

INSTRUCTIONS FOR USE



TO GET THE CORRECT TEST RESULT...

...DO NOT eat, drink, chew gum or smoke for at least 10 minutes prior to the collection.



The goal is to collect saliva into the collection tube.

- 1** Open the collection set and mount the funnel onto the collection tube.



Important: Cough out several times before collection (wearing a respirator or a facemask).

- 3** Build up a sufficient amount of saliva in your mouth and roll it around in your mouth several times.

- 4** Let the saliva drip freely from your mouth into the collection funnel until there is at least 1 cm of liquid (not foam) in the tube.



- 5** Remove the funnel and dispose of it. **Make sure the tube is tightly capped.**

- 6** Wipe the collection tube using a disinfectant wipe and hand it over.



INSTRUCTIONS FOR SAMPLING SITES

DB-1225 Saliva Collection Set 1.41M

DB-1230 Saliva Collection Set 1.41F

Cat. no.: DB-1225-1.41M-100sets (100 sets)

Cat. no.: DB-1230-1.41F-100sets (100 sets)

Cat. no.: DB-1225-1.41M-200sets (200 sets)

Cat. no.: DB-1230-1.41F-200sets (200 sets)

Cat. no.: DB-1225-1.41M-500sets (500 sets)

Cat. no.: DB-1230-1.41F-500sets (500 sets)

Each collection set consists of a collection tube, a funnel, and a screw cap.

Intended purpose: The Saliva Collection Set is intended for the collection, transport and storage of biological samples, especially saliva, swabs, liquids (aspirates) and lavages.

Procedure for collecting saliva or other biological samples:

- ❖ The tested person must be familiarized with the collection procedure prior to collection, see instructions overleaf.
- ❖ For correct collection of saliva for respiratory disease testing, it is important that the subject coughs several times before collection.
- ❖ After collection, check that the level of the liquid part of the sample (saliva without foam, aspirates or lavages) is high enough:
 - ❖ The level of saliva must be at least 1 cm above the dark bottom of the tube, corresponding to a volume of 0.2 ml.
 - ❖ In case of insufficient sample volume, the sample must be repeated.
 - ❖ For swab samples, a swab stick containing the sample is inserted into the sample tube and the tube is closed. The terminal end of the stick can be shortened if necessary.
- ❖ Make sure the tube cap is properly closed before storing the tube for transport.
- ❖ It is recommended to wear protective gloves whenever handling tubes, optionally always disinfect your hands.

Storage of empty collection sets, samples, and transport:

- ❖ Before use, store the collection set at temperatures between 2 °C to 30 °C.
- ❖ After unpacking the collection set, immediately collect the sample and screw the tube thoroughly to avoid contamination of the surrounding environment.
- ❖ The tube with the collected saliva can be stored for up to 72 hours at temperatures between 4 °C to 25 °C in a dark environment. Other types of samples can be stored for up to 24 hours at temperatures between 4 °C to 8 °C.
- ❖ For easier handling of samples, we recommend stacking the DB-1225 Collection Sets in the DB-1228 Sample Rack 1.41M. In the case of DB-1230 Collection Sets, the DB-1240 Sample Rack 1.41F racks can be used similarly.

Sample identification (scanning):

- ❖ For easy sample identification, each tube has a 2D matrix code on the bottom that allows you to pair the sample with the patient's information directly at the collection site.
- ❖ We highly recommend providing disinfectant wipes at the collection site for tested persons to disinfect their hands and wipe the tube after the collection (before handling the tube over to the staff of the testing site).

Leaflet and Instructions for Use for DB-1225 Saliva Collection Set 1.41M; DB-1230 Saliva Collection Set 1.41F

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DIANA Biotechnologies s.r.o., Nad Safinou II 366, 25250 Vestec, Czech Republic

Email: support@dianabiotech.com | Web: www.dianabiotech.com



Alerts and warnings:

- ❖ The device is intended for single use and can never be reused.
- ❖ Avoid the unnecessary handling of samples due to their possible infectivity.
- ❖ The collection set is made of polypropylene, do not lick or chew its parts. In rare cases, an allergic reaction to the plastic material may occur.
- ❖ The collection set contains small parts that could be inhaled. Keep them out of the reach of children.
- ❖ Do not use the device if any part is broken, visibly dirty or missing.
- ❖ Dispose of packaging material in accordance with local regulations.
- ❖ Any serious adverse event (i.e., one in which there is a temporary serious, or permanent deterioration in the health status or death of a patient, user or another person, or one in which there is a serious threat to public health) occurring in connection with the use of this device must be reported to the manufacturer and the competent authority of the member state.
- ❖ The used funnel may contain infectious saliva or other biological samples. After use, dispose of it in an infectious waste container.



Manufacturer



In vitro Diagnostic Medical Device



CE marking



Lot Number



Operator's manual, operating instruction



Catalog Number



Temperature limit



Do not use if package is damaged



Use by date



Do not reuse



Package contains