Hemoccult® BRAND ICT

Immunochemical Fecal Occult Blood Test

BECKMAN COULTER

Background

The Hemoccult® ICT (Immunochemical Test) is a rapid, visually read, qualitative immunochemical chromatographic method for detection of human hemoglobin from blood in fecal samples. Fecal occult blood tests are useful screening aids for detecting primarily lower gastrointestinal (g.i.) disorders that may be related to iron deficiency anemia, diverticulitis, ulcerative colitis, polyps, adenomas, colorectal cancers or other g.i. lesions that can bleed. Hemoccult® ICT is recommended for use by health professionals as part of routine physical examinations or when lower g.i. disorders are suspected.

Specimen Preparation, Collection and Handling

Patient Preparation

No special drug or dietary restrictions are required for this test. However, patients should closely follow the Patient Instructions to assure the most accurate test results. Patients should not collect samples three days before, during or three days after their menstrual period, if they have bleeding hemorrhoids, blood in their urine, open cuts on their hands, or if they have strained during their bowel movement. Roughage in the diet can increase test accuracy by helping uncover "silent" lesions which bleed intermittently.

Specimen Collection and Handling

The Hemoccult® ICT test is intended for human fecal samples. Handle all patient samples, controls, and test components as biohazardous. Proper disposal methods should be followed.

Materials Provided

- Hemoccult® ICT Test Devices
- Hemoccult® ICT Buffer

Storage and Stability

Store product at 2 to 8° C; DO NOT FREEZE. When stored as directed, Hemoccult® ICT Test Devices and components are stable until their labeled expiration dates. Alternatively, the Hemoccult® ICT Test Device Kit may be stored at controlled room temperature, 15 to 30° C for up to 90 days. Under these storage conditions, the kit expires 90 days from the date it is placed at room temperature or the stated expiration date on the kit, whichever occurs first. If the product is stored at room temperature, the room temperature expiration date should be written on the outside of the kit box.

Materials Required (but not provided)

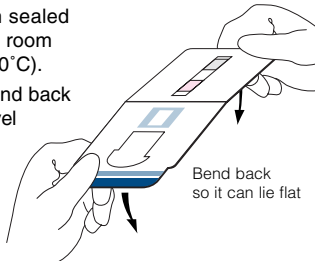
- Hemoccult® ICT Collection Cards (Product No. 395065), or
- Hemoccult® ICT Patient Screening Kits (Product No. 395066, Three-day Kit, or Product No. 395261, Two-day Kit)

Procedure

IMPORTANT **Do not touch patient sample, test strip, or pads on Test Device with reagent bottles or hands.**

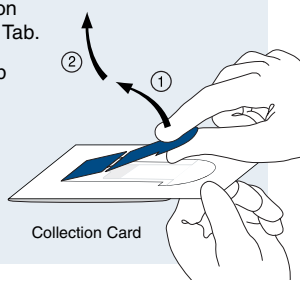
1

- Bring Test Device (in sealed pouch) and Buffer to room temperature (15 to 30˚C).
- Open Test Device, bend back and **lay it flat** on a level surface.



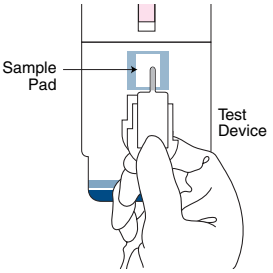
2

- From **back** of Collection Card, remove Sample Tab.
- Lift up blue Sample Tab from bottom.
- Pull off as shown.



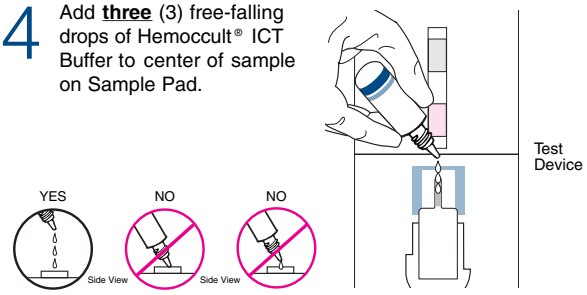
3

Place Sample Tab, **blue side down** in Test Device with fecal sample on top of Sample Pad.



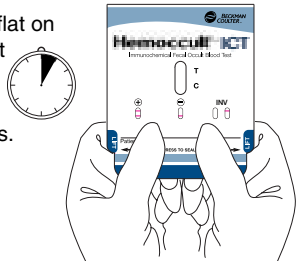
4

Add **three** (3) free-falling drops of Hemoccult® ICT Buffer to center of sample on Sample Pad.

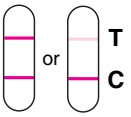


5

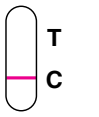
- With Test Device flat on surface, snap Test Device closed.
- Keeping device flat, wait 5 minutes.
- Read test Result. (DO NOT reopen Test Device.)



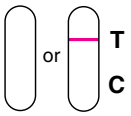
Interpretation of Test Results



Positive Test
The test is **positive** (⊕) indicating the presence of fecal occult blood above the threshold of normal if two pink lines, Test (**T**) and Control (**C**), are visible in the Reading Window. Any trace of a pink line in the Test Line area is a positive test result. (see NOTES)



Negative Test
The test is **negative** (⊖) indicating no fecal occult blood was detected if only the Control Line is visible and there is no trace of a pink line in the Test Line area.



