

Occasionally, a light blue discoloration may be noticed on the guaiac test paper. This discoloration does not affect the accuracy or performance of the test when it is developed and interpreted according to the recommended procedure. When developer is added **directly over** the fecal smear on a discolored slide, the blue background color migrates outward. A blue ring forms at the edge of the wetted area, leaving the guaiac paper around the fecal smear off-white in color. Any blue on or at the edge of the smear is positive for occult blood. Proper storage of Hemoccult® SENSE® Slides will help prevent blue discoloration.

Some specimens have a high bile content which causes the feces to appear green. A distinct green color (no blue), appearing on or at the edge of the smear within 60 seconds after adding Hemoccult®SENSE® Developer, should be interpreted as negative for occult blood. A blue or blue-green color should be interpreted as positive for occult blood.

PERFORMANCE MONITOR® FEATURE (Quality Control)

The function and stability of the slides and developer can be tested using the on-slide Performance Monitor® feature. The positive (+) and negative (-) Performance Monitor® areas are located under the sample area on the developing side of the slides.

The positive Performance Monitor® area contains a hemoglobin-derived catalyst which will turn blue within 10 seconds after applying developer. The negative Performance Monitor® area contains no such catalyst and should not turn blue after applying developer.

The Performance Monitor® feature provides assurance that the guaiac paper and developer are functional. In the unlikely event that the Performance Monitor® areas do not react as expected after applying developer, the test results should be regarded as invalid. Should this occur, contact the Technical Marketing Department at 800-877-6242 for assistance.

LIMITATIONS OF PROCEDURE

Bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently. Also, blood, if present, may not be distributed uniformly in the fecal specimen. Consequently, a test result may be negative even when disease is present.^{3, 5}

Conversely, a Hemoccult® SENSE® test result may be positive on specimens from healthy patients. This may be due to interfering substances in the diet or to medications. It may also be due to low but detectable levels of blood loss, common to both healthy adults and patients with gastrointestinal disease.¹⁶

Therefore, as with any occult blood test, results with the Hemoccult®SENSE® test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult® SENSE® tests are designed for preliminary screening as an aid to diagnosis. They are not intended to replace other diagnostic procedures such as sigmoidoscopy, colonoscopy, barium enema, or other x-ray studies.

The Hemoccult® SENSE® test, as well as other unmodified fecal occult blood tests, should not be used to test gastric specimens. Interfering factors, such as low pH, high drug concentrations, metal ions or plant peroxidase in food, may affect the function of guaiac-based occult blood tests. Gastrocult®, available from Beckman Coulter Primary Care Diagnostics, is specifically designed to detect occult blood in gastric specimens.

Addition of a drop of water (rehydration) to the guaiac test card prior to the addition of the developer increases the sensitivity of the test, but also increases the number of false-positive test results.^{4,10, 17} For this reason, **rehydration is not a recommended procedure** for the Hemoccult® SENSE® test.

EXPECTED RESULTS

In a general screening population of highly compliant asymptomatic individuals, a positivity rate of approximately 3% was obtained; among a similar group of less compliant individuals, a positivity rate of about 7% was observed. The false-positivity rate for colorectal disease was 1 to 3% depending on the population studied.¹⁸

Positivity rates for fecal occult blood tests have been shown to vary in each patient population depending on diet, age, predisposition to colorectal disease, and other factors that may be associated with bleeding gastrointestinal lesions.^{16, 19}

PERFORMANCE CHARACTERISTICS

Early detection of colorectal cancer in asymptomatic, average risk individuals is necessary to reduce mortality. The detection of occult blood in stool using Hemoccult® SENSE®, a more sensitive and readable test than Hemoccult®, is a highly effective method for detecting bleeding associated with colorectal cancer.

Clinical studies²⁰ using [⁵¹Cr] chromium - labeled blood cells suggest that a daily blood loss of 2-3 mL (approximately 0.3 mg hemoglobin/gm feces) is the lower limit of blood loss that may be associated with gastrointestinal pathology. Based on *in vitro* studies in which fecal samples from asymptomatic, normal volunteers were spiked with fresh whole blood, Hemoccult® SENSE® gave positive test results about 75% of the time at 0.3 mg Hb / gm feces. The positivity rates increased as the equivalent daily blood loss increased. Virtually all Hemoccult® SENSE® tests were positive at an equivalent daily blood loss equal to or greater than 10 mL.

