DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop H21-7 Atlanta, GA 30329 Telephone: 404-718-2077; 404-488-7100 (after hours) Email: importpermit@cdc.gov



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. : 20231128-4342A

ISSUED DATE: 12/08/2023

EXPIRATION DATE: 12/08/2024

1. DESCRIPTION OF MATERIAL

BLOOD/BLOOD PRODUCTS, TISSUES FROM HUMANS THAT MAY CONTAIN: MYCOBACTERIUM TUBERCULOSIS; MYCOBACTERIUM SPECIES (EXCLUDING RG3 AGENTS); NOCARDIA SPECIES; CYTOMEGALOVIRUS (HUMAN HERPESVIRUS 5); LYMPHOCRYPTOVIRUS (EPSTEIN BARR VIRUS); HEPATITIS A VIRUS; HEPATITIS B VIRUS; HEPATITIS C VIRUS; SIMPLEXVIRUS (HUMAN HERPESVIRUS 1, 2); LENTIVIRUS (HUMAN IMMUNODEFICIENCY VIRUS 1, 2); MEASLES MORBILLIVIRUS; ORTHORUBULAVIRUS (MUMPS VIRUS); VARICELLOVIRUS (VARICELLA-ZOSTER VIRUS); SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2; INFLUENZA A VIRUSES (EXCLUDING SELECT AGENTS AND RG3 AGENTS); INFLUENZA B VIRUS; ORTHOPNEUMOVIRUS (RESPIRATORY SYNCYTIAL VIRUS)

2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)	TERRIE KOYAMATSU (808) 589-5196
	DIAGNOSTIC LABORATORY SERVICES, INC 99-859 IWAIWA STREET AIEA HI 96701
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	WORLDWIDE
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	MULTIPLE IMPORTATIONS
	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.
	THE CONDITIONS FOR IMPORTATION AND CONTINUED POSSESSION LISTED ON THE CDC PERMIT REMAIN IN EFFECT UNTIL THE IMPORTER IS NO LONGER IN POSSESSION OF THE IMPORTED MATERIAL.
	ALL MATERIAL IS FOR LABORATORY USE ONLY - NOT FOR USE IN THE PRODUCTION OF BIOLOGICS FOR HUMANS OR ANIMALS.
	THE SUBSEQUENT DISTRIBUTION OF SARS-COV-2 WILL REQUIRE AN ADDITIONAL SEPARATE PERMIT. WORK SHOULD BE CONDUCTED IN ACCORDANCE WITH THE INTERIM RISK ASSESSMENT HTTPS://WWW.CDC.GOV/CORONAVIRUS/2019-NCOV/ LAB/LAB-BIOSAFETY-GUIDELINES.HTML
6.SIGNATURE OF ISSUING OFFICER	En le Edizia

Damuel J. Zawin

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

CDC 0728 (F 13.40) REV. 4-13

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

A person may not import into the United States any infections 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.