

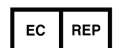
## Glossary of Symbols

Symbol	Meaning	Symbol	Meaning
	<i>In vitro</i> diagnostic medical device		Temperature limit
	Manufacturer		Use-by date
	Date of Manufacture		Do not re-use
	Batch code		Consult instructions for use
	Authorized representative in the European Community / European Union		CE Symbol
	Caution		Unique device identifier
	Catalogue number		Do not use if package is damaged and consult instructions for use

## Basic Information



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# Urine DNA Storage Tube Instructions for Use

## Packaging Specifications

10 sets

## Intended Use

The Urine DNA Storage Tube is used for collection, transport and storage of human Urine, and stabilization of cell-free DNA in human Urine. Urine collected and stored in Storage Tube are compatible with most commercially available nucleic acid extraction kits. And extracted nucleic acid can be for downstream analysis. The product is suitable for noninvasive prenatal screening and research related to early diagnosis of some diseases.

The Urine 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 2 of Urine DNA Storage Tubes with DNA storage buffer.

Storage buffer contains EDTA, preservation reagent, etc., which can rapidly inhibit nuclease in Urine and stabilize Urine DNA.

## Storage Condition and Shelf Life

Manufacturing and expiration dates are printed on the label.

This product can be stored and transported at 4-30°C for 18 months prior to use.

## Specimen Collection, Handling, and Storage

Urine samples collected using the Urine DNA Storage Tube are stabilized and can be preserved at 6-35°C for up to 7 days.

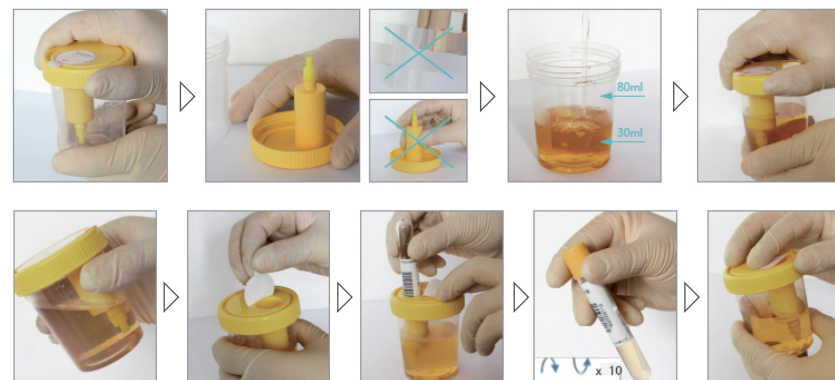
## Urine Collection Preparation

Open package containing Collection Cup and Urine DNA Storage Tube.

## Urine Collection

1. Unscrew the lid counterclockwise. (Do not open protective sticker).
2. Place unscrewed lid down on clean table (Do not touch the surface of cylinder, suction nozzle, as well as inner surface of cup). The volume of collected urine should be between 30 mL and 80 mL, approximately 60 mL of urine is appropriate.
3. Cover the lid and tighten the lid clockwise, shake the urine sample.
4. Open the protective sticker to expose collection hole.
5. Take 2 of Storage Tubes respectively, insert caps of tube into collection hole and press down, puncture the butyl capsule with the puncture needle, and make the urine fully sucked into the tubes (10 mL per tube).
6. After collection, immediately and gently invert Urine DNA Storage Tubes 10 times to fully mix urine and storage buffer.
7. Cap & screw urine collection cup securely, then discard the Collection Cup as requirement of local regulation. Collected urine in Urine DNA Storage Tube is for testing.

The operation diagram is as follows:



8. The collected urine should be stored and transported according to requirements of instructions for use.
9. Separation of urine: centrifuge collected urine storage tube at 4000 rpm for 10 minutes, carefully pipette the upper layer of urine into a new centrifuge tube, taking care not to pipette the lower layer of cells.
10. Extraction of cell-free DNA: separated urine could be compatible with most commercially available nucleic acid extraction kits.

## 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. If the contents of the tube contact your skin, flush thoroughly with water.
7. This product is suitable for preservation 2 vials of 10 mL of urine, too much or too little urine will result in an inappropriate urine/protectant ratio and will not achieve the optimal performance of the product.
8. The best time for collection urine is in the morning. After collection, recommended to immediately and gently invert Urine DNA Storage Tube 10 times. Insufficient or too vigorous mixing may affect the protective effect, do not refrigerate or freeze.
9. If there are precipitates or insoluble prior to use, please stop using it, and contact after-sale service of Jiangsu CoWin Biotech Co., Ltd.