

INSTRUCTIONS FOR NASAL/ SALIVA USE – English

Caution: Read all steps before collecting samples.

DEVICE NAME

iSWAB™-Microbiome-EL
(Extraction-Less) Collection Device

INDICATION FOR USE

The iSWAB™-Microbiome-EL (MB-EL) collection device is intended to stabilize and inactivate nucleic acids from upper and lower respiratory human specimens (collected with the iSPIT™ Funnel, NextSWAB®, or traditional flocked swabs) that are suspected of containing infectious microbes or viruses such as SARS-CoV-2. The iSWAB™-MB-EL stabilizing buffer allows for the direct testing of collected samples on qPCR-based SARS-CoV-2, RT-LAMP, and RT-LAMP-LFIA diagnostic tests without the need for RNA extraction, reducing diagnostic turnaround time, the possibility of human error during long extraction protocols, and the cost of extraction reagents. This Device can be used for the collection and storage of collected samples at ambient temperature (20-25°C) and allows for the transportation of the collected sample(s) without a swab. Specimens collected and stored in the iSWAB™-MB-EL collection device are suitable for use with regulatory approved molecular diagnostic assays.

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iSWAB™-Microbiome-EL Device

Swabs sold separately*

iSPIT™ funnel sold separately*[§]

NextSWAB® sold separately*[§]

*Not included in rack or bag format

[§]Item may not be included in certain countries.

STORAGE AND STABILITY

Pre-collection: 18 months from date of manufacture between 15-30° C. Transport temperature, post-collection: 15-30° C. Sample stability and storage, post-collection: 14 days for microbial nucleic acids at 15-30° C; if longer storage time is required, collected samples can be stored at -20 to -80° C. Additional information available at www.mawidna.com.

WARNING AND PRECAUTIONS

For external use and single use only. DO NOT drink, touch, or remove the buffer from the device. Do Not use if device is broken, leaking, or visibly damaged. These products should only be used in accordance with the instructions provided. Avoid skin and eye contact with the liquid in the tube. If Ingested Call a POISON CENTER. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Not a Hazardous Combustion Product. Device cap can be a choking hazard. Do not ingest.

DEVICES

All the iSWAB™-Microbiome-EL family of products consist of one device pre-filled with 800 µL stabilizing buffer.

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

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 device gently 2-3 times before collection to concentrate all liquid to the bottom.

If using saliva collection skip to step number 8

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

1 Place device standing up on a flat surface. Peel open bags containing swabs and remove a swab. Unscrew device cap before collecting sample.

2 For nasal mid-turbinate collection: Insert the swab head into your nostril no more than 3/4" (1.5cm) in. 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.

3 Pick up tube and hold steady in one hand. Slowly twist swab into iSWAB™ tube with a corkscrew motion. There will be resistance, but push swab to the bottom of tube.

4 Hold tube steady and move swab up and down rapidly inside the tube 10-15 times without moving the swab out of the liquid.

5 At this point remove the swab. Hold tube firmly and remove swab by slowly twisting out with a corkscrew motion.

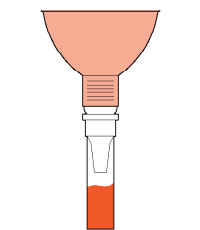
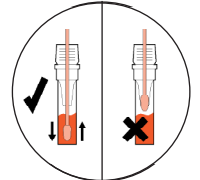
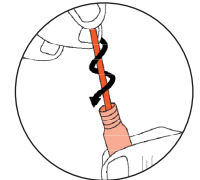
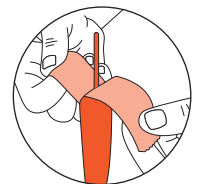
6 For a more concentrated sample, a second sample may be collected by repeating steps 2-5 with another swab. Skip this step if unnecessary.

7 After all samples have been taken, replace cap tightly. Properly dispose used swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations. The sample is now ready for further testing.

8 Steps For Saliva Collection (Ignore if using swabs for collection):

(1) Remove cap from device and place on a clean surface. (2) Place iSPIT™ funnel onto 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 iSPIT™ funnel into the tube. (6) Remove funnel and discard in the appropriate biohazard waste in accordance with federal, state, and local regulations. (7) Replace cap securely onto tube. (8) Gently shake the device 5-10x to allow mixing. (9) The sample is now ready for further testing.

9 For Lab or onsite collection: Proceed with sample processing or storage.



⚠ Attention. See instructions for use.

🌡 Storage temperature.

🕒 Use by date (collect sample by).

📄 Consult package insert before use.

👤 For one use only.

CE CE marking.

🚫 Do not use if package is damaged.

📄 LOT Lot number.

REF Catalog Number.

👤 Authorized representative.

🏭 Manufacturer.

IVD In vitro diagnostic medical device.

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