# iSWAB™-Microbiome-EL Technology



### INSTRUCTIONS FOR NASAL/ SALIVA USE - English

Caution: Read all steps before collecting samples.

#### **DEVICE NAME**

iSWAB-Microbiome-EL (Extraction-Less) Technology

#### **INDICATION FOR USE**

iSWAB-Microbiome-EL sample collection technology is intended for specimen collection of biological samples. It is a non-invasive sample collection method and is intended to be used for longterm room-temperature. Allows stable transport and storage of microbial DNA and RNA from various sample types including nasal and saliva. The iSWAB-Microbiome-EL device is designed to recover and stabilize collected sample from a nylon flocked or molded swab head and then the swab is discarded at the point of collection. The iSWAB-Microbiome-EL device is designed to eliminate the RNA extraction step in the COVID-19 Molecular testing workflow, allowing researchers to perform direct RT-PCR on individual and pooled samples. For saliva collection only a iSPIT funnel is needed to facilitate collection of saliva into the iSWAB-Microbiome-EL.

#### **CONTENTS**

iSWAB-Microbiome-EL Tube

Swabs sold separately\*

iSPIT funnel sold separately\* §

§ Item may not be included in certain

#### STORAGE AND STABILITY

Pre-collection: 18 months from date of manufacture between 15-30° C.

Transport temperature, post-collection:

Sample stability and storage, postcollection: 21 days for microbial RNA and 40 days for microbial DNA at 15-30° C; if longer storage time is required, collected samples can be stored at -20

> Additional information available at www.mawidna.com.

#### WARNING AND PRECAUTIONS

For external use only. This product is a specimen collection device for biological samples If the reagent inside the tube comes in contact with your eyes or your skin, it is recommended to immediately wash with water and soap. Tube cap can be a choking hazard. Do not ingest.

#### **DEVICES**

All the iSWAB-Microbiome-EL family of products consist of one tube pre-filled with 800 μL stabilizing liquid.

REF /Catalog Number	Product Family Name	Stabilizing Liquid
ISM-T-EL	iSWAB-Microbiome Extraction Less	800 μL
ISM-T-EL-R	iSWAB Microbiome-Extraction Less Tube Rack	800 μL x 50

For saliva self-collection, the iSPIT funnel is purchased separately.

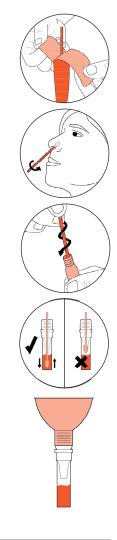
#### PREPARATION FOR USE

Before sample collection, verify preferred method of collection with your processing lab.

- Note: It is recommended not to eat, drink, or smoke for 30 minutes before collecting your sample
- Do not touch swab tips or allow contact with any other object.
- For swab collection, use either 1 or 2 swabs depending on the test protocol.
- Tap the tube gently 2-3 times before collection to concentrate all liquid to the bottom.

If using saliva collection skip to step number 7

- Place vial standing up on a flat surface. Peel open bags containing swabs and remove a swab. Unscrew vial cap before collecting sample.
- For nasal mid-turbinate collection: Insert the swab head into your nostril no more than 3/4" (1.5cm) into one nostril. Slowly rotate at least 3 times, gently pressing against the inside of your nostril. Gently remove the swab and repeat this step in your other nostril
- Pick up vial and hold steady in one hand. Slowly twist swab into iSWAB vial with a corkscrew motion. There will be resistance, but push swab to the bottom of tube.
- Hold vial steady and move swab up and down rapidly inside the tube 10-15 times without moving the swab out of the liquid.
- At this point remove and discard the swab. Hold vial firmly and remove swab by slowly twisting out with a corkscrew motion.
- If necessary, collect second sample according to established procedures and repeat steps 2-5.
- Steps For Saliva Collection (Ignore if using only swabs for collection):
  - (1) Remove cap from tube and place on a clean surface. (2) Place funnel into the tube so that it is resting upright as shown in the picture. (3) Stimulate saliva production in your mouth. (4) Spit 1 or 2 times directly into the funnel. (5) Allow several seconds for all saliva to pass through the funnel into the tube. (6) Remove funnel and replace cap securely. (7) Gently shake the vial 5-10x to allow mixing.
- After all samples have been taken, replace cap tightly. Make sure all swabs or funnel have been properly disposed of.





Use by date (collect sample by). Consult package insert before use

( CE marking.

Do not use if package is damaged. LOT Lot number.

REF Catalog Number. EC REP Authorized representative

IVD In vitro diagnostic medical device.

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