Beckman Coulter, Inc.
4300 N. Harbor Blvd.
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Safe...Simple...Life-Saving

Hemoccult®ICT
Immunochemical Fecal Occult Blood Test

Collection Card   Test Device

PRODUCT INSTRUCTIONS

IVD

[1]Product of Beckman Coulter, Inc.

INTENDED USE / INDICATIONS FOR USE

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.

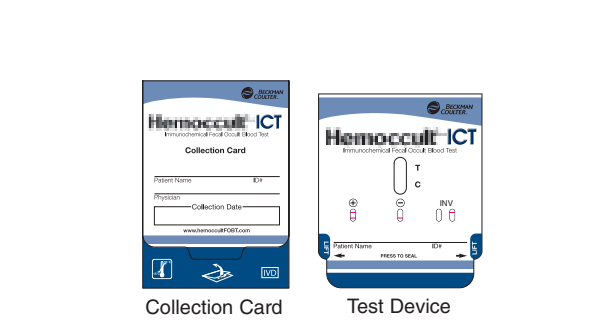## SUMMARY AND EXPLANATION OF THE TEST

The fecal occult blood test was described for general medical use more than 50 years ago.[1] The first commercial standardized fecal occult blood tests were guaiac (leucocyte) tests such as Hemoccult®[1]. The active ingredients, guaiac-treated filter paper and hydrogen peroxide, react with hemoglobin or other substances(e.g.,hematin and heme,as well as peroxidases from fruits and vegetables) to give a visible blue color. Hemoccult® is designed for testing fecal samples promptly after defecation and drying to stabilize the hemoglobin, if present.[2] The principal use of these tests is to screen for lower g.i. pathologies such as colorectal cancers and large adenomas that bleed. A number of long-term randomized controlled trials and case-control studies using Hemoccult® have reported a significant reduction in mortality from the early detection of colorectal cancer.[3-7] Hemoccult® tests can detect bleeding from both upper and lower g.i. lesions, but they require that patients follow dietary restrictions to minimize false-positive and false-negative results.[2,8] Dietary restrictions are not well tolerated, reduce patient compliance and, if not adhered to, can increase the cost of following up positive test results.[10,11]

Immunochemical fecal occult blood tests, such as HemeSelect® and Hemoccult® ICT, are specifically designed to detect human hemoglobin in dried fecal samples.[9,10] Hemoccult® ICT contains polyclonal anti-human hemoglobin antibodies that react with the globin portion of undegraded hemoglobin. Hemoglobin from upper g.i. bleeding (i.e., oral cavity, esophagus, stomach or small intestine) is generally degraded by bacterial and digestive enzymes before reaching the large intestine and is therefore rendered immunochemically non-reactive.[2,8,11-15] Conversely, hemoglobinfrom lower g.i. bleeding (i.e., cecum, colon or rectum) undergoes less degradation and can therefore remain immunochemically reactive. Thus, immunochemical fecal occult blood tests which detect undegraded hemoglobin have increased biological specificity for lower g.i. bleeding and any associated pathology.[2,9,11-15] Because Hemoccult® ICT is specific for human blood in feces, no special dietary restrictions are required. Immunochemical fecal occult blood test methods have improved specificity for the detection of lower g.i. disorders that bleed, including colorectal cancers and adenomas, and can lower the overall cost of detecting these disorders. All fecal occult blood tests are subject to certain limitations such aslesions that bleed intermittently and non-uniform distribution of blood in feces. Detection of occult blood is not always an indication of g.i. pathology (see LIMITATIONS OF PROCEDURE).

PRINCIPLES OF THE PROCEDURE

Hemoccult® ICT uses the principle of immunochromatography to detect human hemoglobin from blood in fecal samples. The test requires a Collection Card and a Test Device for each fecal sample. A portion of feces from two different areas of the stool is applied in a thin smear to the Collection Card which serves as a means to transport the sample to the testing site.The dried sample is transferred from the Collection Card to the Test Device using a pull-out Sample Tab. Next it is rehydrated with buffer to extract the hemoglobin, if present, from the sample. When the Test Device is closed, the sample is brought into contact with the test strip which initiates chromatographic flow. The sample flows down the test strip, rehydrates the colloidal gold anti-human hemoglobin antibody conjugate and, if hemoglobin is present in the sample, forms a hemoglobin-conjugate immune complex. The complex is then captured on the test strip in a zone containing anti-human hemoglobin antibodies to form a visible Test Line – a *positive* test. No Test Line forms in the absence of human hemoglobin in the sample – a *negative* test. Unbound conjugate continues to migrate down the test strip and binds to the Control Line which contains conjugate-specific antibodies.[19]

MATERIALS

Materials provided:
- **Hemoccult® ICT Test Devices** containing goat anti-human hemoglobin polyclonal antibodies (Test Line), conjugate-specific polyclonal antibodies (Control Line), and goat anti-human hemoglobin conjugate (polyclonal antibodies bound to colored particles); all antibodies are from a U.S. source.
- **Hemoccult® ICT Buffer** (8 mL) containing phosphate buffered saline, bovine serum albumin (from a U.S. source), and 0.09% sodium azide.

