

## MedSchenker® Smart Extraction Tube

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

#### INTENDED USE

MedSchenker® Smart Extraction Tube is used to apply a single droplet or more onto a lateral flow test cartridge for point of care rapid testing.

#### PRINCIPLES

One of the routine procedures in the diagnosis of infections involves the collection and testing of swab samples.

This can be accomplished using the MedSchenker® Smart Extraction Tube. The Smart Extraction Tube is made from soft squeezable PVC plastic and packed in a plastic bag.

#### PRECAUTIONS

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

#### STORAGE

Store the MedSchenker® Smart Extraction Tube at 2 - 25°C. If the product is stored at a different temperature, it would not maintain the stated specifications.

#### PRODUCT DETERIORATION

The MedSchenker® Smart Extraction Tube 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 microbiology specimens

1. Open the plastic bag and extract the tube.
2. Fill the tube with your desired reagent in the appropriate amount required for the specific test being conducted.
3. Collect the sample.
4. Place the sample in the extraction tube, squeezing the bottom to ensure the entire tip of the swab is immersed within the reagent to elute the most amount of specimen.
5. Pull the swab midway up the tube so that the tip is parallel to the alternating hash marks. Squeeze the tube around the tip to remove any excess reagent, then pull the swab out and discard.
6. Close the connected cap and apply the appropriate number of droplets required onto the lateral flow test cartridge.

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 clinical specimens. 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. MedSchenker® Smart Extraction Tube 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 reuse the Smart Extraction Tube.
3. Do not re-pack.
4. Not suitable for any other application than intended use.
5. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
6. Do not use the Smart Extraction Tube if it is visibly damaged.
7. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
8. To be handled by trained personnel only.
9. It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

#### WASTE DISPOSAL

Unused tubes may be considered as nonhazardous waste and disposed of accordingly. Dispose of used tubes 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.

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