

q-FOB™ Fecal Sample Collection Kit



INTENDED USE

q-FOB™ Fecal Sample Collection Kit is a device intended for human fecal sample collection and extraction. The extracted sample can be used directly for detection of fecal occult blood by the quantitative determination of human hemoglobin levels in stool samples by professional laboratories.

For in-vitro diagnostics purpose only

REAGENTS AND MATERIALS PROVIDED

1. Fecal Sample Collection Tube (31150): 50 units/kit. Each tube contains 4.5mL q-FOB™ 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

1. Plastic wide-mouth stool collection container

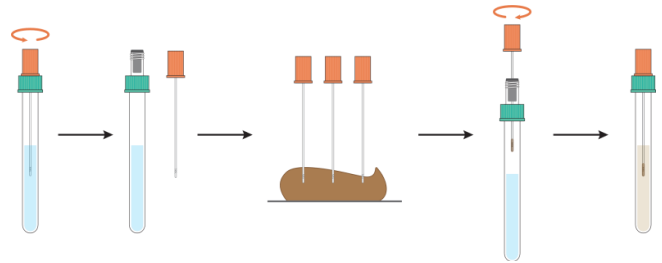
SPECIMEN COLLECTION

1. Open the lid of primary stool collection container
2. Open the device sampling lid (orange color) and 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.
4. Insert the sampling wand and screw the sampling lid back into the sampling tube in a vertical position. Do not spill any solution from the tube.
5. Tightly seal the sampling lid against the tube.
6. The collected sample is ready for vortex extraction and test.

PROCEDURAL NOTES

1. 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.
2. Careful technique is necessary to ensure reproducibility and maximum detective sensitivity.

SAMPLE COLLECTION PROCEDURE



STORAGE

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

WARRANTY

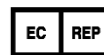
This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Diagnostics, Inc. DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Diagnostics, Inc. be liable for 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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