Materials required but not provided:
- Hemoccult® ICT Collection Cards, available separately:
  Single Collection Cards (Product No. 395065)
  Patient Screening Kits (Product No. 395066)
- Timer

PRECAUTIONS

1. For *In vitro* Diagnostic Use.
2. 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.
3. Use Hemoccult® ICT Collection Cards in the single card kits (Product No. 395065) or Patient Screening Kits (Product No. 395066) for preparing fecal samples.
4. DO NOT remove Test Devices from protective foil pouches until ready to use.
5. DO NOT use Test Devices and reagents beyond their labeled expiration dates.
6. DO NOT use any reagents from a container that appears to have leaked.
7. 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.

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 30 days. Under these storage conditions, the kit expires 30 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.
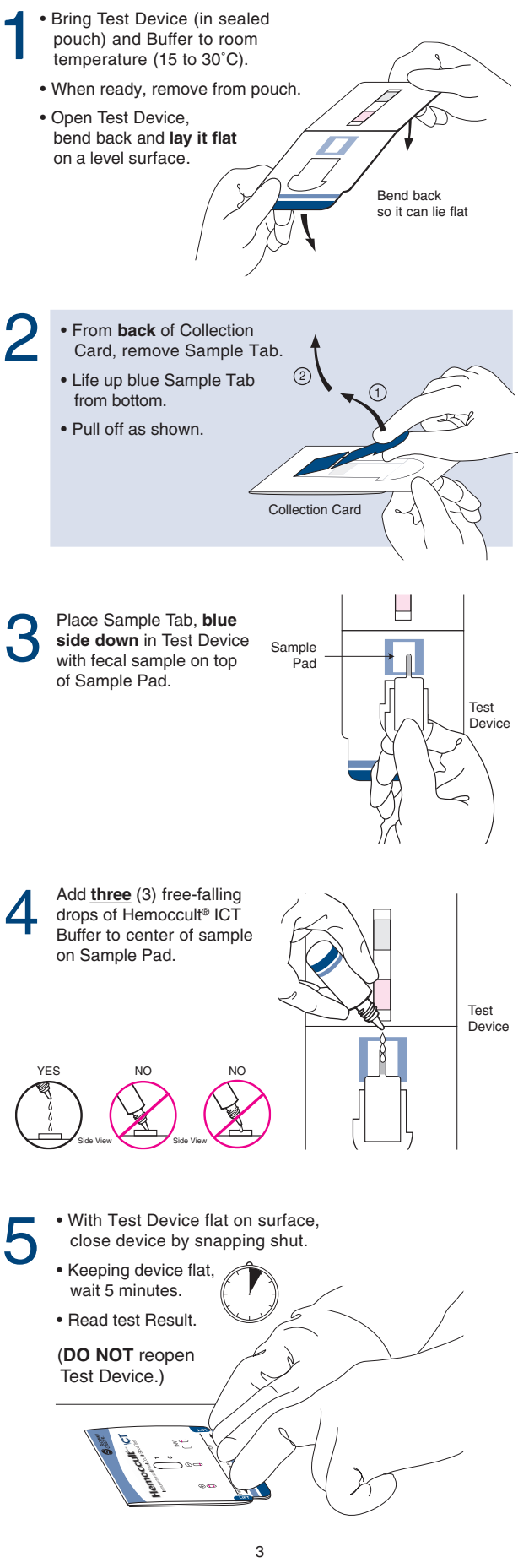
PATIENT PREPARATION

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.[20]

SAMPLE COLLECTION AND STORAGE

Physician Instructions and Patient Instructions for sample collection and handling are included in the Hemoccult® ICT Collection Cards (Product No. 395065) and Hemoccult® ICT Patient Screening Kits (Product No. 395066). Dried fecal samples, when collected and stored as directed, are stable for up to 14 days at room temperature.[21]

TEST PROCEDURE

⚠️ **IMPORTANT** Keep Test Device level when handling. 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).
- When ready, remove from pouch.
- Open Test Device, bend back and lay it flat on a level surface.

