

DEVICE NAME

iSWAB™-Microbiome (MB) collection device

INDICATION FOR USE

The iSWAB™-Microbiome collection device is intended for the stabilization and inactivation of upper and lower respiratory human specimens suspected of containing SARS-CoV-2 and for the microbial community characterization of fecal samples. This device can be used for the collection, transport, and storage of samples at ambient temperature and allows for the transportation of samples without a swab. The nucleic acids extracted from the collected samples are suitable for use with legally marketed molecular diagnostic assays.

CONTENTS

iSWAB-Microbiome Device

2 swabs*

FecesCatcher*[§]

Plastic “biohazard” bag w/ absorbent pad *[§]

Extra barcode label (for lab use only)*

“Exempt Human Specimen” label*[§]

Outer box (used to mail sample back)*

* Not included in rack 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: 42 days for SARS-CoV-2 RNA and 40 days for microbial DNA 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 eye contact with the liquid in the device. IF IN EYES: Rinse cautiously with water for several minutes. IF INGESTED: Call POISON CENTER. Rinse mouth. Not a Hazardous Combustion Product. Device cap can be a choking hazard. Do not ingest.

DEVICES

All the iSWAB™-Microbiome (MB) collection device family of products consist of one device pre-filled with 1.0 mL stabilizing buffer.

REF /Catalog Number	Product Name	Stabilizing Buffer
ISWAB-MB-1200	iSWAB™-Microbiome Collection Kit	1.0 mL
ISM-T-1200-R	iSWAB™-Microbiome Collection Device Rack	1.0 mL x 50 units
ISM-T-1200	iSWAB™-Microbiome Collection Device	1.0 mL x 500 units
ISWAB-MBF-1200	iSWAB™-Microbiome Collection Kit (with Feces Catcher)	1.0 mL

PREPARATION FOR USE

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

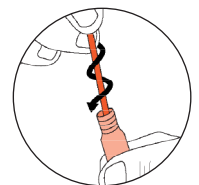
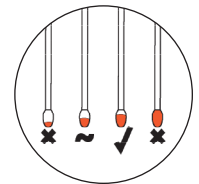
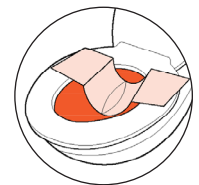
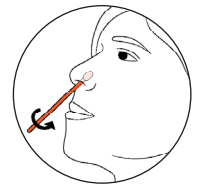
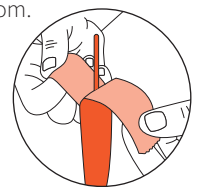
- Do not touch swab tips or allow contact with any other object.
- For swab collection, use either 1 or 2 swabs depending on the test protocol.
- Tap the tube gently 2-3 times before collection to concentrate all liquid to the bottom.

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 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.

For fecal collection: Only 1 swab will be used. Insert swab firmly into sample and rotate several times. Ensure the swab tip is about 75% covered. Refer to instructions on the FecesCatcher for feces collection.

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.



Attention. See instructions for use.

Storage temperature.

Use by date (collect sample by).

Consult package insert before use.

For one use only.

CE marking.

Non-sterile

Do not use if package is damaged.

Lot number.

Catalog Number.

Authorized representative.

Manufacturer.

In vitro diagnostic medical device.

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www.MawiDNA.com



EC REP

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Maarn | The Netherlands

www.cepartner4u.com

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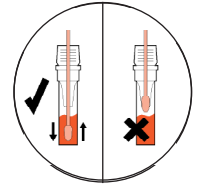
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4 Hold tube steady and move swab up and down rapidly inside the tube 10-15 times without moving the swab out of the liquid.

5 At this point remove and discard the swab according to your local regulations. Hold tube firmly and remove swab by slowly twisting out with a corkscrew motion.

6 Optional: For a more concentrated sample, collect second sample according to established procedures and repeat steps 3-5.

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.

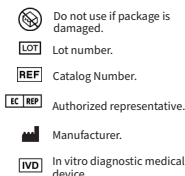
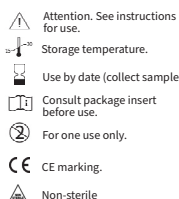


For lab or on-site collection: Proceed with sample processing or storage.

For home collection: Continue with steps 9 and 10.

8 Place device in Biohazard bag. The extra barcode label is for lab use only. Place Biohazard bag with device and extra barcode label back in the box. Place a return address label on top of the box over the original label, and return postage on the upper right corner.

9 Place the “Exempt Human Specimen” label on the bottom left, so it is not covering the postage or the return address label. Peel the tape strip from under the top flap and re-seal the box.



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