

INSTRUCTIONS FOR ORAL USE – English

Caution: Read all steps before collecting samples.

DEVICE NAME

iSWAB-RNA-v2 Technology

INDICATION FOR USE

The iSWAB-RNA-v2 device allows for the non-invasive collection, concentration, and stabilization of intact buccal cells and/or any mammalian cells collected with a swab or cytobrush. Allows for real time ambient stabilization of total RNA from the point of collection to processing. The iSWAB-RNA-v2 maintains RNA stability and protects RNA from degradation. The device allows extended shelf life stability (up to 4 weeks at room temp, several years at -20 C and -80 C), reduced processing time, and minimal storage footprint.

CONTENTS

- iSWAB-RNA-v2 Vial
- 4 sterile applicators*
- Plastic Biohazard bag with absorbant pad
- Extra barcode label (for lab use only)*
- “Exempt Human Specimen” label*[§]
- The outer box will be used to mail back* sample
- *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: 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 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-RNA-v2 family of products consist of one tube with 1000 µL stabilizing liquid.

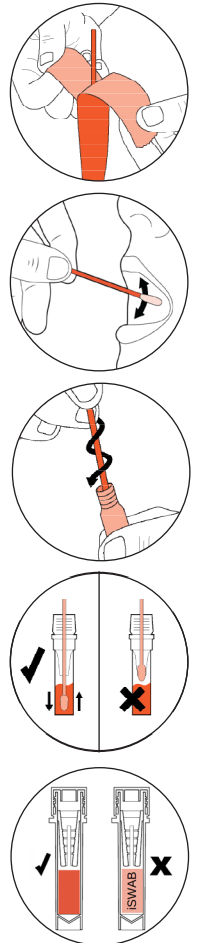
REF /Catalog Number	Product Family Name	Volume
iSWAB-RNA-v2	iSWAB-RNAv2 Collection Kit	1000 µL
ISR2-T-1200-R	iSWAB-RNA2 Collection Tube Rack	1000 µL x 50
ISR2-T-1200	iSWAB-RNA2 Collection Tube	1000 µL

PREPARATION FOR USE

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

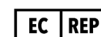
- Note: It is recommended not to eat, drink, or smoke for 30 minutes before collecting your sample
- Do not touch swab tips or allow contact with any other object.
- Tap the tube gently 2-3 times before collection to concentrate all liquid to the bottom.
- Use all 4 swabs included in kit. Read all steps before collecting samples.

- 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
 - a. Rotate swab tip as you are rubbing
 - b. Cover entire cheek from the top to bottom and side to side. Use all applicators on the same cheek. Do not alternate cheeks during collection.
- 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. Dispose used swab. **DO NOT PLACE SWABS IN THE BIOHAZARD BAG**
- 6** Repeat steps 2-5 with all 4 swabs included in the kit. Use all applicators on the same cheek. Do not alternate cheeks during collection. Make sure all swabs are used.
- 7** STOP: After using all swabs, inspect the solution through the opening between the label. If the collection has been done properly the word “SWAB” should disappear. If sample is stored, the sample may need to be shaken to homogenize the sample.
- 8** If you can still read the word “SWAB”: Repeat swabbing process after 2hrs or the next morning before eating or brushing your teeth using Q-Tips® swabs, or any standard cotton swab. Make sure the word “SWAB” is not visible before sending the sample back to the lab.
- 9** For Lab or onsite collection: Proceed with sample processing or storage. For home collection: 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. Place the “Exempt Human Specimen” label on the bottom left. Do not cover postage or return address. Peel the tape strip from under the top flap and re-seal the box



- Attention. See instructions for use.
- Storage temperature.
- Use by date (collect sample by).
- Consult package insert before use.
- For one use only.
- 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
 26203 Production Ave, Suite No.3 | Hayward, CA 94545
 Tel: 510-256-5186 Toll Free (US & Canada): 855-DNA-SWAB
www.MawiDNA.com



CEpartner4U
 Esdoornlaan 13 | 3951 DB
 Maarn | The Netherlands
www.cepartner4u.com

IFU-0079 (A) iSWAB-RNA v2
 Effective Date: 2022-03-30