Bend back so it can lie flat

2
- From back of Collection Card, remove Sample Tab.
- Life up blue Sample Tab from bottom.
- Pull off as shown.

Collection Card

3
Place Sample Tab, blue side down in Test Device with fecal sample on top of Sample Pad.

Sample Pad
Test Device

4
Add three (3) free-falling drops of Hemoccult® ICT Buffer to center of sample on Sample Pad.

YES   NO   NO

Test Device

5
- With Test Device flat on surface, close device by snapping shut.
- 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 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 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 650-845-3526 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 NegativeControl 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.

LIMITATIONS OF THE PROCEDURE

1. Hemoccult® ICTis 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.

2. 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.

3. Because blood degrades as it passes through the g.i. tract, with possibly losing its immunochemically reactive properties, Hemoccult® ICT may be less sensitive than guaiac-based fecal occult blood methods for detecting upper g.i. bleeding.[2,14-19]

4. Urine and excessive dilution of samples with water from the toilet bowl may cause erroneous test results. For best results, use the collection tissues included in the Hemoccult® ICT Collection Kit.

5. Hemoccult® ICT is not for use in testing urine, gastric specimens, or other body fluids.

EXPECTED VALUES

Positivity rates with immunochemical fecal occult blood tests have been shown to vary in each patient population depending on the test used, age, ethnicity, predisposition to colorectal disease, and other factors that may be associated with lower g.i. lesions that bleed.[2,14-18]

Immunochemical fecal occult blood test positivity rates of approximately 2% should be expected in a screening population of average risk, asymptomatic individuals, age 50 or older. The Hemoccult® ICT positivity rate was approximately 2% in a group of 88 young, presumed normal volunteers, ages 17-33, who did not follow a restricted diet. The Hemoccult® ICT positivity rate and estimated positive predictive value for colorectal neoplasia were 1.8% and 15.6%, respectively, in a group of 1734 average risk individuals, ages 41-97, who followed a restricted diet. Among high risk patients, Hemoccult® ICT had a clinical sensitivity of 90% for colorectal cancer and 28% for large adenomas; in this study, Hemoccult® ICT had low sensitivity for non-neoplastic colorectal lesions (see CLINICAL PERFORMANCE).[21]

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
In vitro studies, following the recommended procedures for sample collection andstorage,demonstrated that 95% of the time Hemoccult® ICT detected 0.2 mL of added blood per 100 g of feces (1 mL of blood/100 g feces is on average 1.5 mg Hb/g feces).Assuming an average transit time of 24 hours and degradation of 80 to 90% of the hemoglobin in the feces, this level of blood is approximately equal to 2 to 3 mL of daily in vivo bleeding. A daily blood loss of 2 to 3 mL is generally considered the lower limit for abnormal bleeding and may be indicative of g.i. pathology.[2,12,19] Hemoccult® ICT reliably detected added blood levels of up to 17 mL per 100 g of feces. At this level and above, blood is generally visible in the stool.

Cross Reactivity
Hemoccult® ICT was examined *in vitro* by spiking fecal samples with myoglobin from horse and hemoglobin from beef, chicken, fish, horse, pig, rabbit, goat, sheep and turkey, to determine whether dietary substances cross reacted with the test. Spiked fecal samples were incubated at 37˚C for 24 hours prior to testing to mimic the transit time in the colon. Hemoccult® ICT gave negative test results when tested with these substances at a concentration of 5 mg/g feces, a level in excess of normal dietary intake which consistently gave positive results with guaiac-based tests.[21]

Effect of Diet
Hemoccult® ICT does not require the patient to follow any special dietary restrictions. Fecal samples from different individuals were spiked with 25 mg/g feces of horseradish peroxidase and 25 mg/g feces of ferrous sulfate to check for possible false-positive test results, and with a mixture of 25 mg/g feces vitamin *C* and 5 mg/g feces of human hemoglobin to check for possible false-negative test results. These studies demonstrated that Hemoccult® ICT was not affected by abnormally high concentrations of substances shown to cause false-positive or false-negative results with guaiac-based tests.[21]

Reproducibility
The *within-site* and *between-site* reproducibility of Hemoccult® ICT was evaluated in blind studies using Collection Cards smeared with fecal samples spiked with a range of blood levels to give negative (0 mg human Hb/g feces), borderline positive (0.075 mg human Hb/g feces),

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PERFORMANCE CHARACTERISTICS (cont.)

