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:

<table>
<thead>
<tr>
<th>FOBT PRODUCT</th>
<th>ANALYTICAL SENSITIVITY CLAIM¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoccult</td>
<td>50% at 0.3 mg Hb/gm feces (100% at 1 mg Hb/gm feces)</td>
</tr>
<tr>
<td>Hemoccult SENSA</td>
<td>75% at 0.3 mg Hb/gm feces (100% at 1 mg Hb/gm feces)</td>
</tr>
<tr>
<td>Coloscreen / Sure Vue</td>
<td>100% at 10 mg of Hb/gm homogenized fecal material</td>
</tr>
<tr>
<td>Coloscreen ES / Sure Vue ES</td>
<td>50–90% at 0.3 mg Hb/gm stool</td>
</tr>
<tr>
<td>Seracult PLUS</td>
<td>100% at 0.0032 mg of hemoglobin /mL (blood dilutions)</td>
</tr>
<tr>
<td>HemaPrompt</td>
<td>100% at 2 mg Hb/gm feces</td>
</tr>
<tr>
<td>Hema-Screen</td>
<td>No specific data provided</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOBT PRODUCT</th>
<th>CLINICAL SENSITIVITY CLAIM²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Adenomas</td>
</tr>
<tr>
<td>Hemoccult</td>
<td>32%</td>
</tr>
<tr>
<td>Hemoccult SENSA</td>
<td>43%</td>
</tr>
<tr>
<td>Coloscreen / Sure Vue</td>
<td>No Clinical Data</td>
</tr>
<tr>
<td>Coloscreen ES / Sure Vue ES</td>
<td>No Clinical Data</td>
</tr>
<tr>
<td>Seracult PLUS</td>
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</table>

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-Test². A separate study of 102 high-risk patients³ showed that Colocare detected only 16% of cases involving either a cancer or a polyp (versus 75% for Hemoccult SENSA).

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 SENSA are CLIA-waived.

References

1. Sensitivity claims from each manufacturer’s Product Instructions.
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.

For immunochemical testing, ask about Hemoccult ICT.

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

Lab Testing Made Easy

Beckman Coulter Rapid Diagnostics Product Offering

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

**Hemoccult SENSA**
- CLIA
  - CPT Code* #82270, #82272QW
  - Waived

**Hemoccult II SENSA elite**
- CLIA

**Hemoccult ICT**
- CLIA

**Gastroccult**
- CLIA

**ICON Hp**
- CLIA

**ICON 20 hCG**
- CLIA

**ICON 25 hCG**
- CLIA

**ICON Mono**
- CLIA

**ICON DS Strep A**
- CLIA

**ICON SC Strep A**
- CLIA

For Beckman Coulter’s worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact