

## 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 Hemoccult. 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 Hemoccult 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 Hemoccult detected 87% more cancers than Coloscreen Self-Test<sup>2</sup>. A separate study of 102 high-risk patients<sup>3</sup> showed that Colocare<sup>a</sup> detected only 16% of cases involving either a cancer or a polyp (versus 75% for Hemoccult SENS<sup>a</sup>).

FOBT PRODUCT	ANALYTICAL SENSITIVITY CLAIM <sup>1</sup>
Hemoccult	50% at 0.3 mg Hb/gm feces (100% at 1 mg Hb/gm feces)
Hemoccult SENS <sup>a</sup>	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 <sup>1</sup>		
	All Adenomas	Adenomas ≥ 1 cm	Colorectal Cancer
Hemoccult	32%	53%	86%
Hemoccult SENS <sup>a</sup>	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.

Hemoccult 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.

Hemoccult and Hemoccult SENS<sup>a</sup> are CLIA-waived.



### References

1. Sensitivity claims from each manufacturer's Product Instructions.
2. Pye, G., et al.: "Comparison of Coloscreen Self-Test and Hemoccult 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 Hemoccult II SENS<sup>a</sup> for Fecal Occult Blood Testing," The American Journal of Gastroenterology. 90:2160-2163, 1995.

## CLIA

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



### Ordering Information

#### Hemoccult Products

##### Hemoccult Single Slides Kit 60151

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

##### Hemoccult Single Slides Without Developer Kit A96635+

- 100 Hemoccult Single Slides
- 100 Applicator Sticks

+To be used in conjunction with product # 62115.

##### Hemoccult Single Slides Kit 60152

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

##### Hemoccult II Triple Slides Kit 61200

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

##### Hemoccult II Dispensapak Patient Screening Kit 61100

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

##### Hemoccult II Dispensapak Plus Patient Screening Kit 61130

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

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### Ordering Information

#### Hemoccult SENA Products

##### Hemoccult SENA Single Slides Kit 64151

- 100 Single Slides
- 100 Applicator Sticks
- 2 X 15 mL Bottles of Hemoccult SENA Developer

##### Hemoccult SENA Single Slides Without Developer Kit A96636+

- 100 Single Slides
- 100 Applicator Sticks

+To be used in conjunction with product # 64115.

##### Hemoccult SENA Single Slides Kit 64152

- 1000 Single Slides
- 1000 Applicator Sticks
- 20 X 15 mL bottles of Hemoccult SENA Developer

##### Patient Screening Kit Hemoccult II SENA Dispensapak Plus 64130

- 40 Patient Screening Kits
- 2 X 15 mL Bottles of Hemoccult SENA Developer

##### Hemoccult SENA Developer 64115

- Box of 20 X 15 mL Bottles of Hemoccult SENA Developer

For immunochemical testing, ask about Hemoccult 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

#### Hemoccult

#### Hemoccult SENA

#### Hemoccult II SENA elite

#### Hemoccult 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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