

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 |
| | Biological risks | | |

Basic Information



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Fecal DNA Storage Tube Instructions for Use

Packaging Specifications

1 set

Intended Use

The Fecal DNA Storage Tube is intended for the collection and transport of fecal specimens to be analyzed. This product is compatible with commercially available nucleic acid extraction kits.

The Fecal 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 Fecal DNA Storage Tube with different volume of DNA storage buffer and mixing ball.

5 mL of Fecal DNA Storage Tube contains 2 mL of DNA storage buffer.

30 mL of Fecal DNA Storage Tube contains 10 mL of DNA storage buffer.

50 mL of Fecal DNA Storage Tube contains 20 mL of DNA storage buffer.

DNA storage buffer pre-filled into tubes ensures sample stability during transport/storage at room temperatures without refrigeration or specialized equipment.

Storage Condition and Shelf Life

Manufacturing and expiration dates are printed on the label.

This product can be stored and transported at 2-37°C for three years prior to use.

Specimen Collection, Handling, and Storage

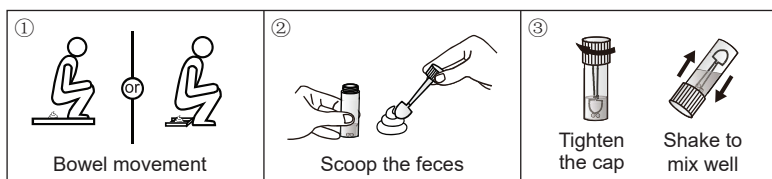
Specimen collected can be stored at room temperature for at least two years. And specimen collected can be stored at -20°C and -80°C for long-term storage.

Collection Preparation

1. Empty your bladder before beginning the collection.
2. Collect fecal sample free of urine or toilet water.
3. Do not spill the storage buffer in the tube.

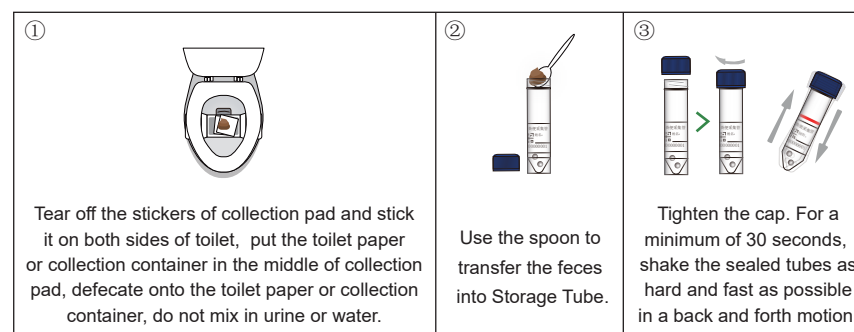
Fecal Specimens Collection

1. For 5 mL of Fecal DNA Storage Tube and 30 mL of Fecal DNA Storage Tube
 - 1.1 Prepare and collect fecal specimen using collection container.
Note: Method of collecting the fecal sample must prevent feces from falling into toilet water to avoid sample contamination.
 - 1.2 Unscrew the collection tube cap and use the spoon to scoop one spoonful of feces from fecal sample.
Note: 5 mL of Fecal DNA Storage Tube can store up to 0.5 gram specimen, that is the liquid level reaches the mark of 2.5 mL. 30 mL of Fecal DNA Storage Tube can store up to 2.5 gram specimen, that is the liquid level reaches the mark of 12.5 mL (marked in red line).
 - 1.3 Place the sample into the Fecal DNA Storage Tube.
 - 1.4 Tighten the cap and shake to mix the contents thoroughly to create a suspension.
Note: Some fecal material may be difficult to re-suspend. Foaming/frothing during shaking is normal.
 - 1.5 Dispose of unused fecal material and thoroughly wash hands.



2. For 50 mL of Fecal DNA Storage Tube
 - 2.1 Prepare and collect fecal specimen using collection container.
Note: Method of collecting the fecal sample must prevent feces from falling into toilet water to avoid sample contamination.

- 2.1 Use the spoon to collect a small amount of fecal sample.
Note: 50 mL of Fecal DNA Storage Tube can store up to 5 gram specimen, that is the liquid level reaches the mark of 25 mL (marked in red line).
- 2.3 Unscrew the collection tube cap and transfer the fecal sample into Fecal DNA Storage Tube.
- 2.4 Tighten the cap and shake to mix the contents thoroughly to create a suspension.
Note: Some fecal material may be difficult to re-suspend. Foaming/frothing during shaking is normal.
- 2.5 Dispose of unused fecal material and spoon, and thoroughly wash hands.



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 vial.
4. Avoid reuse.
5. Small mixing ball may pose a choking hazard.
6. If any serious incident that has occurred in relation to the product shall be reported to the manufacturer and the competent authority.



GHS07

H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.