and positive (0.75 mg human Hb/g feces) test results. The *within-site* study was performed by three technicians, working independently in the same laboratory, who tested each sample 10 times. The *within-site* reproducibility was 100% (90/90). The *between-site* study was performed by three individual technicians, working in three geographically separated locations, who tested each sample 10 times. The *between-site* reproducibility was 97% (30/30 for the negative sample, 30/30 for the positive sample and 27/30 for the borderline positive sample).[21]

Readability
Comparable results were obtained with both experienced and inexperienced reader groups, each testing blind-coded fecal samples spiked with low to moderate levels of human blood. The "experienced" group was comprised of three in-house technicians who had used the test extensively, one with a doctorate degree and two with BA/BS degrees. The "inexperienced" group consisted of 16 individuals with varied educational backgrounds from High School to M.D. located in the U.S., Europe, Australia and Canada. Greater than 95% positive results were found by a group including both experienced and inexperienced readers with levels of blood at or above the analytical threshold of the test. The results of this study demonstrate that Hemoccult® ICT is easily interpreted by users of different skills, training and experience.

CLINICAL PERFORMANCE

Average Risk Screening Study
The test positivity rate,estimated positive predictive value, relative sensitivity, and false positivity rate for lower g.i. pathology, based on the detection of bleeding, was evaluated using Hemoccult® ICT and Hemoccult® in a group of 1734 asymptomatic, average risk individuals following the usual dietary restrictions for guaiac-based tests (44% male, 56% female, ages 41-97 and having an ethnic background of 93% Caucasian, 3% African American, 2% Hispanic,1% Asian, and 1% other races). Individuals with a positive result on Hemoccult® or Hemoccult® ICT were scheduled for follow-up colonoscopy to confirm the presence or absence of any lower g.i. pathology. Patients who were negative by both fecal occult blood tests were "presumed" to be negative for lower g.i. pathology.[21]

The test positivity rates were 1.8% (32/1734) for Hemoccult® ICT and 2.9% (51/1734) for Hemoccult® (TABLE1). In order to estimate the sensitivity, positive predictive value, and false positivity rate, the results obtained were independently compared directly to clinical pathology findings. As expected in an average risk screening population, few cases of colorectal neoplasia were found; these data are summarized in TABLE 1. The estimated positive predictive value for colorectal neoplasia was 15.6% (5/32) for Hemoccult® ICT and 3.9% (2/51) for Hemoccult®. The false positivity rate for other g.i. pathology was 0.9% (15/1681) for Hemoccult® ICT and 1.2% (20/1681) for Hemoccult®. The apparent specificity was 99.1% for Hemoccult® ICT and 98.8% for Hemoccult®.

TABLE 1
AVERAGE RISK SCREENING STUDY
Hemoccult® ICT and Hemoccult® vs. Clinical Pathology

	Hemoccult® ICT	Hemoccult®
Test Positivity Rate	1.8% (32/1734) [1-3%]*	2.9% (51/1734) [2-4%]
Estimated Positive Predictive Value		
Colorectal Neoplasia**	15.6% (5/32) [5-33%]	3.9% (2/51) [0-14%]
Any G.I. Pathology	53.1% (17/32) [35-71%]	60.8% (31/51) [46-74%]
Sensitivity for Specified Pathology		
Colorectal Cancer	1/1	1/1
Adenomas ≥ 1 cm	4/4	1/4
Colorectal Neoplasia**	5/5	2/5
False Positivity Rate		
Colorectal Neoplasia**	1.6% (27/1729) [1-2%]	2.8% (49/1729) [2-4%]
Any Lower G.I. Pathology	0.9% (15/1681) [0-1%]	1.2% (20/1681) [0-2%]
Apparent Specificity†	99.1%	98.8%

* 95% confidence interval in brackets [ ]
** Colorectal cancer and adenomas ≥ 1 cm
† Apparent specificity for any g.i. pathology was determined by subtracting the false positivity rate from 100%.

Average Risk Screening Study– Detection of Lower G.I. Pathology
The relative sensitivity of Hemoccult® ICT and Hemoccult® for lower g.i. disorders, including colorectal neoplasia, was determined from the data presented in TABLE 1 (Average Risk Screening Study), and is presented in TABLE 2.[18]

TABLE 2
AVERAGE RISK SCREENING STUDY
Relative Sensitivity for Lower G.I. Pathologies