The specificities of the Hemoccult® SENSE® test and the Hemoccult® test are the same when normal subjects follow the Patient Instructions as recommended. When normal subjects consume large amounts of red meat, the false-positive rate will be higher with the Hemoccult® SENSE® test. Raw fruits and vegetables in the diet give about the same number of false-positive test results when samples are tested immediately after collection. **To reduce the rate of false-positive tests due to consumption of raw fruits and vegetables, the Hemoccult® SENSE® test is best developed three days after sample application. This three day delay allows for degradation of any fruit and vegetable peroxidases that may be present in the fecal sample.**⁸⁻¹⁰

The clinical performance of the Hemoccult® SENSE® test was compared to the Hemoccult® test in multi-site clinical evaluations. The results are shown in Figure 1 and Table 1.¹⁸

Figure 1 illustrates that the Hemoccult® SENSE® test is more effective than the Hemoccult® test in detecting bleeding associated with colorectal cancer and adenomas. The differences in sensitivity between the two tests are statistically significant.^{18, 25}

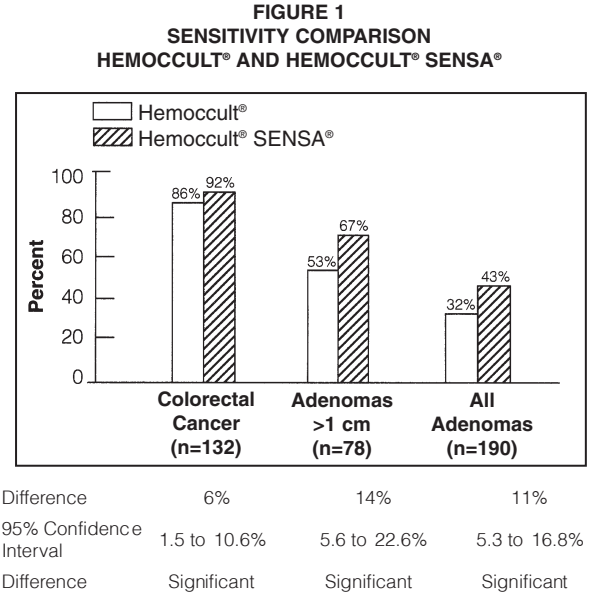
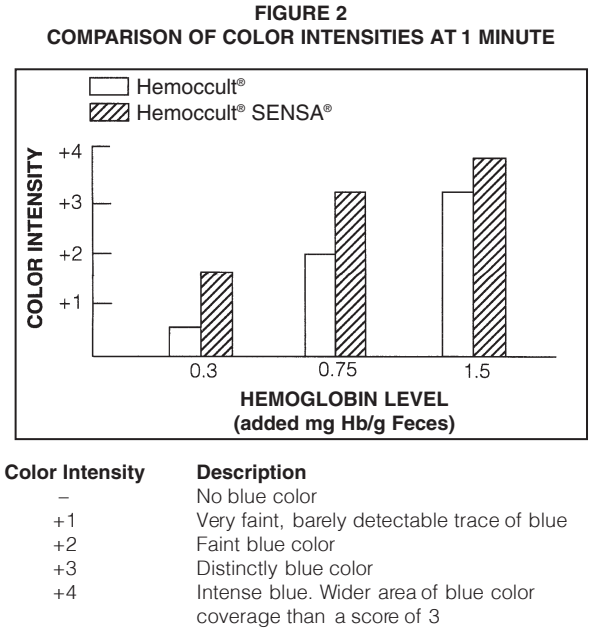


Table 1 summarizes the data comparing the specificity of the Hemoccult® SENSE® test (96.5%) to that of the Hemoccult® test (98%). In an individual study where patients were highly motivated to comply with the restricted diet, the specificity of the Hemoccult® SENSE® test was the same as the Hemoccult® test (99%).^{18, 25}

TABLE 1 COMPARISON OF SPECIFICITY Asymptomatic Individuals Confirmed and Presumed Normals on Restricted Diet		
	Hemoccult®	Hemoccult® SENSE®
No. of Cases Studied	1586	2197
Specificity	98%	96.5%
Difference in Specificity	1.5%	
95% Confidence Interval	0.5 to 2.5%	

The Hemoccult® SENSE® test is more readable than the Hemoccult® test at low but abnormal levels of hemoglobin in feces. Figure 2 compares the color intensity and stability of positive test results from samples containing different levels of added hemoglobin. Experienced and inexperienced readers preferred the more intense, stable blue color of the Hemoccult® SENSE® test, which made it easier to read a positive test result against the dark sample background. Experienced readers correctly interpreted test results a higher percentage of the time than inexperienced readers, pointing to the benefit of some training in reading guaiac-based fecal occult blood tests.

