

INSTRUCTIONS FOR ORAL USE – English

Caution: Read all steps before collecting samples.

DEVICE NAME

iSWAB™-DNA-1200

INDICATION FOR USE

The iSWAB™-DNA-1200 collection device is intended for the collection of double-stranded, large fragment DNA at the point of collection without the need for swab inclusion. The gentle collection and lysis chemistry of the nontoxic iSWAB™-DNA buffer allows for recovery of DNA similar to the genomic DNA generated from blood, making it suitable for complex genomics downstream assays such as microarrays, NGS, and Sanger sequencing. The device can be used for ambient temperature (15-30 °C) transport and storage. Ideal for: paternity testing, genealogy, ancestry, population genomics, cancer research, HLA typing, and epidemiology.

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iSWAB™-DNA-1200 Device

4 sterile swabs*

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*

* Included in Kit format only.

[§] Item may not be included in certain countries.

STORAGE AND STABILITY

Pre-collection: 3 years from date of manufacture between 15-30° C.

Transport temperature, post-collection: 15-30° C.

Sample stability and storage, post-collection: 60 days real time (3 years accelerated time); 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.

DEVICES

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

REF /Catalog Number	Product Family Name	Stabilizing Buffer
iSWAB-DNA-1200	iSWAB-DNA Collection Kit	1.0 mL
ISD-T-1200-R	iSWAB-DNA Collection Device Rack	1.0 mL x 50 units
ISD-T-1200	iSWAB-DNA Collection Device	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.

1 Place device standing up on a flat surface. Peel open all 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
 a. Rotate swab tip as you are rubbing
 b. Cover entire cheek from the top to bottom and side to side

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.

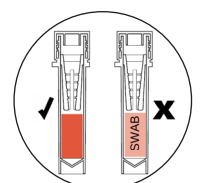
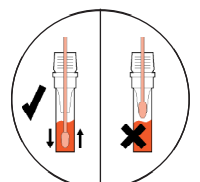
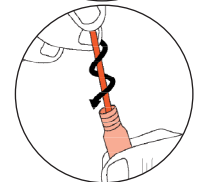
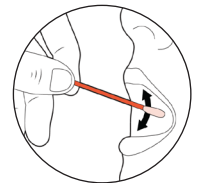
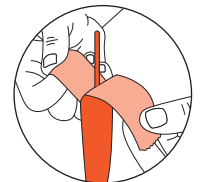
5 At this point remove and discard the swab. Hold tube firmly and remove swab by slowly twisting out with a corkscrew motion. Properly dispose used swab in the appropriate biohazard waste in accordance with federal, state, and local regulations. **DO NOT PLACE SWABS IN THE BIOHAZARD BAG**

6 Repeat steps 2-5 with all 4 swabs included in the kit. Alternating between the left and right side of the cheeks. 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. Replace cap tightly, the sample is now ready for further testing.

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. 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.

9 For Lab or onsite collection: Proceed with sample processing or storage.
 For home collection: Place iSWAB™ device in “Biohazard” bag containing the absorbant 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.

Non-sterile

Do not use if package is damaged.

Lot number.

Use by date (collect sample by).

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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