

Hemoccult[®] BRAND ICT

Immunochemical Fecal Occult Blood Test

Clinical reasoning and proof supporting this easy to use
and effective immunochemical FOBT

An immunochemical FOBT has superior specificity for lower GI disease ¹⁻⁴

An immunochemical FOBT is highly specific for lower GI bleeding.

An immunochemical FOBT yields inherently superior clinical specificity when compared to a chemical-based test (e.g., guaiac). Hemoccult[®] ICT does not require any dietary restrictions and can recognize small amounts of human hemoglobin as a biological indicator of gastrointestinal (GI) disease.

FOBT Method	What's Detected	Probable Location of Bleeding
Immunochemical	Intact human hemoglobin protein (globin)	Large intestine (colon) only
Guaiac	Peroxidase activity (heme)	Mainly stomach, small intestine and large intestine

Clinical trials support 3-day stool sampling ^{1,5-9}

Three-day stool sampling is best for detecting occult GI bleeding from polyps and cancer.

Occult bleeding from colorectal polyps and cancer is subject to biological variation because some lesions bleed intermittently and the blood that is released is not distributed uniformly in the stool. All occult blood test methods must take these biological facts into account. The most proven method to overcome these variations is 3-day multiple sample testing.

Sensitivity of Hemoccult[®] ICT determined by a research study using patient samples ^{10,11}

Sensitivity of Hemoccult[®] ICT is based on clinical performance studies.

The sensitivity (lower limit of positive test results for occult blood) for Hemoccult[®] ICT was selected on the basis of a clinical research study using actual patient samples. Fecal samples were collected for 3 days from individuals with known cancers and polyps (adenomas) and from normal individuals. The samples were used to evaluate an array of capture antibodies and colloidal gold conjugates. Individuals were placed

into two groups after testing: (1) those who tested positive on one or more days of sampling and had cancer or clinically significant polyps, and (2) those who tested negative and had no significant GI disorders. These findings were used to establish the optimal test formulation for Hemoccult[®] ICT.

High clinical specificity of Hemoccult[®] ICT was found in an average risk population study ^{10,11}

Hemoccult[®] ICT has excellent clinical specificity.

The clinical specificity of Hemoccult[®] ICT was determined in a group of average risk individuals. The presence of any lower GI pathology that could be related to bleeding was determined by follow-up colonoscopy of all individuals with a positive FOBT. Specificity was then calculated by subtracting the false positivity rate for any

lower GI pathology from 100%. The relative sensitivity was determined based on the detection of adenomas and cancer in this low prevalence average risk group. The results are summarized below.

	Hemoccult [®] ICT	Hemoccult [®] (guaiac)
False positivity rate for any lower GI pathology	0.9% (15/1681)	1.2% (20/1681)
Apparent specificity (100% - false positivity rate)	99.1%	98.8%
Relative sensitivity (adenomas and cancer)	100% (5/5)	40% (2/5)

Hemoccult® ICT clinical test performance established in clinical trials ^{2,3,10,12}

Proof of performance through clinical trials.

The performance (sensitivity and specificity) of the Hemoccult® ICT is based on the proprietary antibodies and conjugate developed exclusively for the test and evaluated in clinical trials. Hemoccult® ICT detected more cancers and adenomas with higher specificity (fewer false-positive results) than the guaiac method. The following table summarizes the results in average risk individuals.

Clinical Test Performance in Average Risk Individuals ¹⁰

	Cumulative Findings		
	Days of Sampling		
	1 day	2 days	3 days
Hemoccult® ICT positivity rate	0.5% (9/1666)	1.2% (20/1666)	1.8% (30/1666)
Hemoccult® ICT detection of CRC and large adenomas	2	4	5
Hemoccult® (guaiac) positivity rate	1.4% (24/1690)	2.0% (33/1693)	3.0% (51/1693)
Hemoccult® (guaiac) detection of CRC and large adenomas	1	2	2

Hemoglobin is stable in dried stool samples ^{1,7,13}

Hemoglobin must be dried after collection and during transport to the laboratory.

Screening individuals for occult blood requires the patient to collect three stool samples immediately after defecation. Samples must be dried on collection cards to stabilize the hemoglobin. This collection method is proven in clinical trials to stabilize the hemoglobin, if present, until the samples can be tested at the laboratory. Hemoglobin in liquid stool samples is inherently unstable. Liquid samples also

require special packaging to comply with transport regulations and must be sent to the laboratory for testing immediately after collection. This procedure is impractical for screening and can lead to erroneous test results (i.e., false negative results).

Beckman Coulter has a commitment to FOBT and colorectal cancer research ^{10, 11}

Beckman Coulter is committed to long-term research in FOBT and colorectal cancer.

Only one company, Beckman Coulter, Inc., has made a long-term investment in the research and development of FOBT technologies including conducting the human clinical trials needed to prove their clinical efficacy in screening for colorectal cancer.

Beckman Coulter delivers quality

Beckman Coulter Primary Care Diagnostics consistently produces high quality products and services in accordance with the FDA Quality System Regulation (21CFR 820) and International Standards (ISO 13485:2000 and ISO 9001:1994).

References

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