



- **Patented, one-step, odorless, and self-contained test.**
- **FDA 510(k) approved.**
- **Test waived for doctors office (CLIA waived test).**
- **The most innovative fecal immunochemical test (FIT), CARE™ FOB uses the unique and advanced methodology breakthrough in FIT with higher sensitivity and specificity.**

Better Healthcare

- Human hemoglobin specific, greatly reduces false positive results.
- Test can be performed at physician's office lab (POL), clinical laboratories or hospital laboratories.
- High SENSITIVITY and SPECIFICITY.

Improved Compliance

FOR PATIENT:

- No dietary restrictions.
- Easy sample collection procedure without unpleasant feeling.
- Return mailer included.
- Each 20 test kit includes 25 patient sample collection packs and 25 return mailers.

FOR LAB STAFF:

- Simple assay procedure: just a screw-in process completes the whole assay procedure. It is CLIA waived and no training required.
- Easy test result interpretation: clearly visual interpretation.
- Improved safety: closed and self-contained test system that eliminates any possible contamination to specimen.
- This is the only odorless iFOB test on the market.
- Two monoclonal antibodies, highly specific to human hemoglobin.
- Recognizes only human blood without any cross reaction to animal blood.
- No interference from vegetables and Vitamin C pill, etc.
- Detects human blood in stool as low as 0.05µg h-hemoglobin per milliliter buffer.

High Specificity

High Sensitivity

Part #	Product	Description	Indication for different packages
KT313	CARE iFOBT Test Kit (20 tests/Kit)	20 Pouched Test Strip Tubes + 25 Sample Collection Packs + 25 Return Mailers	Suitable for patients to collect samples at home then mail back to clinical or physician office laboratory for testing
KT313.25	CARE iFOBT Test Kit	25 Pouched Test Strip Tubes + 25 Sample Collection Packs	Suitable for on site sample collection and testing. Save Money and Earth.
30158	CARE iFOBT Test Strip Tube	20 Pouched Test Strip Tubes	Suitable for laboratory to perform the testing only. The laboratory does not give out the sample collection pack directly to patients.
30159/30181	CARE iFOBT Sample Collection Kit	25 Sample Collection Packs + 25 Return Mailers	Suitable for outpatient clinic to give patients the sample collection pack then mail directly to the off site laboratory for testing.

CPT Code	Reimbursement	Use
G0328QW	USD 22.73	Screen code used for colorectal cancer screening by immunochemical FOB test.
82274QW	USD 22.73	Diagnostic code used for detection of blood in feces from whatever causes by immunoassay.

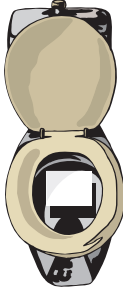


EPITOPE DIAGNOSTICS, INC.

7110 Carroll Road • San Diego, CA 92121 • Tel: 858-693-7877 • Fax: 858-693-7678

Patient Instructions

1. Collect a stool sample using the enclosed stool sampling paper:
 - a. Clean the bowl and flush the toilet two times. Unfold an lay the Sample Collection Paper directly on the top of the water in the toilet bowl (the paper should float above the water).



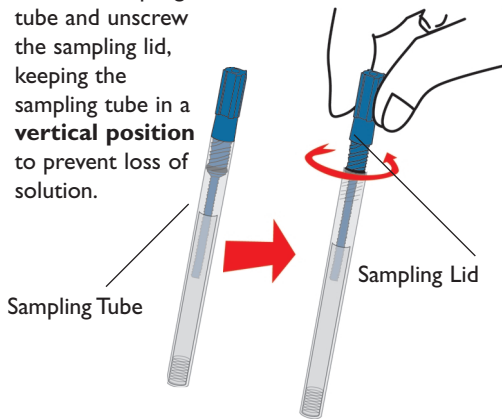
2. After bowel movement, proceed to Sample Collection Section.



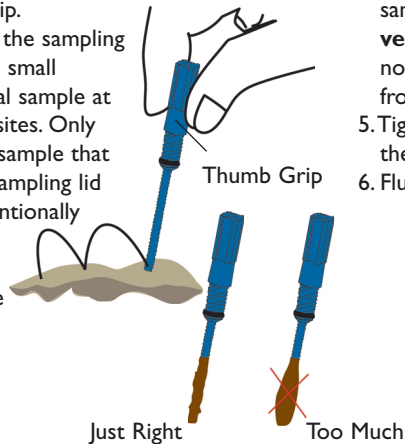
Easy sample collection procedure without unpleasant feeling.

Sample Collection

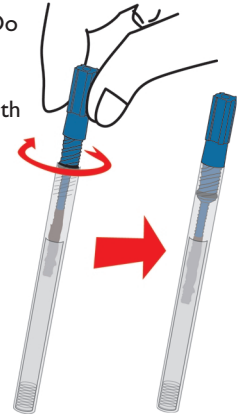
1. Take the sampling tube and unscrew the sampling lid, keeping the sampling tube in a **vertical position** to prevent loss of solution.



2. Hold the sampling lid by the Thumb Grip.
3. 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).

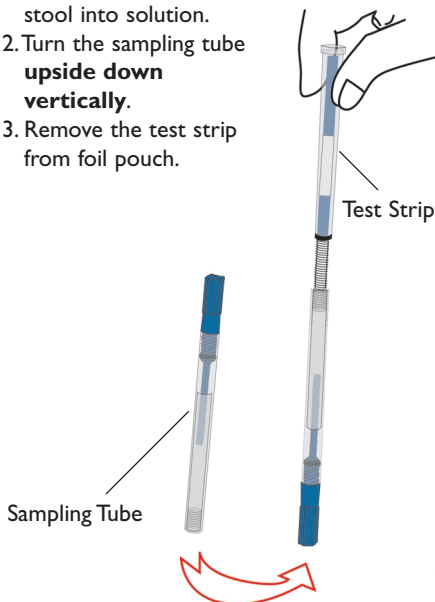


4. Insert and screw the sampling lid in a **vertical position**. Do not spill any solution from the tube.
5. Tightly seal the lid with the tube.
6. Flush the toilet.

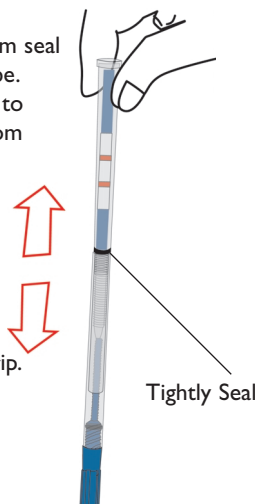


Test Procedure

1. Shake to dissolve the stool into solution.
2. Turn the sampling tube **upside down vertically**.
3. Remove the test strip from foil pouch.



4. Insert and screw the test strip **in a vertical position** into the sampling tube by breaking the bottom seal of the sampling tube.
5. Allow the solution to flow into the bottom space of test strip, keeping the device **in a vertical position**.
6. You may soon see a red fluid moving across the white area of the test strip.



7. Read test results in five minutes. **DO NOT INTERPRET RESULT AFTER 10 MINUTES.**