The reproducibility of test results on positive fecal specimens is improved with Hemoccult® SENSE® as a result of the increased readability of the test.^{18, 25}



Prospective, randomized controlled clinical trials extending for up to 18 years have demonstrated that the Hemoccult® products are effective in detecting occult blood in stool as an early indication of colorectal cancer. In clinical trials that enrolled over 339,000 individuals, mortality from colorectal cancer was reduced up to 33% when fecal occult blood tests were performed annually²⁷⁻²⁹ and 15-21% when performed biennially.³⁰ The program sensitivity for detecting colorectal cancer was 90% when Hemoccult® was repeated annually.³¹⁻³²

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PRODUCT INFORMATION		
All products listed are CLIA Waived.		
Product Name	Product No.	
Hemoccult® SENSE[®]<i>elite</i> Dispensapak™ Plus (case of 4 boxes)	395035	
Each box contains:		
<ul style="list-style-type: none">• 40 Patient Screening Kits• Two 15 mL bottles of Hemoccult® SENSE[®] Developer		
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Hemoccult® SENSE[®] Single Slides (case of 10 boxes)	64151	
Each box contains:		
<ul style="list-style-type: none">• 100 Slides• 100 Applicator Sticks• Two 15 mL bottles of Hemoccult® SENSE[®] Developer		
Hemoccult® SENSE[®] Single Slides (case)	64152	
<ul style="list-style-type: none">• 1000 Slides• 1000 Applicator Sticks• Twenty 15 mL bottles of Hemoccult® SENSE[®] Developer		
Hemoccult II® SENSE[®] Dispensapak™ Plus (case of 4 boxes)	64130	
Each box contains:		
<ul style="list-style-type: none">• 40 Patient Screening Kits• Two 15 mL bottles of Hemoccult® SENSE[®] Developer		
Hemoccult® SENSE[®] Developer (box)	64115	
<ul style="list-style-type: none">• Twenty 15 mL bottle s		
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Hemoccult® Single Slides (case of 10 boxes)	60151	
Each box contains:		
<ul style="list-style-type: none">• 100 Slides• 100 Applicator Sticks• Two 15 mL bottles of Hemoccult® Developer		
Hemoccult® Single Slides (case)	60152	
<ul style="list-style-type: none">• 1000 Slides• 1000 Applicator Sticks• Twenty 15 mL bottles of Hemoccult® Developer		
Hemoccult II® Dispensapak™ (case of 2 boxes)	61100	
Each box contains:		
<ul style="list-style-type: none">• 50 Patient Kits (Triple Slide and Applicator Sticks ONLY)• Three 15 mL bottles of Hemoccult® Developer		
Hemoccult II® Dispensapak™ Plus (case of 4 boxes)	61130	
Each box contains:		
<ul style="list-style-type: none">• 40 Patient Screening Kits• Two 15 mL bottles of Hemoccult® Developer		
Hemoccult II® (case of 10 boxes)	61200	
Each box contains:		
<ul style="list-style-type: none">• 34 Triple Slides• 102 Applicator Sticks• Two 15 mL bottles of Hemoccult® Developer		
Hemoccult® Developer (box)	62115	
<ul style="list-style-type: none">• Twenty 15 mL bottle s		
Hemoccult® Mailing Pouches (box)	62200	
<ul style="list-style-type: none">• 100 pouches		
Hemoccult® Tape (case of 12 boxes)	63202	
Each box contains:		
<ul style="list-style-type: none">• 2 Tape Dispensers• Two 15 mL bottles of Hemoccult® Developer		
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Gastrocult® Test Kit	66040	
<ul style="list-style-type: none">• Box of 40 Slides		
Gastrocult® Developer	66115	
<ul style="list-style-type: none">• Six 15 mL bottles		
Gastrocult® Straw Applicators	66140	
<ul style="list-style-type: none">• 40 Applicator		