	Hemoccult® ICT	Hemoccult®
Relative Sensitivity for Significant Pathology		
Colorectal Cancers	1/1	1/1
Adenomas ≥ 1 cm	4/4	1/4
Colorectal Neoplasia**	5/5	2/5
Relative Sensitivity for Other Pathology	25% (12/48) [14-40%]*	60% (29/48) [45-74%]
Adenomas < 1 cm	4/9	5/9
Hyperplastic Polyps	2/11	8/11
Ulcerative Colitis	0/1	1/1
Irritable Bowel	1/1	0/1
Diverticular Disease	3/16	9/16
Hemorrhoids/Anal Fissures	1/9	6/9
Other Lower G.I. Disorders	1/1	0/1

* 95% confidence interval in brackets [ ]
** Colorectal cancer and adenomas ≥ 1 cm

Clinical Sensitivity in a High Risk Population Study
High risk patients with a personal or family history of colorectal neoplasia and/or physical signs or symptoms suggestive of lower g.i. disorders were recruited for a study designed to evaluate fecal occult blood tests relative to clinical pathology. A diagnostic work-up was performed on all patients using either colonoscopy or a combination of flexible sigmoidoscopy and double contrast barium x-ray. A clinical diagnosis based on endoscopy was made for each patient and compared to test results.[21]

A comparison of Hemoccult® ICT and Hemoccult® versus clinical diagnosis of colorectal neoplasia was completed for 45 patients (TABLE 3). The clinical sensitivity of Hemoccult® ICT and Hemoccult® for colorectal cancer was 90% (18/20); the clinical sensitivity of Hemoccult® ICT for large adenomas was 28% (7/25) and for Hemoccult® was 20% (5/25). The clinical sensitivity of Hemoccult® ICT for colorectal neoplasia (cancers and large adenomas combined) was 56% (25/45) and for Hemoccult® was 51% (23/45).[21]

TABLE 3
HIGH RISK POPULATION STUDY
Hemoccult® ICT and Hemoccult® vs. Clinical Pathology

	Hemoccult® ICT	Hemoccult®
Clinical Sensitivity		
Colorectal Cancer	90% (18/20)	90% (18/20)
Adenomas ≥ 1 cm	28% (7/25)	20% (5/25)
Colorectal Neoplasia**	56% (25/45) [40-70%]*	51% (23/45) [36-66%]

* 95% confidence interval in brackets [ ]
** Colorectal cancer and adenomas ≥ 1 cm

To evaluate the performance of Hemoccult® ICT and HemeSelect® (reference immunochemical test) versus clinical diagnosis of colorectal neoplasia, a study was completed with 53 patients. Hemoccult® ICT and HemeSelect® had a clinical sensitivity for colorectal cancer of 90% (27/30); Hemoccult® ICT had a clinical sensitivity of 30% (7/23) for large adenomas, and HemeSelect® had a clinical sensitivity of 26% (6/23) for large adenomas. The clinical sensitivityfor colorectal neoplasia (cancers and large adenomas combined) was 64% (34/53) for Hemoccult® ICT and 62% (33/53) for HemeSelect®.[21]

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PRODUCT INFORMATION

Hemoccult® ICT is CLIA Waived.

Product Name	Product No.
Hemoccult® ICT Collection Cards (case of 10 boxes)	395065

Each box contains:
- 100 Collection Cards
- 100 Applicator Sticks
- 1 Physician Instructions
- 1 Sample Collection Instructions

Hemoccult® ICT Patient Screening Kits (case of 4 boxes)	395066

Each box contains:
- 40 Patient Screening Kits
- 1 Physician Instructions

Each Patient Screening Kit contains:
- 1 Dispensing Envelope with Patient Instructions
- 3 Hemoccult® ICT Collection Cards
- 3 Flushable Collection Tissues
- 3 Applicator Sticks
- 1 Mailing Pouch

Hemoccult® ICT Tests (case of 4 boxes)	395067

Each box contains:
- 20 Test Devices
- 1 bottle Hemoccult® ICT Buffer/8.0 mL
- 1 Product Instructions
- (To be used with Hemoccult® ICT Collection Cards Product No. 395065 and Patient Screening Kits Product No. 395066)

Hemoccult® ICT Controls (case of 4 boxes)	395068

Each box contains:
- 4 bottles (2 Positive and 2 Negative/0.8 mL each)
- 1 Controls Product Instructions

For more information visit www.hemoccultFOBT.com.

For technical assistance call Technical Marketing at 800–877–6242 or 650–845–3526 or e-mail askpcd@beckman.com.

To order product, contact your medical supply distributor.

SYMBOL KEY

Symbol	Description	Symbol	Description
⊕	Positive	⧖	Expiration
⊖	Negative		Open here
INV	Invalid		Store at room temperature
	Manufactured by		Refrigerate
IVD	For *In Vitro* Diagnostic Use		Do not freeze
LOT	Lot number		