

iSWAB™-Cells-1200 Technology

mawi

INSTRUCTIONS FOR ORAL USE – English

Caution: Read all steps before collecting samples.

DEVICE NAME

iSWAB™-Cells-1200

INDICATION FOR USE

iSWAB™-Cells Collection Kit is a non-invasive device for room temperature collection, stabilization, concentration, transport, and storage of intact buccal cells. iSWAB™-Cells, a universal cell collection device, can analyze gDNA, RNA, proteins, and cell morphology from the same sample. iSWAB™ Cells is designed for non-invasive, self-collection of intact and viable buccal cells using a flocked swab or cytobrush. Suitable for all ages, ethnicities, race, and genders.

CONTENTS

iSWAB™-Cells device

4 sterile applicators*

Plastic "Biohazard" bag with absorbent pad*

Extra barcode label (for lab use only)*

"Exempt Human Specimen" label*

The outer box will be used to mail back sample*

* Included in Kit format only.

*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: viable cells are stabilized for up to 4 weeks 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.

Refer to SDS

DEVICES

All the iSWAB™-Cells-1200 family of products consist of one device pre-filled with 1.0mL stabilizing buffer.

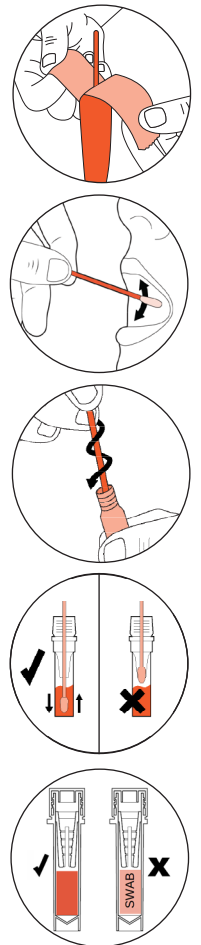
REF /Catalog Number	Product Family Name	Stabilizing Buffer
iSWAB™-Cells-1200	iSWAB™-Cells Collection Kit	1.0 mL
ISC-T-1200-R	iSWAB™-Cells Collection Device Rack	1.0 mL x 50 units
ISC-T-1200	iSWAB™-Cells Collection Device Bag	1.0 mL x 500 units

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. Use all 4 swabs included in kit.
- Tap the device gently 2-3 times before collection to concentrate all liquid to the bottom.

- Place device standing up on a flat surface. Peel open bags containing applicators and remove a swab. Unscrew device cap before collecting sample.
- For oral collection:** Rub applicator 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 applicators on the same cheek. Do not alternate cheeks during collection.
- Pick up tube and hold steady in one hand. Slowly twist applicator into iSWAB™ tube with a corkscrew motion. There will be resistance, but push swab to the bottom of tube.
- Hold tube steady and move applicator up and down rapidly inside the vial 10-15 times without moving the applicator out of the liquid.
- At this point remove the applicator. Hold vial firmly and remove applicator by slowly twisting out with a corkscrew motion. Properly dispose used applicators in the appropriate biohazard waste in accordance with federal, state, and local regulations. **DO NOT PLACE SWABS IN THE BIOHAZARD BAG.**
- Repeat steps 2-5 with all 4 applicators included in the kit. Use all applicators on the same cheek. Do not alternate cheeks during collection. Make sure all applicators are used.
- STOP:** After using all applicators, inspect the solution through the opening between the label. If the collection has been done properly the word "SWAB" should disappear. Replace cap tightly; the sample is now ready for further testing.
- 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. Usually 1-2 extra swabs for re-swabbing might be sufficient, but make sure the word "SWAB" is not visible before sending the sample back to the lab.
- For Lab or onsite collection:** Proceed with sample processing or storage. **For home collection:** Place iSWAB™ device in "Biohazard" bag with absorbent pad. 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. 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.

*The products shown contain the CE Mark and are approved for IVD use in countries recognizing this standard. In the USA, products are designated For Research Use Only and not for use in diagnostic procedures, and will be labeled accordingly.

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IFU-0107(D) iSWAB-Cells 1200 | Effective Date: 2023-08-31