

INSTRUCTIONS FOR VARIOUS SAMPLE TYPES – English

Caution: Read all steps before collecting samples.

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 other biosamples with microbial communities. This device can be used for the collection, transport, and storage of SARS-CoV-2 specimens at ambient temperature (15-30 °C) for 42 days and allows for the transportation of samples without a swab. The RNA extracted from the collected samples is suitable for use with legally marketed molecular diagnostic assays.

CONTENTS

iSWAB-Microbiome Device

2 swabs*

FecesCatcher*[§]

iSPIT Funnel*[§]

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

Extra barcode label (for lab use only)*

“Exempt Human Specimen” label*[§]

Outer box (used to mail sample back)*

iSPIT Purchased Separately

* 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 samples, 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 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 a 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.

- 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.

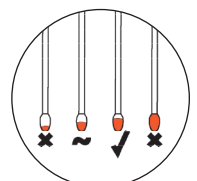
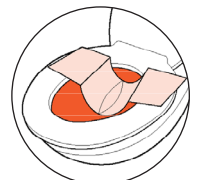
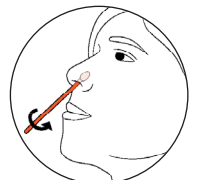
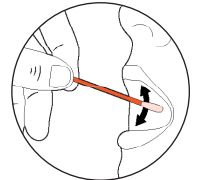
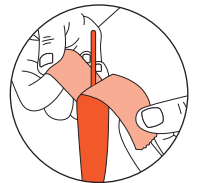
If collecting saliva, skip to step number 7

- 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 oral collection: Rub swab tip firmly against the inside of your cheek 15-20 times, using light pressure similar to brushing your teeth. Rotate swab tip as you are rubbing. Cover entire cheek from top to bottom and side to side. Repeat with second swab on opposite cheek.

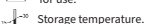
For vaginal, nasal, or rectal collection: Gently insert swab into cavity and gently rotate swab several times. Cover entire swab area from top to bottom and side to side. Repeat with second swab.

For fecal and soil samples: 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 surface or skin collection: To moisten swab, position swab into vial opening, tilt the tube slightly until the swab head is moistened. Note: Do Not insert swab fully into the tube. Remove swab from device opening. Select a section of skin or surface to swab, and rub swab tip firmly against the surface of interest 15-20 times, using light pressure. Rotate swab tip as you are rubbing to cover entire swab. Repeat with second swab.



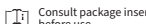
Attention. See instructions for use.



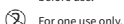
Storage temperature.



Use by date (collect sample by).



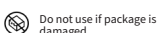
Consult package insert before use.



For one use only.



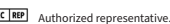
CE marking.



Lot number.



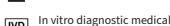
Catalog Number.



Authorized representative.



Manufacturer.



In vitro diagnostic medical device.

Mawi DNA Technologies LLC

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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 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 **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 discard (according to local regulations) and replace cap securely. (7) Gently shake the vial 5-10x to allow mixing.

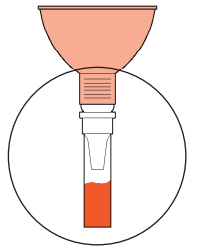
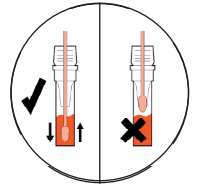
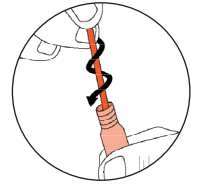
8 After all samples have been taken, replace cap tightly. Properly dispose used swabs in the appropriate biohazard waste in accordance with federal, state, and local regulations. The sample is now ready for further testing.

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

For home collection: Continue with steps 9 and 10.

9 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.

10 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.



Non-sterile	Attention. See instructions for use.	Do not use if package is damaged.
Storage temperature.	Lot number.	Catalog Number.
Use by date (collect sample by).	Authorized representative.	Manufacturer.
Consult package insert before use.	In vitro diagnostic medical device.	
For one use only.		
CE marking.		

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