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(F IVD

Saliva DNA Storage Tube Instructions for Use

Packaging Specifications

1 set; 20 sets

Intended Use

The Saliva DNA Storage Tube is used for collecting and stabilizing DNA from human saliva and for the transportation and long-term room temperature storage of a saliva sample.

Saliva collected and stored in Saliva DNA Storage Tube are compatible with most commercially available nucleic acid extraction kits. And extracted nucleic acid can be for downstream analysis.

The Saliva DNA Storage Tube is intended for use by qualified clinical personnel and *in vitro* diagnostic procedures.

Components

Each set of this product is composed of 1 of Collection Cup and 1 of Saliva DNA Storage Tube with 1 mL of DNA storage buffer.

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Basic Information



Jiangsu CoWin Biotech Co., Ltd.

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EC REP

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Storage Condition and Shelf Life

Manufacturing and expiration dates are printed on the label.

This product can be stored and transported below 40°C for three years prior to use.

Specimen Collection, Handling, and Storage

Saliva samples collected using the Saliva DNA Storage Tube are stabilized and can be preserved below 40°C for two years.

Saliva Collection Preparation

- 1. Clean the mouth with drinking water 30 minutes before saliva sample collection.
- 2. Relax your cheeks and gently massage checks with fingers for 15-30 seconds to produce saliva before collecting saliva.
- 3. Open package containing Collection Cup and Saliva DNA Storage Tube.

Saliva Collection



 Remove the protective sticker of Collection Cup to expose the collection slot and collection port.



Spit saliva into rectangular collection slot of Collection Cup, avoid presenting too many bubbles.



Fill saliva to the fill line (not including bubbles).



4. Take the Saliva DNA Storage Tube, insert the cap down along the cover hole and press down, puncture the butyl rubber stopper with the puncture needle to fully suck the saliva into the Storage Tube.



 Gently invert the Saliva DNA Storage Tube 10 times to fully mix saliva with storage buffer.

6. Discard the Collection
Cup as requirement of
local regulation.

Warnings and Precautions

- 1. For in vitro diagnostic use (IVD) only.
- 2. Check the package before use. If damaged, it is strictly prohibited to use.
- 3. DO NOT drink, touch or remove the reagent from the tube.
- 4. Avoid reuse.
- 5. If any serious incident that has occurred in relation to the product shall be reported to the manufacturer and the competent authority.
- 6. Do not eat, drink, smoke, use tobacco products, or chew gum for at least 30 minutes before giving your saliva sample.
- 7. If the contents of the tube contact your skin, flush thoroughly with water.
- 8. Most people take 2-5 minutes to collect saliva sample following the steps above.



GHS07

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Glossary of Symbols

Symbol	Meaning	Symbol	Meaning
IVD	<i>In vitro</i> diagnostic medical device	1	Temperature limit
***	Manufacturer	\subseteq	Use-by date
س	Date of Manufacture	2	Do not re-use
LOT	Batch code	[]i	Consult instructions for use
EC REP	Authorized representative in the European Community / European Union	(€	CE Symbol
\triangle	Caution	UDI	Unique device identifier
REF	Catalogue number	®	Do not use if package is damaged and consult instructions for use