

CLIAwaived, Inc. Saliva Collection Kit (Dry)

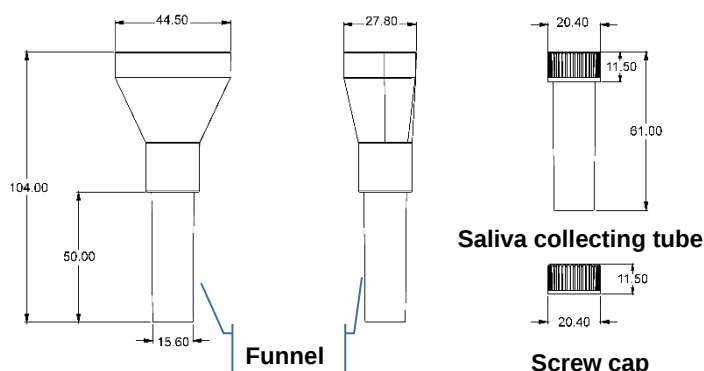
INTENDED USE

The CLIAwaived, Inc. Saliva Collection Kit is intended for the controlled, standardized saliva specimen collection and transportation for subsequent testing, analysis, or research applications, not for use in diagnostic procedures.

SUMMARY/ PRINCIPLE

CLIAwaived, Inc. Saliva Collection Kit is composed of a saliva collecting funnel, a saliva collecting tube, and a saliva collecting tube screw cap. Each kit is sealed in an individual package and is only for one-time use. The funnel is designed to fit human mouth and make the collection of saliva samples easier. Once the saliva sample has been collected in the tube, the funnel can be removed from the tube and discarded.

PRODUCT COMPOSITION



MATERIALS SUPPLIED

- Funnel*
- Saliva collecting tube*
- Saliva Collecting tube screw cap

* The funnel and the saliva collecting tube are assembled before packaging

Sterilization

EO Sterilization

WARNINGS AND PRECAUTIONS

1. **SINGLE USE ONLY.** Do not reuse or substitute kit components.
2. Please read the product package insert carefully.
3. Strictly follow the operating procedures listed in the package insert.
4. Used collectors and samples should be treated as potentially infectious materials and should be handled based on current regulations.
5. The length of time for collection and the quantity of saliva collected will vary between individuals due to inherent differences in saliva viscosity, hydration levels and medical conditions such as dry mouth.

STORAGE CONDITIONS

The product shall be stored at room temperature in a dry and clean environment without exposure to direct sunlight. The shelf life is 24months. Improper storage will result in a loss of efficacy.

SAMPLE COLLECTION AND PREPARATION

1. Specimens should be collected and handled following laboratory guidelines. Once the specimen is collected, the specimen should be refrigerated at 2~8°C and transport to the laboratory as soon as possible to sustain the optimal recovery rate.
2. For the best viability, specimens should be refrigerated at 2~8°C or kept on wet ice after collection and in transit. If long term storage is needed, the specimens need to be stored at -70°C or below. Specimens should be processed as soon as possible.
3. Do not use if the package is damaged or opened.
4. Do not use the product if the packaging and/or product components have showed evidence of microbial contamination, cloudy appearance, discoloration, drying, cracking, or other signs of deterioration.

PROCEDURE

1. Clean the mouth with drinking water before saliva specimen collection.
2. Gently spit saliva into the funnel until the liquid saliva reaches the height of 2.0 ml scale line.
3. Keep the collecting tube upright, unscrew the funnel, screw and tighten the screw tube cap on the saliva collecting tube.



Manufactured for CLIAwaived, Inc.

ADD : 2721 Loker Avenue W, Carlsbad, CA, 92010

TEL: 888-882-7739

FAX: 801-720-7568

Web: <https://cliawaived.com/>