

CITOSWAB® Saliva Collection Kit

Intended Use

CITOSWAB® Saliva Collection Kit is intended for the controlled, standardized collection and transportation of saliva specimens for subsequent testing, analysis, or research applications, not for use in diagnostic procedures.

Summary and Principle

CITOSWAB® Saliva Collection Kit is composed with a saliva collection funnel, an accessory screw cap for saliva sample tube, and a transport tube prefilled with 2ml of saliva protective solution. Each kit is sealed in an individual package for one-time use. The large funnel with low adsorption allows for easy collection of saliva samples. Once the saliva sample has been collected in the tube, the funnel can be disconnected from the tube and disposed. A 2ml saliva protective solution is then added to the tube and the tube is closed with a screw-on accessory cap. The solution effectively inactivates pathogens (e.g. bacteria) in collected samples, and preserves nucleic acids in samples at ambient temperature. Samples in buffer can be frozen (-20/-80°C) for prolonged periods.

Precautions

1. Single use only for In-vitro Diagnostic.
2. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Sterilize all biohazard waste including specimens, containers and media after their use.
3. 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.
4. Don't use after expiry date, and don't use if there is evidence of leakage, damaged package, the color of the medium has changed color or appears turbid.
5. Wash with plenty of water if protective solution comes in contact with eyes or skin. Don't ingest.
6. **DO NOT REUSE OR SUBSTITUTE KIT COMPONENTS.** Risks include simply contamination, cross-contamination, and infection etc.
7. Prior to use, directions should be read and followed carefully.

Storage

Room temperature, optimum storage temperature is 15°C to 30°C. The shelf life is 12 months. Improper storage will result in a loss of efficacy. Don't use after expiration date which is clearly printed on the outer box and on each individual package.

Material Provided

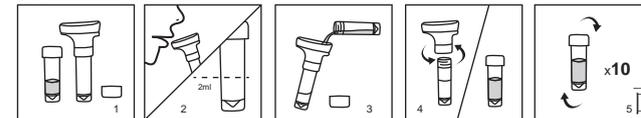
Depending on whether the product contains preservation solution, two configurations are available:

- SC-1: a collector and a transport tube without preservation solution.
- SC-2: a collector and a transport tube prefilled with preservation solution.

Material Not Provided

Other materials required for culturing, identification and extracting purposes.

Directions for Use



1. Remove the kit from packaging.
2. Deep cough and spit into the saliva collector, up to 2ml marker.
3. Add the preservation solution prefilled in tube.
4. Remove the saliva collector and screw the cap.
5. Invert tube to mix.

Note: DO NOT drink, touch the preservation solution. The solution can be harmful if ingested and may cause irritation if exposed to the skin and eyes.

Quality Control

All raw materials and batches of finished product are subjected to rigorous quality control by CITOTEST. Certificates of sterility and quality assurance are available on request.

Results

Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

Limitations

This production is designed to capture and store saliva samples deposited directly from patients. It does not diagnose any disease, just for research use only, not for use in diagnostic procedures.



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