

Only one fecal occult blood test manufacturer provides clinical sensitivity data.

Introduction

Nearly all fecal occult blood test (FOBT) manufacturers make analytical (laboratory) sensitivity claims when comparing their products to Hemocult. Analytical sensitivity of a test represents the smallest amount of substance that can accurately be measured in a biological sample. Examples of these claims include:

Only Hemocult products provide clinical sensitivity data, as well as numerous references to medical literature documenting their clinical performance in their Product Instructions. These sensitivity claims are based on prospective clinical studies that define the ability of the test to determine if there is a significant risk of colorectal cancer and/or adenomas in the patient undergoing screening.

Self-tests ('throw in the bowl') are ineffective in detecting colon cancer. A study of 450 average-risk patients showed that Hemocult detected 87% more cancers than Coloscreen Self-Test². A separate study of 102 high-risk patients³ showed that Colocare^a detected only 16% of cases involving either a cancer or a polyp (versus 75% for Hemocult SENSEA).

FOBT PRODUCT	ANALYTICAL SENSITIVITY CLAIM ¹
Hemocult	50% at 0.3 mg Hb/gm feces (100% at 1 mg Hb/gm feces)
Hemocult SENSEA	75% at 0.3 mg Hb/gm feces (100% at 1 mg Hb/gm feces)
Coloscreen / Sure Vue	100% at 10 mg of Hb/gm homogenized fecal material
Coloscreen ES / Sure Vue ES	50–90% at 0.3 mg Hb/gm stool
Seracult PLUS	100% at 0.0032 mg of hemoglobin /mL (blood dilutions)
HemaPrompt	100% at 2 mg Hb/gm feces
Hema-Screen	No specific data provided

FOBT PRODUCT	CLINICAL SENSITIVITY CLAIMS ¹		
	All Adenomas	Adenomas ≥ 1 cm	Colorectal Cancer
Hemocult	32%	53%	86%
Hemocult SENSEA	43%	67%	92%
Coloscreen / Sure Vue	No Clinical Data		
Coloscreen ES / Sure Vue ES	No Clinical Data		
Seracult PLUS	No Clinical Data		
HemaPrompt	No Clinical Data		
Hema-Screen	No Clinical Data		

Conclusions

Analytical sensitivity claims developed from “in-house” studies do not prove a product’s ability to detect cancer or polyps. Only clinical studies in real patients can establish a test’s clinical sensitivity and predictive value.

Hemocult products are the only FOBTs that provide extensive clinical sensitivity data and, therefore, provide assurance to physicians that cancers and polyps will be detected on followup exams.

Hemocult and Hemocult SENSEA are CLIA-waived.



References

1. Sensitivity claims from each manufacturer’s Product Instructions.
2. Pye, G., et al.: “Comparison of Coloscreen Self-Test and Hemocult Fecal Occult Blood Tests in the Detection of Colorectal Cancer in Symptomatic Patients,” Br. J. Surg, 77:630-631, 1990.
3. Foliente, Roy L. et al.: “Colocare Self Test versus Hemocult II SENSEA for Fecal Occult Blood Testing,” The American Journal of Gastroenterology. 90:2160-2163, 1995.

CLIA

- CPT Code* #82270, #82272QW
- Waived



Ordering Information

Hemocult Products

Hemocult Single Slides Kit 60151

- 100 Slides
- 100 Applicator Sticks
- 2 X 15 mL Bottles of Hemocult Developer

Hemocult Single Slides Without Developer Kit A96635+

- 100 Hemocult Single Slides
- 100 Applicator Sticks

+To be used in conjunction with product # 62115.

Hemocult Single Slides Kit 60152

- 1000 Single Slides
- 1000 Applicator Sticks
- 20 X 15 mL Bottles of Hemocult Developer

Hemocult II Triple Slides Kit 61200

- 34 Triple Slides
- 102 Applicator Sticks
- 2 X 15 mL Bottles of Hemocult Developer

Hemocult II Dispensapak Patient Screening Kit 61100

- 100 Patient Screening Kits (Triple Slide and Applicator Sticks only)
- 3 X 15 mL Bottles of Hemocult Developer per Case

Hemocult II Dispensapak Plus Patient Screening Kit 61130

- 40 Patient Screening Kits
- 3 Applicator Sticks
- 1 Triple Slide
- 2 x 15 mL Bottles of Hemocult Developer

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Ordering Information

Hemocult SENSEA Products

Hemocult SENSEA Single Slides Kit 64151

- 100 Single Slides
- 100 Applicator Sticks
- 2 X 15 mL Bottles of Hemocult SENSEA Developer

Hemocult SENSEA Single Slides Without Developer Kit A96636+

- 100 Single Slides
- 100 Applicator Sticks

+To be used in conjunction with product # 64115.

Hemocult SENSEA Single Slides Kit 64152

- 1000 Single Slides
- 1000 Applicator Sticks
- 20 X 15 mL bottles of Hemocult SENSEA Developer

Patient Screening Kit Hemocult II SENSEA Dispensapak Plus 64130

- 40 Patient Screening Kits
- 2 X 15 mL Bottles of Hemocult SENSEA Developer

Hemocult SENSEA Developer 64115

- Box of 20 X 15 mL Bottles of Hemocult SENSEA Developer

For immunochemical testing, ask about Hemocult ICT.

*Exemplar CPT provided. Refer to regional CMS fee schedule for relevant/current CPT codes.

Beckman Coulter is the leader in fecal occult blood testing and offers the very best in rapid tests designed to simplify the diagnostic process. Early detection is the single most important advantage a patient can have to survive life-threatening diseases. Beckman Coulter provides the tools and tests physicians need to aid in the diagnosis and management of a variety of disease states.

Beckman Coulter also provides a variety of Immunoassay, Chemistry, Hematology and Centrifugation instruments to aid in the diagnosis and management of a full spectrum of medical conditions. Each system's compact design and cost-effective performance makes it a perfect complement to a physician's office laboratory.

To order product, contact your medical supply distributor. For technical assistance regarding rapid test kits, call Technical Marketing at 800-877-6242 or email askpcd@beckman.com.

Lab Testing Made Easy

Beckman Coulter Rapid Diagnostics Product Offering

Hemocult

Hemocult SENSEA

Hemocult II SENSEA elite

Hemocult ICT

CLIA-waived rapid tests for the detection of hidden blood in feces

Gastrocult

CLIA-waived rapid test for detecting hidden blood in gastric fluid and determining gastric pH

ICON Hp

CLIA-waived (whole blood) and moderately complex (serum) rapid test for the detection of antibodies to *H. pylori*

ICON 20 hCG

ICON 25 hCG

CLIA-waived (urine) and moderately complex (serum) rapid tests for the detection of hCG

ICON Mono

CLIA-waived (whole blood) and moderately complex (serum) antibody test for infectious mononucleosis

ICON DS Strep A

ICON SC Strep A

CLIA-waived dipstick and cassette rapid format tests for the detection of Strep A, using throat swab sample



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