

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 Regulators, 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.

PHS PERMIT NO. : 20200721-2418A

ISSUED DATE: 08/03/2020

EXPIRATION DATE: 08/03/2021

1. DESCRIPTION OF MATERIAL

HUMAN BLOOD/BLOOD PRODUCTS THAT MAY CONTAIN HUMAN IMMUNODEFICIENCY VIRUS, HEPATITIS C VIRUS, OR HEPATITIS B VIRUS.

2. PERMITTEE

(NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)

BRANDON HARPER (512) 717-9231

CENETRON DIAGNOSTICS, LLC
2111 W. BRAKER LANE, SUITE 300
AUSTIN TX 78758

3. SOURCE OF MATERIAL

(NAME, ORGANIZATION, ADDRESS, COUNTRY)

WORLDWIDE

4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE

MULTIPLE IMPORTATIONS WITHIN THE U.S.

A. RECORD OF EACH IMPORTATION SHALL BE MAINTAINED ON PERMANENT FILE BY PERMITTEE.

B. USDA/APHIS MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ANIMALS, MATERIALS EXPOSED TO ANIMAL PRODUCTS/BYPRODUCTS, AND AGENTS THAT ARE INFECTIOUS TO ANIMALS OR PLANTS. U.S. FISH AND WILDLIFE SERVICE MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ENDANGERED ANIMALS.

5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED

PACKAGING MUST CONFORM TO 49 CFR SECTIONS 171-180.

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".

AS THE PERMITTEE, YOUR FACILITY WILL BE SUBJECT TO INSPECTION AT SOME TIME IN THE FUTURE TO CONFIRM THAT THE IMPORTERS BIOSAFETY MEASURES ARE COMMENSURATE WITH THE HAZARD POSED BY THE ITEMS TO BE IMPORTED AND THE LEVEL OF RISK GIVEN ITS INTENDED USE.

ALL MATERIAL IS FOR LABORATORY USE ONLY - NOT FOR USE IN THE PRODUCTION OF BIOLOGICS FOR HUMANS OR ANIMALS.

6. SIGNATURE OF ISSUING OFFICER



SAMUEL S. EDWIN, PH.D. DIRECTOR, DIVISION OF SELECT AGENTS AND TOXINS