

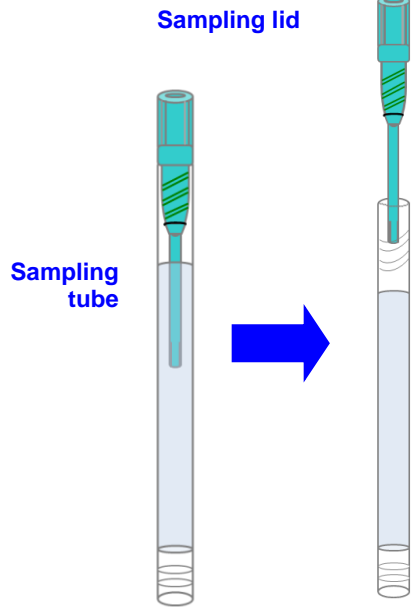
EpiTuub® Calprotectin/i-FOB DUO Test Kit - Instructions for Fecal Sample Collection

Monoclonal antibody based immunoassay test for the detection of bowel inflammation and bleeding

Version 4

1

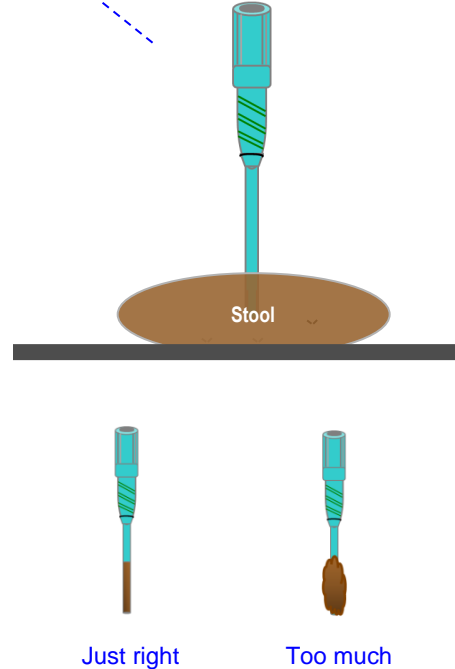
1. Collect a stool sample using the enclosed stool sampling paper:
 - a. Clean the bowl and flush the toilet two times. Unfold and lay the Sample Collection Paper directly on the top of the water in the toilet bowl (the paper should float above the water).
 - b. After bowel movement, take the sampling tube and unscrew the sampling lid, keeping the sampling tube in a **vertical position** to prevent loss of solution.



2

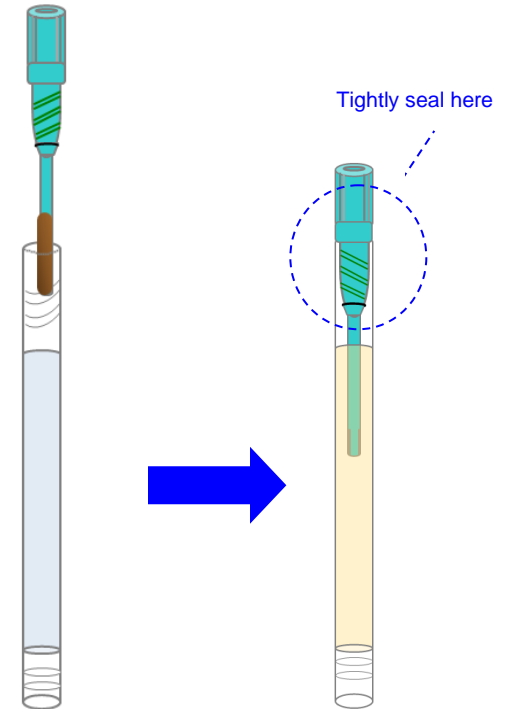
1. Hold the sampling lid by the **Thumb Grip**.
2. Use the tip of the sampling lid to collect a small amount of fecal sample at two or more sites. Only take the fecal sample that sticks to the sampling lid tip (never intentionally place any separate piece of fecal sample into the tube). The total amount of stool collected should be less than one grain of cooked rice. For liquid stool, collect 0.1 mL into the sampling tube.

