

## MedSchenker® Saliva Collection Kit in Pouch

### Product Insert & How-to-Use Guide

#### INTENDED USE

MedSchenker® Saliva Collection Kit in pouch is a ready-for-use Kit intended for saliva collection for clinical procedure and testing. Product should be used as directed.

#### SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of infections involves the collection of Saliva samples. This can be accomplished using the MedSchenker® Saliva Collection Kit. MedSchenker® Saliva Collection Kit products are used to collect, store and transport both saliva DNA & RNA samples. They are made from polypropylene and packed into a medical grade paper pouch.

The MedSchenker® Saliva Collection Kit consists of

1. Funnel
2. Tube



#### PRECAUTIONS

1. Carefully follow the instructions for use.
2. Product cannot be reused.

#### KIT STORAGE

Store the MedSchenker® Saliva Collection Kit device at 2-30°C (59-77°F). If the product is stored at a different temperature, it would not maintain the stated specifications.

#### SAMPLE/SPECIMEN FOR STORAGE/TRANSPORT

If the samples are not tested within 60 minutes of collection, refrigerate the sample at 4°C (39°F) for no longer than 24hrs.

#### PRODUCT DETERIORATION

The MedSchenker® Saliva Collection Kit should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the package is open or damaged, or (4) there are other signs of deterioration.

#### DIRECTIONS FOR USE, SPECIMEN COLLECTION

NOTE: Sterile gloves, protective clothing and eyewear should be worn when collecting and handling Saliva samples

1. Open the peel pouch and extract the Saliva Collection Kit.
2. Collect the appropriate amount of sample for the desired test in the tube with the help of the funnel.
3. Do not forget to cap the saliva tube tightly.

Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines. Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with internal guidelines of the institution.

#### LIMITATIONS

1. In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling Saliva samples. Observe Biosafety recommendations when handling or analyzing patient samples.
2. Condition, timing and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
3. The MedSchenker® Saliva Collection Kit must be used by skilled personnel only.



## WARNINGS

1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. Do not re-pack or re-use.
3. Not suitable for any other application than intended use.
4. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
5. Do not use if the product or packaging is visibly damaged.
6. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
7. To be handled by trained personnel only.
8. It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens must be handled with appropriate precautions. After use, the Saliva collection kit must be disposed of according to laboratory regulations for infectious waste.

## WASTE DISPOSAL

Unused Saliva Collection Kits may be considered as nonhazardous waste and disposed of accordingly. Dispose of used Saliva Collection Kits as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.