

ACCU-TELL[®]**FOB Cassette (Feces)***For in vitro diagnostic use only**for Fecal sample***This package insert is applied to the below products:**

Catalog No.	Product Name
ABT-FOB-B22	FOB Cassette (Feces)

INTENDED USE

ACCU-TELL[®] FOB Cassette (Feces) is a rapid visual immunoassay for the qualitative, presumptive detection of human hemoglobin in human fecal specimens. This kit is intended for use as an aid in the diagnosis of lower gastrointestinal (g.i.) pathologies.

INTRODUCTION

Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer-related death in the United States. Screening for colorectal cancer is likely to improve the odds of detecting cancer at an early stage, reducing mortality. Earlier commercially available FOB tests utilized a guaiac test, requiring special dietary restrictions to minimize false positive and false negative results. ACCU-TELL[®] FOB Cassette (Feces) is designed especially to detect human hemoglobin in fecal samples using immunochemical methods, improving specificity for the detection of lower gastrointestinal disorders, including colorectal cancers and adenomas, without the need for dietary restrictions.

PRINCIPLE

ACCU-TELL[®] FOB Cassette (Feces) detects human hemoglobin through visual interpretation of color development on the internal strip. Anti-human hemoglobin antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-human hemoglobin antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient human hemoglobin in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS**Materials Provided**

- Test devices
- Specimen dilution tubes with buffer
- Package insert

Materials Required but Not Provided

- Timer
- Specimen collection container

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package.

Do not use the test if the foil pouch is damaged. Do not reuse tests.

- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The specimen dilution buffer contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of the specimen dilution buffer or extracted samples, always flush with copious quantities of water to prevent azide buildup.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

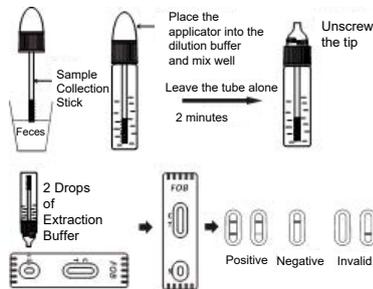
SPECIMEN COLLECTION AND STORAGE

- ACCU-TELL[®] FOB Cassette (Feces) is intended for use with human fecal specimens only.
- Patients should not collect samples during or within 3 days of their menstrual period if they have bleeding hemorrhoids, blood in the urine, or if they experienced strain during their bowel movement.
- Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
- No dietary restrictions are necessary before testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

- Specimen collection and pre-treatment:
 - Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces.
 - Replace the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
 - Shake the specimen collection tube vigorously to mix the specimen and extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20° C if not tested within 1 hour after preparation.
- Testing
 - Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
 - Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 2 drops of solution into the specimen well (S) of the test device. **Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.**
As the test begins to work, color will migrate across the membrane.
 - Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- ACCU-TELL® FOB Cassette (Feces) is for

- professional in vitro diagnostic use, and should only be used for the qualitative detection of human hemoglobin.
- The presence of blood in stool specimens may be due to causes other than colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritation.
- Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
- Urine and excessive dilution of specimens with toilet water may cause erroneous test results.
- This test may exhibit decreased sensitivity for upper gastrointestinal bleeding, as blood degrades as it passes through the gastrointestinal tract.
- Not all colorectal bleeding is due to precancerous or cancerous polyps. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Table:ACCU-TELL® FOB Cassette (Feces) vs. Another Commercially Available Rapid Test

Relative Sensitivity: >97.3% (95.0%-98.6%)*	Other Rapid Test				
		+	-	Total	
Relative Specificity: 98.5%(97.5%-99.1%)*	ACCU-TELL® FOB Cassette (Feces)	+	325	16	341
		-	9	1024	1033
Overall Agreement: >98.2%(97.3%-98.8%)*					
*95%Confidence Interval	Total		334	1040	1374

A. Analytical Sensitivity

Specimens containing human hemoglobin at concentrations of 40 ng/mL or above produce a positive result. In some cases, specimens containing human hemoglobin at concentrations of less than 40 ng/mL can produce positive results.

B. Hook or Prozone effect:

Specimens containing as much as 1 mg/mL hemoglobin can still test positive. Tests do not show a hook or prozone Effect up to maximum observed physiological concentrations (1 mg/mL). Thus, the working range of the FOB Rapid Test Device (Feces) is from 40 ng/mL to 1 mg/mL.

C. Analytical Specificity:

The test is specific for human hemoglobin and does not show any cross-reaction with hemoglobin from b pig, bovine, chicken, goat, rabbit, horse, turkey at concentrations up to 1mg/mL.

D. Interfering Substances

No substances listed interference with the test

Analytes	Concentration	Analytes	Concentration
Ascorbic acid	20mg/dL	Urea	2000mg/mL
Oxalic acid	60mg/dL	Glucose	2000mg/dL
Bilirubin	100mg/dL	Caffeine	40mg/dL
Uric acid	60mg/dL	Albumin	2000mg/dL
Aspirin	20mg/dL		

LITERATURE REFERENCES

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PRAXISDIENST
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GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse