



RE: Content of human buccal cell lysis buffer vials

To Whom It May Concern,

Description of material: Human buccal cells suspended in cell lysis buffer vials. The contents of these vials include human DNA from an individual not known or suspected to have any infectious disease, and also salts and detergents (the lysis buffer consists of the following reagents: water, 100mM Tris HCl pH 8.5, 0.5M EDTA, 10% SDS and 5M NaCl). The human DNA is to be used for relationship testing purposes and does not contain infectious material.

As per the Public Health Service Foreign Quarantine Regulations (42CFR, Section 71.54 (f) 2 and Section 71.54 (f) 4), there is no known/suspected etiological agent within these vials. The vials consist of nucleic acid (DNA) from a human with no known communicable disease.

42CFR, Section 71.54 (f): A US PHS Import permit is NOT required for the item if:

1. It is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.
2. With the exception of bat or nonhuman primate specimens, it is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent and is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious.
3. With the exception of live bats or bat or nonhuman primate products, it is an animal or animal product being imported for educational, exhibition, or scientific purposes and is accompanied by documentation confirming that the animal or animal product is not known to contain (or suspected of containing) an infectious biological agent or has been rendered noninfectious.
4. It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.

This human DNA specimen will be delivered to the AABB accredited laboratory of Gene By Gene in Houston, Texas for the DNA relationship testing. If you would require further details on the cell lysis buffer vials contained within the shipment, please contact by email at info@genebygene.com.

Sincerely

Phuc Nguyen

Quality and Regulatory Affairs