Invalid Test
The test is **invalid** (**INV**) if the Control Line does not appear. If this occurs, the test should be repeated (see NOTES).

NOTES:

- **The test result is positive even if the Test Line appears lighter or darker than the Control Line.**
- Positive test results may appear before 5 minutes. To verify a negative test result, wait the full 5 minutes after closing the Test Device. To avoid misinterpretation, do not interpret results after 5 minutes.
- Neither the intensity nor the shade of the Test Line produced by the external Positive Control should be used as a reference for the appearance of a positive test result.
- Discard used Collection Cards and Test Devices in proper waste containers, as they contain potentially infectious agents.
- If an invalid test result occurs repeatedly or for technical assistance, call Technical Marketing at 800-877-6242 or email askpcd@beckman.com.
- If there is no buffer flow within 30 seconds, re-open Test Device, add one drop of buffer to the center of the Sample Pad, re-snap Test Device closed, wait 5 minutes, and read test result

Quality Control

Hemoccult® ICT Control Procedure

- Add one (1) drop of Positive or Negative Control to the Sample Pad.
- Add two (2) drops of Hemoccult® ICT Buffer.
- Snap Test Device closed. Wait 5 minutes and read test result (step 5 of Test Procedure).

Controls Built Into the Test Device

Hemoccult® ICT contains built-in procedural controls including a positive Control Line and a negative background control area on the test strip. A test is valid when the built-in procedural controls perform as indicated, assuring that the Test Device and Buffer reagents are functioning properly and that the procedure has been performed correctly.

The positive Control Line contains immobilized conjugate-specific antibodies. A visible pink color on the positive Control Line indicates that the conjugate (located on the Test Strip) was properly rehydrated, flowed through the Test and Control Line areas, the Control Line antibodies were immunoreactive and the conjugate was intact. If the positive Control Line does not turn pink, the test is invalid. Since the Test Line and conjugate contain the same antibodies, the appearance of a Control Line also indicates that these antibodies are functional.

The negative background control area is the region just below the Control Line on the Test Strip. A white to light pink background color in this region indicates that the reagents and conjugate-sample complex, if formed, flowed properly. If distinct areas of dark pink remain in the window below the Control Line, the test is invalid.

To monitor test validity, the built-in procedural controls should be observed for each patient test performed. Patient test results should not be reported when the built-in controls indicate an invalid test.

External Quality Control

Good laboratory practice recommends the use of external controls to assure the functionality of reagents and proper performance of the test procedure. If your laboratory quality assurance plan requires external control testing, Hemoccult® ICT Controls (Product No. 395068) are available for this purpose; the Positive Control contains stabilized human hemoglobin and the Negative Control contains a buffer matrix. If you are running Hemoccult® ICT for the first time, it is recommended that external controls be tested and the correct results obtained before proceeding to patient samples.

Precautions

- For *in vitro* Diagnostic Use.
- CAUTION: Observe universal safety precautions and other appropriate laboratory procedures when collecting and handling patient fecal samples. All samples and materials that come in contact with them should be handled as potentially infectious.

- Use Hemoccult® ICT Collection Cards in the single card kits (Product No. 395065) or Patient Screening Kits (Product No. 395066 or Product No. 395261) for preparing fecal samples.
- DO NOT remove Test Devices from protective foil pouches until ready to use.
- DO NOT use Test Devices and reagents beyond their labeled expiration dates.
- Do NOT use any reagents from a container that appears to have leaked.
- WARNING: The buffer contains sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide buildup. Avoid reagent contact with eyes, mucous membranes or skin lesions. If contact occurs, flush affected area with water for 15 minutes and consult a physician.

Limitations

- Hemoccult® ICT is a valuable aid to the physician in early detection of lower g.i. disorders that bleed. However, bowel lesions, including some polyps and colorectal cancers, may bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples and a test result may be negative even when blood or g.i. disease is present.
- As with any occult blood test, results obtained with Hemoccult® ICT should not be considered conclusive evidence of the presence or absence of g.i. bleeding or pathology. Hemoccult® ICT is designed for preliminary screening. It is not intended to replace other diagnostic procedures such as colonoscopy, or sigmoidoscopy in combination with double contrast barium x-ray.
- Because blood degrades as it passes through the g.i. tract, possibly losing its immunochemically reactive properties, Hemoccult® ICT may be less sensitive than guaiac-based fecal occult methods for detecting upper g.i. bleeding.
- Urine and excessive dilution of samples with water from the toilet bowl may cause erroneous test results. For best results, collect samples as instructed in the Patient Instructions included in each Hemoccult® ICT Patient Screening Kit (Product No. 395066 or 395261) or the Sample Collection Instructions included in the Hemoccult® ICT Collection Cards (Product No. 395065).
- Hemoccult® ICT is not for use in testing urine, gastric specimens, or other body fluids.

References

Refer to Manufacturer's Instructions.

Review and Update

A. Reviewed By: _____

B. Title: _____

C. Review Date: _____

Technical assistance may be obtained by calling 1-800-877-6242 or by sending an email to askpcd@beckman.com

Manufactured by:

Beckman Coulter, Inc.
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