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Gene by Gene Ltd. is a CLIA-certified clinical laboratory accredited by College of American Pathologists. All testing performed in the laboratory meets high standards of CLIA/CAP accreditation.

Each kit contains two dry swabs inside the packaging bag, the release form and instruction for collection. The swabs are individually wrapped single use only to ensure safe and sterile usage.

Dry Swab Sample Collection

After sample collection, each swab will contain human buccal cells placed inside the packaging bag, which will be delivered to Gene By Gene, an accredited laboratory in Houston, Texas, USA for DNA genetic testing.

As per the Public Health Service Foreign Quarantine Regulations (42CFR, Section71.54 (f) 2 and Section71.54 (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
- 5. 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.

If you would require further details please contact <u>info@genebygene.com</u>.