Thumb Grip



3

1. Insert and screw the sampling lid back into the sampling tube **in a vertical position**. Do not spill any solution from the tube.
2. Tightly seal the lid with the tube.
3. Flush toilet.

**READ ALL THE INFORMATION IN THIS LEAFLET BEFORE SAMPLING**

Store at 2-8°C. Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally. Not to be sampled directly from anus. If you have any questions, please contact your physician or laboratory staff or call Epitepe Diagnostics at 858-693-7877 from 8:00 a.m. to 5:00 p.m. PST



Manufactured by Epitepe Diagnostics, Inc. San Diego CA 92121, USA

(V04/2019-06)

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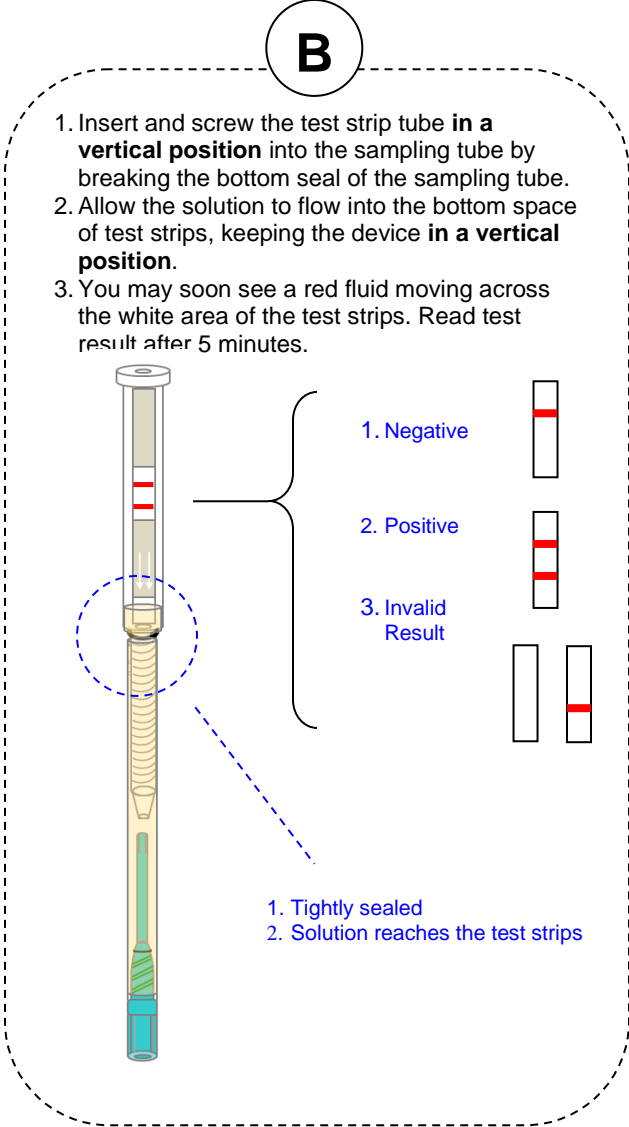
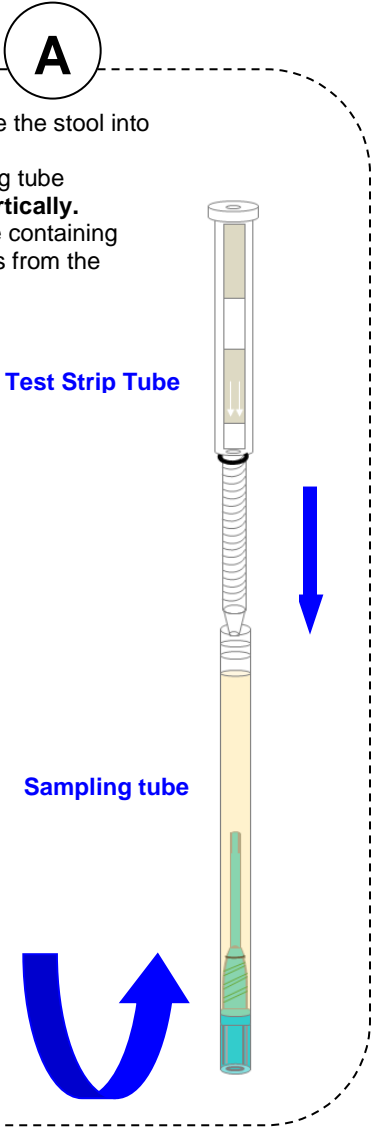


MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

US Patent: 7,780,915

EpiTuub® Calprotectin/i-FOB DUO Test - Instructions for Test Procedures

Monoclonal antibody based immunoassay test for the detection of bowel inflammation and bleeding



For In-Vitro Diagnostic Use

Catalog Number: KT-922 (30T/kit)
KT-922.10 (10T/kit)

INTENDED USE

This EpiTuub® Calprotectin/i-FOB Test Device is a rapid immunological test intended for the qualitative detection of both Calprotectin and occult blood in feces by professional laboratories and physician office laboratories. The test is used as an aid in the diagnosis of inflammatory bowel disease (Crohn's disease, ulcerative colitis), and bowel bleeding related to colorectal cancer, polyps, etc.

SUMMARY OF PHYSIOLOGY

Colorectal cancer is the third most common cancer in the world. The appearance of fecal occult blood is often the first indicator associated with colorectal cancer and polyps. Other disorders may also be associated with the presence of fecal occult blood, such as diverticulitis, Crohn's disease and ulcerative colitis. Calprotectin (MRP 8/14) is a heterodimer of two calcium-binding proteins present in the cytoplasm of neutrophils and expressed by the membranes of monocytes. It constitutes nearly 60% of the soluble cytosol proteins in neutrophils and plays a central role in neutrophils defense. Upon neutrophil activation or endothelial adhesion of monocytes, Calprotectin is released and may be detected in serum, body fluids or stool as a potentially useful clinical inflammatory marker.

TEST PRINCIPLE

The EpiTuub Calprotectin/i-FOB test is a "sandwich" immunoassay utilizing two monoclonal antibodies to specifically detect the presence of Calprotectin and blood in feces. It consists of two units, a fecal sampling device and a test strip tube. A stool specimen is collected into the sampling tube containing extraction solution. After mixing the stool sample, a test strip tube containing two test strips is screwed into the sampling tube by breaking the bottom seal of the sampling tube while maintaining a vertical position. The extracted fecal solution flows into the bottom space of the test strips and triggers the start of the Calprotectin and occult blood immunoassays. If the Calprotectin level is greater than 50 µg/g in a fecal sample, or the hemoglobin level is greater than 1 µg/g, an immuno-complex is formed. A red colored band appears in the test region, which is located in the lower half of the test membrane. A similar colored band must appear in the control region located in the upper half of the test membrane, indicating the test strip is functioning properly and the result is valid.

REAGENTS AND MATERIALS PROVIDED

1. Fecal specimen collection device (30436): contains sampling tube, sampling lid and pre-added extraction solution in the sampling tube. This device should be stored at 2 to 8°C. Do not freeze.

READ ALL THE INFORMATION IN THIS INSERT BEFORE TESTING
Store at 2-8°C. Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally. Not to be sampled directly from anus. If you have any questions, call customer information staff of Epitepe Diagnostics at 1-858-693-7877, 8:00 a.m. to 5:00 p.m. PST.



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EpiTuub[®] Calprotectin/i-FOB DUO Test - Instructions for Test Procedures

Monoclonal antibody based immunoassay test for the detection of bowel inflammation and bleeding

- Test strip tube (30660 and 30158): one dipstick for the Calprotectin/i-FOB DUO test is assembled as a two-in-one test containing 1 Calprotectin antigen test strip and 1 i-FOB antigen test strip that are back-to-back positioned in this tube. This tube is sealed in a foil pouch with desiccant. It should remain in its original sealed pouch until ready for use. The test strips should be stored at 2 to 8°C. Do not freeze.
- Instructions for use.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Timer or clock

PRECAUTIONS

- For in-vitro diagnostic use only. Not to be taken internally.
- Do not use product beyond the expiration date.
- Handle all specimens as potentially infectious.
- Do not reuse the test.

