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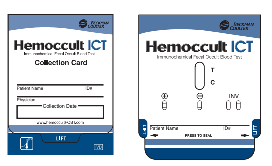
Safe...Simple...Life-Saving

Hemoccult ICT

Immunochemical Fecal Occult Blood Test



Collection Card Test Device

PRODUCT INSTRUCTIONS

IVD CE

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 (leucodye) tests such as Hemoccult[†]. 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.[2,9,11-15] Conversely, hemoglobin from 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 as lesions 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]

[†]Product of Beckman Coulter, Inc.

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 (REF 395065)
  Patient Screening Kits, 3 Day (REF 395066)
  Patient Screening Kits, 2 Day (REF 395261)
  Hemoccult ICT Controls, 2 Positive and 2 Negative (REF 395068)
- 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 (REF 395065) or Patient Screening Kits (REF 395066 or 395261) 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 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.

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]

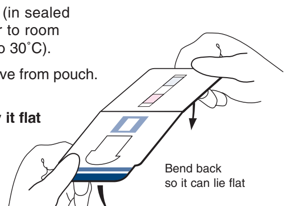
SAMPLE COLLECTION AND STORAGE

Physician Instructions and Patient Instructions for sample collection and handling are included in the Hemoccult ICT Collection Cards (REF 395065) and Hemoccult ICT Patient Screening Kits (REF 395066 and 395261). Dried fecal samples, when collected and stored as directed, are stable for up to 14 days at room temperature.[21]

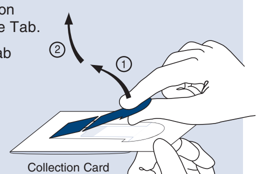
TEST PROCEDURE

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

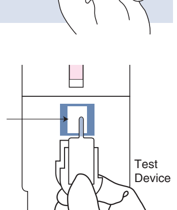
1
- Bring Test Device (in sealed pouch) and Buffer to room temperature (15 to 30˚C).
- When ready, remove from pouch.
- Open Test Device, bend back and **lay it flat** on a level surface.



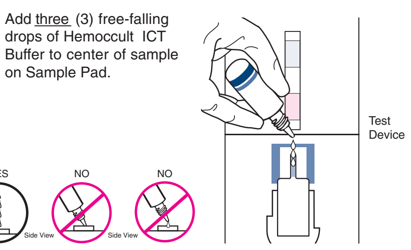
2
- From back of Collection Card, remove Sample Tab.
- Lift up blue Sample Tab from bottom.
- Pull off as shown.



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

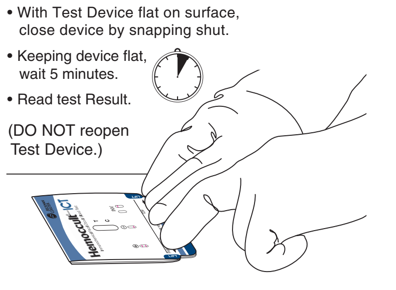


4 Add three (3) free-falling drops of Hemoccult ICT Buffer to center of sample on Sample Pad.

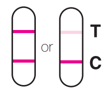


5
- With Test Device flat on surface, close device by snapping shut.
- Keeping device flat, wait 5 minutes.
- Read test Result.

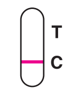
(DO NOT reopen Test Device.)



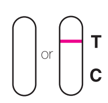
INTERPRETATION OF TEST RESULTS



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 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 e-mail askpcd@beckman.com. If outside the North American continent, please use: +41 22 365 37 36.
- 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 (REF 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.

LIMITATIONS OF THE PROCEDURE

1. 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.
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.
6. The American Cancer Society cautions a fecal immunochemical test (FIT) done during a digital rectal exam in the doctor's office is not adequate for screening. For a FIT used as a screening test, the take-home multiple sample method should be used.

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 was evaluated using multi-day fecal collections (all returned collections of the three dispensed slides regardless of number of days), one day fecal collections (day one results only), two day collections (day one and day two results) and three day collections (only those individuals who returned all three days of fecal collections). The positivity rate for multi-day collections was approximately 2% in a group of 88 young, presumed normal volunteers, ages 17-33. The Hemoccult ICT multi-day screening 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 multi-day screening 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). Corresponding results for one, two and three day collections are reported on TABLES 1, 2 and 3.[21]

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
In vitro studies, following the recommended procedures for sample collectionand storage, 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 false-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

PERFORMANCE CHARACTERISTICS (cont.)

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]

Precision/Reproducibility
The precision and 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), and positive (0.75 mg human Hb/g feces) test results. The precision study was performed by three technicians, working independently in the same laboratory, who tested each sample 10 times. The agreement was 100% (90/90). The reproducibility study was performed by three individual technicians, working in three geographically separate locations, who tested each sample 10 times. The reproducibility was 97% (30/30 for the negative samples, 30/30 for the positive samples and 27/30 for the borderline positive samples).[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 for multi-day screening were 1.8% (32/1734) for Hemoccult ICT and 2.9% (51/1734) for Hemoccult (TABLE 1). 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 . One day, two day and three day results are also presented in TABLE 1.

