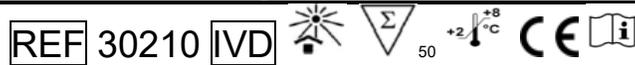


Fecal Sample Collection Kit



INTENDED USE

Fecal Sample Collection Kit is a device intended for human fecal sample collection and extraction. The extracted sample can be used directly for quantitative or qualitative detection of Fecal Occult Blood, Pancreatic Elastase-1, Calprotectin, Lactoferrin and/or Secretory IgA level in stool samples by professional laboratories.

For in-vitro diagnostics purpose only

REAGENTS AND MATERIALS PROVIDED

1. Fecal Sample Collection Tube (31330): 50 units/kit. Each tube contains 4.5mL fecal sample collection and extraction buffer.
2. Instructions for Use

SAFETY PRECAUTIONS

The reagents must be used in professional laboratory environment and are for in vitro diagnostic use only. Wear gloves while performing sample collection and treat the reagent as if they are hazardous. The buffer may cause irritation on skin upon contact. Do not get in the eyes, on skin, or clothing. Never transfer any reagents with mouth. Do not ingest or inhale. On contact, flush with copious amounts of water for at least 15 minutes. Exercise Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

Plastic wide-mouth stool collection container for primary patient stool collection at home or hospital

- **Stool Sampler Kit (Catalog KT-848):**

A designated, pre-packed collection kit for primary patient stool collection.

- **Stool Sampler Container (Catalog 31315):**

A designated container for primary patient stool collection.

STOOL SAMPLE TRANSPORTATION & STORAGE

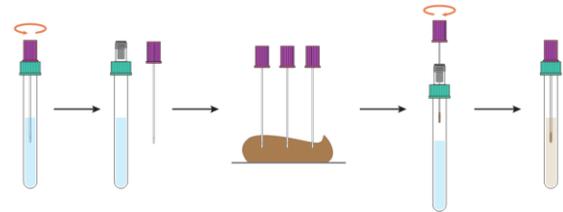
1. **Specimen transport:** After primary stool collection by patient, the specimen should be stored at 2–8 °C prior to shipment and must be received by the laboratory for processing within 3 days of collection. The specimen may be shipped at room temperature or on cold pack.
2. **Specimen storage:** Stool specimen should be refrigerated at 2-8 °C and extracted within 3 days of receipt at the laboratory. Same day extraction is preferred.

SPECIMEN EXTRACTION

1. Open the lid of primary stool collection container
2. Open the device sampling lid (purple color) and slowly pull the sampling lid out of the tube.
3. Use the grooved region of the wand to stir and mix soft stool or dip into hard stool multiple times (3 - 5 sites) to collect a small amount of stool sample. The whole

grooved region of the wand must be covered with stool sample.

4. Insert the sampling wand and screw the sampling lid back into the sampling tube in a vertical position. Tightly seal the sampling lid against the tube. Let the sample soak in extraction buffer at least 10 minutes.
5. Vortex the tube on upright position at least 10 seconds to dissolve the stool sample completely. It is important to ensure that the grooved region of the wand is completely free of stool sample residue. (A digital roller mixer can be used to assist in facilitating the mixing process.)
6. Place the extracted sample upright on a rack for 1 to 5 minutes to allow stool particles to settle. If bubbles or foam are present, remove them before performing the assay.



7. The extracted stool specimen should be tested within 8 hours. Store the extracted specimen at 2-8 °C as retention for 3 days. It may be stored below -20 °C for a longer storage period. Avoid more than three freeze - thaw cycles for each specimen.

PROCEDURAL NOTES

1. As an alternative to the above manual collection procedure, we recommend using **QSE180 Autosampler**. It is intended for fully automated, random-access sampling and extraction of patient stool prior to measurement.
2. In case the laboratory intends to centrifuge the Fecal Sample Collection Tube (31330) after the stool is fully dissolved, we recommend a rotational speed of 1,200-1,500 RPM for a duration of 5 minutes.
3. For entirely liquid stool, unscrew the green cap and pipet 15 µL of liquid stool into Fecal Sample Collection Tube (31330). Recap the green cap and proceed with **SPECIMEN EXTRACTION** Step 5.
4. For liquid stool with minimum consistency, which cannot be effectively collected by sampling wand, weighing between 15mg and 20mg, unscrew the green cap and place the weighed stool sample into Fecal Sample Collection Tube (31330). Recap the green cap and proceed with **SPECIMEN EXTRACTION** Step 5.
5. This device is recommended for the secondary collection of stool sample in professional laboratories, while patient should perform primary collection of stool

sample into a plastic wide-mouth stool collection container in bathroom.

6. Careful technique is necessary to ensure reproducibility and maximum detective sensitivity.
7. The devices must not be used after the expiration date printed on the labels.
8. The devices can be shipped at room temperature.
9. The devices must not be reused for stool sample collection.

WARRANTY

This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Diagnostics, Inc. DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Diagnostics, Inc. be liable for consequential damages. Replacement of the product or refund of the purchase price is the exclusive remedy for the purchaser. This warranty gives you specific legal rights and you may have other rights, which vary from state to state.

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For technical assistance or to place an order, please contact Epitope Diagnostics, Inc. at +1 (858) 693-7877 or fax to +1 (858) 693-7678 or email at cs@epitopediagnostic.com

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Read the **Reflex** test kit IFU for instructions.



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Manufacturer	No. of tests
Catalog Number	Keep away from heat and direct sun light
Lot No.	Store at
In Vitro Diagnostic Device	Use by