIN, TX 78758</b>	<b>TEL: 512-717-9224 FAX: 512-439-5006</b>
<b>3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)</b>	<b>WORLDWIDE</b>	
<b>4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE</b>	<p>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.</p> <p> <input type="checkbox"/> Single Importation into the U.S.                      <input type="checkbox"/> Single Transfer Within the U.S.  <input checked="" type="checkbox"/> Multiple Importation into the U.S.                      <input type="checkbox"/> Multiple Transfer Within the U.S.                 </p> <p>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.</p>	
<b>5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED</b>	<p> <input type="checkbox"/> A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service.  <input checked="" type="checkbox"/> B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals.  <input checked="" type="checkbox"/> C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines.  <input type="checkbox"/> D. Additional Requirements:                      <input type="checkbox"/> IATA Packaged to preclude escape.                      <input type="checkbox"/> USDA permit may be required (Telephone: 301-851-3300).  <input checked="" type="checkbox"/> E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."  <input checked="" type="checkbox"/> F. Packaging must conform to 49 CFR Sections 171-180.                 </p>	
	<p><b>6. Signature of Issuing officer</b></p> <p><i>Samuel S. Edwin</i></p> <p>Samuel S. Edwin, Ph.D. Director, Division of Select Agents and Toxins</p>	



To: Importer, Public Health Service Import Permit

Subject: Approval to import infectious biological agents, infectious substances or vectors

Attached, find your Public Health Service (PHS) import permit. The PHS import permit is valid only for the material(s), locations and conditions described in your application. The issuance and expiration dates located on the import permit pertain only to the dates that the importer is allowed to import into the United States the infectious biological agents, infectious substances, and vectors listed on the import permit. These dates do not relate to the conditions of continued possession associated with the permit. The conditions of continued possession listed on the permit remain in effect until the importer is no longer in possession of the imported material. 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

The permittee must ensure that:

1. The enclosed import permit and labels are forwarded to the shipper(s). The enclosed permit and labels may be photocopied if more are needed.
2. The shipper includes the PHS import permit with the shipping documents and the enclosed label (or copy of label) should be affixed to the outer shipping container.
3. A record of each importation (including permits and shipping documents) is maintained.
4. The shipment of infectious biological agents, infectious substance or vectors must be packaged, labeled, and shipped in accordance with all applicable federal and international regulations. Please note that the issuance of an import permit is not an authorization to hand carry the material.

Other permits may be required for the importation of infectious biological agents, infectious substances or vectors. If you have questions regarding this correspondence, contact CDC Import Permit Program at (404) 718-2077 or visit our website at <http://www.cdc.gov/od/eaipp/>.

Glen DeGruy  
Team Lead, Import Permit Program  
Division of Select Agents and Toxins  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention

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IMPORTATION OR TRANSFER AUTHORIZED BY

PHS Permit No. \_\_\_\_\_

Expiration Date \_\_\_\_\_

TO:



**DO NOT OPEN INTRANSIT**

**BIOMEDICAL MATERIALS  
ETIOLOGICAL AGENTS OR VECTORS**

**NOTICE TO CARRIER:** If inspection on arrival in U.S. reveals evidence of damage, leakage, or suspected contamination involving an infectious substance, immediately notify: DOT National Response Center 1-800-424-8802.

CDC 0.1007 3/2008



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