FamilyTreeDNA
Tax ID (EIN): 76-0640295 | shipments@genebygene.com (kit number required)
1445 North Loop West, Suite 820, Houston, TX 77008 | +1 832-968-8132

**Date:** REQUIRED **Kit Number** REQUIRED

**Tracking :** REQUIRED

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## Manufacturer Declaration - NOT for MEDICAL or DIAGNOSTIC PURPOSES
## Returns to the United States for Processing

1. **HTS Code:** **HTS 3002.90.5250** (6-digit: 3002.90) - Exempt human specimen (Human biological specimens, non-infectious, for laboratory research/testing)
   **(NOT for MEDICAL or DIAGNOSTIC PURPOSES)**
   **Collection Kit FDA Exempt - Class I (21 CFR 864.3250) - FDA Reg. No. 3007261225**
2. **Country of Origin:** United States - All components were manufactured & assembled in the U.S.A.
3. **Purpose/Use:** The contents listed above are being returned to the United States for ancestry research (non-medical, non-diagnostic) processing and therefore have no commercial value.
4. **Toxic Substance Control Act (TSCA) Certification:** Cell lysis buffer is used to store the sample until processing. It consists of the following reagents: water, 100mM Tris HCl pH 8.5, 0.5M EDTA, 10% SDS and 5M NaCl. I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder. The components (Tris-HCl, SDS, EDTA, and NaCl) are listed as Active on the TSCA Inventory.
5. **CDC Public Health Service (PHS) Certification (42 CFR § 71.54(f)):** A U.S. PHS Import Permit is **NOT** required for this shipment. The enclosed material consists of buccal cheek swabs collected for ancestry research. The specimen is not known or suspected to contain an infectious biological agent, and any extracted nucleic acids cannot produce infectious forms of any biological agent. The specimen is accompanied by an importer certification statement (page 2, item 4.2) confirming that the material is not known to contain or suspected of containing an infectious biological agent.
6. **I, Kelly Jenkins, declare that the kit components described above were manufactured in the United States. This package does not contain dangerous goods, drugs, medications, flammable materials, or liquid nitrogen.**

Sincerely,

Kelly Jenkins

Kelly Jenkins
Vice President, Operations

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# INTERNATIONAL CUSTOMS DECLARATION
# IMPORT PERMIT NOT REQUIRED
# LYSIS BUFFER

Tax ID (EIN): 76-0640295

1. **These buccal swab samples are for ancestry research testing and are NOT used for Medical or Diagnostic Purposes.**
2. **Contents of the Collection Kit**
   - **2.1.** Each collection tube contains our cell lysis buffer used to store the sample until processing. The buffer consists of salts and detergents (water, 100mM Tris HCl pH 8.5, 0.5M EDTA, 10% SDS and 5M NaCl).
   - **2.2.** **The components of this package are manufactured and assembled in the United States.**
   - **2.3.** The contents of the vials do not fall under the **Public Health Service Foreign Quarantine Regulations,** as there is no etiological agent within these vials; vials only contain salts and detergents.
3. **Description of Material *After* Buccal Swab Sample Collection**
   - **3.1.** The buccal sample is used for ancestry research only and does **NOT** contain infectious material.
   - **3.2.** Vials consist of nucleic acid with **NO KNOWN** communicable disease. As per the **Public Health Service Foreign Quarantine Regulations (42 CFR § 71.54(f)(2) and § 71.54(f)(4)), there is NO known/suspected etiological agent within these vials.**
4. **CDC Public Health Service (PHS) Certification (42 CFR § 71.54(f))**
   - **4.1.** **A U.S. PHS Import Permit is NOT required for this shipment.** The enclosed material consists of buccal cheek swabs collected for ancestry research only. The specimen is not known or suspected to contain an infectious biological agent, and any extracted nucleic acids cannot produce infectious forms of any biological agent.
   - **4.2.** **Importer certification statement:** Gene by Gene, Ltd. dba FamilyTreeDNA, importer number 76-0640295, certifies that the material identified by the kit number and tracking number on page 1 is buccal swab material for ancestry research and is not known or suspected to contain an infectious biological agent. Basis: the sample comes from a consenting consumer taking part in ancestry research, not from a patient, and the company has no knowledge that the donor has a communicable disease.

If you require further details, logistics and custom parties may contact shipments@genebygene.com (kit number required).

Regards,

Kelly Jenkins

Kelly Jenkins
Vice President, Operations