

### DEVICE NAME

iSWAB-Microbiome Technology

### INDICATION FOR USE

iSWAB-Microbiome sample collection technology is intended for specimen collection of biological samples. It is a non-invasive, non-toxic sample collection method and is intended to be used for long-term room temperature, stable transport and storage of microbial DNA and RNA from various sample types including: fecal, vaginal, skin, soil, nasal, and oral. The iSWAB-Microbiome 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. For saliva collection only a spit funnel is needed to facilitate collection of saliva into the iSWAB -Microbiome device.

### CONTENTS

iSWAB-Microbiome Tube

2 swabs\*

FecesCatcher\*<sup>§</sup>

iSPIT Funnel\*<sup>§</sup>

Plastic “biohazard” bag w/ absorbent pad \*<sup>§</sup>

Extra barcode label (for lab use only)\*

“Exempt Human Specimen” label\*<sup>§</sup>

Outer box (used to mail sample back)\*

\* Not included in rack format.

<sup>§</sup> 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: 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](http://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 family of products consist of one tube pre-filled with 1.0 mL stabilizing liquid.

REF /Catalog Number	Product Family Name	Stabilizing Liquid
ISWAB-MB-1200	iSWAB-Microbiome Collection Kit	1.0 mL
ISM-T-1200-R	iSWAB-Microbiome Collection Tube Rack	1.0 mL x 50
ISM-T-1200	iSWAB-Microbiome Collection Tube	1.0 mL
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

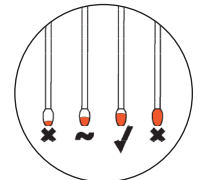
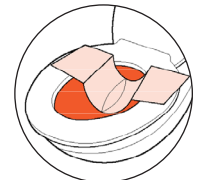
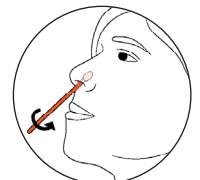
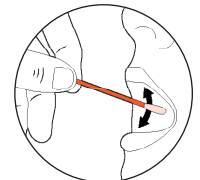
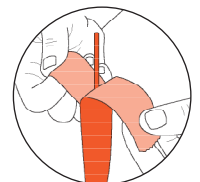
**1** Place vial standing up on a flat surface. Peel open bags containing swabs and remove a swab. Unscrew vial cap before collecting sample.

**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 vial. 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 CE marking.

🚫 Do not use if package is damaged.

🏷️ Lot number.

📄 Catalog Number.

👤 Authorized representative.

🏭 Manufacturer.

🏠 In vitro diagnostic medical device.

## Mawi DNA Technologies LLC

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## INSTRUCTIONS FOR VARIOUS SAMPLE TYPES – English

Caution: Read all steps before collecting samples.

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**3** 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.

**4** Hold vial 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. Hold vial firmly and remove swab by slowly twisting out with a corkscrew motion.

**6** If necessary, 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 replace cap securely. (7) Gently shake the vial 5-10x to allow mixing.

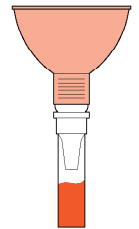
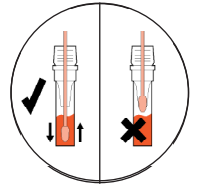
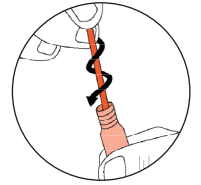
**8** After all samples have been taken, replace cap tightly. Make sure all swabs or funnel have been properly disposed of.

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

**For home collection: Continue with steps 9 and 10.**

**9** Replace cap tightly and place vial in Biohazard bag. The extra barcode label is for lab use only. Place Biohazard bag with vial 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.



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