

INSTRUCTIONS FOR ORAL USE – English

Caution: Read all steps before collecting samples.

DEVICE NAME

iSWAB-Cells-1200 Technology

INDICATION FOR USE

iSWAB-Cells, a universal non-invasive cell collection device, from which gDNA, RNA, proteins, and cell morphology can be analyzed from the same sample. iSWAB Cells is designed for non-invasive, self-collection of intact and viable buccal cells.

CONTENTS

iSWAB-DNA Vial

4 cytobrushes*

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 choking hazard. Do not ingest.

DEVICES

All the iSWAB-Cells-1200 family of products consist of one tube with 1000 µL collection volume and stabilizing liquid.

REF /Catalog Number	Product Family Name	Collection Volume
iSWAB-Cells-1200	iSWAB-Cells Collection Kit	1000 µL
ISC-T-1200-R	iSWAB-Cells Collection Tube Rack	1000 µL x 50
ISC-T-1200	iSWAB-Cells 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 cytobrushes included in kit

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 the top to bottom and side to side.

USE ALL BRUSHES ON THE SAME CHEEK. DO NOT ALTERNATE CHEEKS DURING COLLECTION

3 Pick up vial and hold steady in one hand. Slowly twist brush 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.

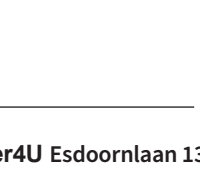
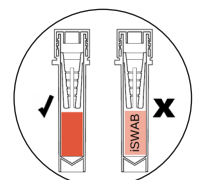
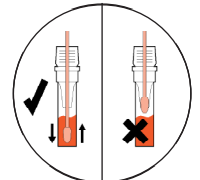
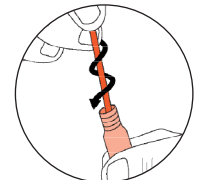
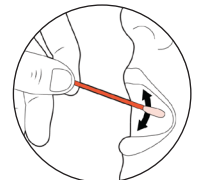
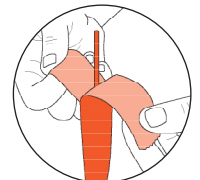
5 At this point remove and discard the brush. Hold vial firmly and remove swab by slowly twisting out with a corkscrew motion. Dispose used brush. **DO NOT PLACE SWABS IN THE BIOHAZARD BAG**

6 Repeat steps 2-5 with all 4 swabs included in the kit. Use all brushes on the same cheek. Do not alternate cheeks during collection. Make sure all 4 brushes are used

7 STOP: After using all brushes, 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 CE marking.

🚫 Do not use if package is damaged.

📦 LOT Lot number.

REF Catalog Number.

EC REP Authorized representative.

🏭 Manufacturer.

IVD 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



EC REP CEpartner4U Esdoornlaan 13 |

3951 DB Maarn | The Netherlands

www.cepartner4u.com

IFU-0107(A) iSWAB-Cells-1200
Effective Date:2022-03-21