TABLE 1
AVERAGE RISK SCREENING STUDY
Hemoccult ICT and Hemoccult vs. Clinical Pathology
Hemoccult ICT and Hemoccult Multi-day Screening
(Analysis of all returned fecal collections of the three dispensed slides regardless of number of days)

	Hemoccult ICT	Hemoccult
Test Positivity Rate	**1.8%** (32/1734) [1.3-2.6%]**	**2.9%** (51/1734) [2.2-3.8%]
Estimated Positive Predictive Value		
Colorectal Neoplasia**	**15.6%** (5/32) [5.3-32.8%]	**3.9%** (2/51) [0.5-13.5%]
Any G.I. Pathology	**53.1%** (17/32) [34.7-70.9%]	**60.8%** (31/51) [46.1-74.2%]

TABLE 1 (cont.)

	Hemoccult ICT	Hemoccult
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) [1.0-2.3%]	**2.8%** (49/1729) [2.1-3.7%]
Any Lower G.I. Pathology	**0.9%** (15/1681) [0.5-1.5%]	**1.2%** (20/1681) [0.7-1.8%]
Apparent Specificity†	**99.1%**	**98.8%**

Hemoccult ICT One, Two, Three Day Screening
(1 Day analysis represents day 1 fecal collections, 2 Day is days 1 and 2, and 3 Day is all 3 days of collection.)

	Hemoccult ICT 1 Day	Hemoccult ICT 2 Day	Hemoccult ICT 3 Day
Test Positivity Rate	**0.6%** (10/1670)* [0.3-1.1%]**	**1.3%** (21/1670)* [0.8-1.9%]	**1.9%** (33/1670)* [1.4-2.8%]
Estimated Positive Predictive Value			
Colorectal Neoplasia***	**20.0%** (2/10) [2.5-55.6%]	**19.0%** (4/21) [5.4-41.9%]	**16.1%** (5/31) [5.5-33.7%]
Any G.I. Pathology	**60.0%** (6/10) [26.2-87.8%]	**52.4%** (11/21) [29.8-74.3%]	**54.8%** (17/31) [36.0-72.7%]
Sensitivity for Specified Pathology			
Colorectal Cancer	1/1	1/1	1/1
Adenomas ≥ 1 cm	1/4	3/4	4/4
Colorectal Neoplasia***	2/5	4/5	5/5
False Positivity Rate			
Colorectal Neoplasia**	**0.5%** (8/1665) [0.2-0.9%]	**1.0%** (17/1665) [0.6-1.6%]	**1.6%** (26/1665) [1.0-2.3%]
Any Lower G.I. Pathology	**0.2%** (4/1617) [0.1-0.6%]	**0.6%** (10/1617) [0.3-1.1%]	**0.9%** (14/1617) [0.5-1.4%]
Apparent Specificity †	**99.8%**	**99.4%**	**99.1%**

*Sixty-four samples were removed from 1,2 & 3 Day analysis due to a lack of paired data for all 3 days.
** 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.[21]

TABLE 2
AVERAGE RISK SCREENING STUDY
Relative Sensitivity for Lower G.I. Pathologies
Hemoccult ICT and Hemoccult Multi-day Screening
(Analysis of all returned fecal collections of the three dispensed slides regardless of number of days)

	Hemoccult ICT	Hemoccult
Relative Sensitivity for Significant Pathology	**100%**	**40%**
Colorectal Cancers	1/1	1/1
Adenomas ≥ 1 cm	4/4	1/4
Colorectal Neoplasia**	5/5	2/5

Hemoccult ICT One, Two and Three Day Screening
(1 Day analysis represents day 1 fecal collections, 2 Day is days 1 and 2, and 3 Day is all 3 days of collection)

	Hemoccult ICT 1 Day	Hemoccult ICT 2 Day	Hemoccult ICT 3 Day
Relative Sensitivity for Significant Pathology	**40%**	**80%**	**100%**
Colorectal Cancers	1/1	1/1	1/1
Adenomas ≥ 1 cm	1/4	3/4	4/4
Colorectal Neoplasia**	2/5	4/5	5/5

** 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 in multi-day screening 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 and Hemoccult Multi-day Screening
(Analysis of all returned fecal collections of the three dispensed slides regardless of number of days)

	Hemoccult ICT Multi-day	Hemoccult Multi-day
Clinical Sensitivity		
Colorectal Cancers	**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%]

Hemoccult ICT One, Two and Three Day Screening
(1 Day analysis represents day 1 fecal collections, 2 Day is days 1 and 2, and 3 Day is all 3 days of collection)

