

Fecal MPO Sample Collection Kit



INTENDED USE

Fecal MPO Sample Collection Kit is a device intended for human fecal sample collection and extraction. The extracted sample can be used directly for MPO level determination by professional laboratories.

For in-vitro diagnostics purpose only

REAGENTS AND MATERIALS PROVIDED

- Fecal MPO Sample Collection Tube (31150): 50 units/kit. Each tube contains 4.5mL MPO fecal sample collection and extraction buffer.
- 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

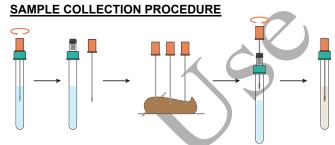
Plastic wide-mouth stool collection container

SPECIMEN COLLECTION

- 1. Open the lid of primary stool collection container
- Open the device sampling lid (orange color) and slowly pull the sampling lid out of the tube.
- Use the grooved region of the wand to stir and mix <u>soft</u> stool or dip into <u>hard stool</u> 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 min.
- 5. Vortex the tube on upright position at least 10 seconds to dissolve the stool sample completely. (A digital roller mixer can be used to assist in facilitating the mixing process.)
- 6. The extracted sample should be on upright position on a rack for 1 5 minutes to sediment stool particles before assay.

PROCEDURAL NOTES

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



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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Manufacturer	$\stackrel{\Sigma}{\bigvee}$ No. of tests
REF Catalog Number	Keep away from heat and direct sun light
LOT Lot No.	★ Store at
IVD In Vitro Diagnostic Device	Use by

Patent: US11293839B2

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