PATIENT PREPARATION

- Dietary restrictions are not necessary.

SPECIMEN COLLECTION

- Stool specimens can be collected at any time of the day.
- Collect a random sample of feces in a clean, dry cup or toilet paper or as indicated in the Figure 1.
- Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution.
- Insert and twist the tip of the sampling lid into the stool specimen at two or more different sites (Figure 2).
- Collect fecal sample that is stuck to the surface of the sampling lid. The total amount of stool sample should be less than one grain of cooked rice. Do not intentionally collect any separate and large pieces of fecal sample into the tube.
- Replace the sampling lid into the tube and secure tightly (Figure 3).
- The specimen is ready for testing, transportation or storage. It can be stored at 2-8°C for up to 21 days and at room temperature for up to 14 days.

TEST PROCEDURE

- Bring the sealed foil pouch test strips and collected specimens to room temperature.
- Shake the sampling tube vigorously to ensure a good liquid suspension.
- Position the sampling tube upside down vertically and let it settle for about 1 minute.
- Remove the test strip from the sealed foil pouch.
- Screw the test strip tube into the sampling tube by **breaking** the bottom seal of the sampling tube. Secure tightly! (Figure A)

- Allow the solution to flow into the bottom space of the test strip and keeping the device **in a vertical position**.
- Read test result at 5 minutes. Do not interpret test result after 10 minutes.

PROCEDURAL NOTES

- After the test strip tube is screwed completely into the sampling tube, a minimum of 5 mm extraction buffer liquid in the bottom of the strip tube should be seen.
- Liquid should be seen migrating across the membrane area right after the screw in process. If not, tap the tube against the table several times, and the migration of the liquid should be observed.

INTERPRETATION OF RESULTS

- Positive:**
If two red/pink colored bands are visible within 5 minutes, the test result is positive and valid (Figure B).
- Negative:**
If test area has no red/pink colored band and the control area displays a red/pink colored band, the test result is negative (Figure B). Refer to Limitation of the Procedure #4 for additional information.
- Invalid:**
If a colored band does not form in the control area regardless of there being any band in the test area, the test result is invalid (Figure B) and needs to be retested.

QUALITY CONTROL

Good laboratory practices recommend the use of appropriate controls. There are two types of controls for the EpiTuub[®] Calprotectin/i-FOB DUO test, the internal procedural control and external controls.

- Internal procedural control:** Each EpiTuub[®] Calprotectin/i-FOB DUO test has built-in procedural controls. They will appear if the test has been performed correctly, sample wicking has occurred and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of calprotectin or occult blood in the tested fecal sample.
- External controls:** It is recommended to use external positive controls. The external positive controls are not provided with this kit, but are commercially available from Epitope Diagnostics. External controls are used to assure that the test line antibody is reactive. However, external controls will not detect an error in performing the patient sample test procedure. It is recommended that the external controls be tested once per kit.

Follow local, state, and federal guidelines for running quality control.

LIMITATION OF THE PROCEDURE












- Urine and excessive dilution of fecal samples with water from toilet bowl may cause erroneous results.
- Intermittent tumor bleeding and irregular distribution of blood in the feces may contribute to false negative results.
- EpiTuub[®] Calprotectin/i-FOB DUO test is not for use in testing urine, gastric specimens or other body fluids.
- Only the red/pink test line should be considered to be positive. It was noticed that some negative fecal samples may form a gray or yellow line at test line.
- As with all diagnostic tests, the definitive clinical diagnosis must not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. EpiTuub[®] Calprotectin/i-FOB DUO test is designed for the preliminary screening and should not replace other diagnostic procedures.

PERFORMANCE CHARACTERISTICS

- Sensitivity: the device detects 0.5 µg Calprotectin and 1 µg hemoglobin per gram stool and higher concentrations in extracted buffer.
- Specificity: The Calprotectin rapid test does not cross-react to human albumin or hemoglobin. The FOB rapid test does not cross-react to Calprotectin or animal hemoglobin.

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	Manufacturer		For in vitro diagnostic use only
	Authorized representative		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
	Catalogue Code		Temperature limitation
	Lot Number		Use by
	Sample diluent		