	Hemoccult ICT 1 Day	Hemoccult ICT 2 Day	Hemoccult ICT 3 Day
Clinical Sensitivity			
Colorectal Cancers	**84% (16/19)*** **	**84% (16/19)**	**89% (17/19)**
Adenomas ≥ 1 cm	20% (5/25)	28% (7/25)	28% (7/25)
Colorectal Neoplasia**	48% (21/44) [32.5-63.3%]	52% (23/44) [36.7-67.5%]	55% (24/44) [38.8-69.6%]

* 95% confidence interval in brackets [ ]
** Colorectal cancer and adenomas ≥ 1 cm
*** One sample was removed from 1, 2 & 3 Day analysis due to a lack of paired data all three days

To evaluate the performance of Hemoccult ICT and HemeSelect (reference immunochemical test) versus clinical diagnosis of colorectal neoplasia, a multi-day screening study was completed with 53 patients (TABLE 4). One day, two day and three day results are also included in TABLE 4. 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 sensitivity for colorectal neoplasia (cancers and large adenomas combined) was 64% (34/53) for Hemoccult ICT and 62% (33/53) for HemeSelect.[21]

TABLE 4
HIGH RISK POPULATION STUDY
Hemoccult ICT and HemeSelect vs. Clinical Pathology
Hemoccult ICT and HemeSelect Multi-day Screening
(Analysis of all returned fecal collections of the three dispensed slides regardless of number of days)

	Hemoccult ICT Multi-day	HemeSelect Multi-day
Clinical Sensitivity		
Colorectal Cancers	**90% (27/30)**	**90% (27/30)**
Adenomas ≥ 1 cm	30% (7/23)	26% (6/23)
Colorectal Neoplasia**	64% (34/53) [49.8-76.9%]*	62% (33/53) [47.9-75.2%]

Hemoccult ICT One, Two and Three Day Screening
(1 Day analysis represents day 1 fecal collections, 2 Day is days 1 and 2, and 3 Day is all 3 days of collection)

	Hemoccult ICT 1 Day	Hemoccult ICT 2 Day	Hemoccult ICT 3 Day
Clinical Sensitivity			
Colorectal Cancers	**89% (25/28)*** **	**89% (25/28)**	**89% (25/28)**
Adenomas ≥ 1 cm	22% (5/23)	30% (7/23)	30% (7/23)
Colorectal Neoplasia**	59% (30/51) [44.7-72.4%]	63% (32/51) [48.1-75.9%]	63% (32/51) [48.1-75.9%]

* 95% confidence interval in brackets [ ]
** Colorectal cancer and adenomas ≥ 1 cm
*** Two samples were removed from 1, 2 and 3 Day analysis due to a lack of paired data all three days

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PRODUCT INFORMATION

Hemoccult ICT is CLIA Waived.

Product Name	**REF**
Hemoccult ICT Collection Cards (case of 10 boxes) Each box contains: • 100 Collection Cards • 100 Applicator Sticks • 1 Physician Instructions • 1 Sample Collection Instructions	**395065**
Hemoccult ICT Patient Screening Kits, 2 Day (case of 4 boxes) Each box contains: • 50 Patient Screening Kits, 2 Day • 1 Physician Instructions Each 2 Day Patient Screening Kit contains: 1 Dispensing Envelope with Patient Instructions 2 Hemoccult ICT Collection Cards 2 Flushable Collection Tissues 2 Applicator Sticks 1 Mailing Pouch	**395261**
Hemoccult ICT Patient Screening Kits, 3 Day (case of 4 boxes) Each box contains: • 40 Patient Screening Kits, 3 Day • 1 Physician Instructions Each 3 Day 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	**395066**
Hemoccult ICT Tests (case of 4 boxes) 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 REF 395065 and Patient Screening Kits REF 395066 or REF 395261)	**395067**
Hemoccult ICT Controls (case of 4 boxes) Each box contains: • 4 bottles (2 Positive and 2 Negative/0.8 mL each) • 1 Controls Product Instructions	**395068**

For more information visit **http://www.beckmancoulter.com/rapids.**
For technical assistance call Technical Marketing at 800-877-6242.
If outside the North American continent, please use:
+41 22 365 37 36 or e-mail askpcd@beckman.com.
To order product, contact your medical supply distributor.

WARNING

H319	Causes serious eye irritation.
P280	Wear protective gloves, protective clothing and eye/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
	Octylphenoxypoly(ethoxyethanol) 1-2%

SDS Safety Data Sheet is available at techdocs.beckmancoulter.com.

SYMBOL KEY

Symbol	Description	Symbol	Description
⊕	Positive		Expiration
⊖	Negative		Open here
INV	Invalid	15°C–30°C	Store at room temperature
	Manufactured by	2°C–8°C	Refrigerate
	Read Product Instructions	CE	CE marked
IVD	For In Vitro Diagnostic Use	EC REP	Representative in the European Union
LOT	Lot number		Caution
REF	Product number		