hema-screen SPECIFIC GOLD FAQ's

Why should patients take this test?

Hema-screen SPECIFIC GOLD, a Fecal Immunochemical Test (FIT), is a rapid and convenient qualitative immunoassay for detecting human hemoglobin in feces, a vital tool in the diagnosis and treatment of gastrointestinal disorders. Studies show that the following risk factors increase a person's chances of developing colorectal cancer:

- Age: Colorectal cancer can occur at younger ages.
- Diet: High in fat and calories, low in fiber, or high in red or processed meat.
- Obesity, physical inactivity, cigarette smoking, and heavy alcohol consumption.
- A personal or family history of polyposis (parents, siblings, children).
- Ulcerative colitis or Crohn's disease.

The American Cancer Society and the United States Preventative Services Task Force both recommend that individuals at average risk begin colorectal cancer screening at age 45.

What does the hema-screen SPECIFIC GOLD iFOB test detect?

The hema-screen SPECIFIC GOLD iFOB test detects human hemoglobin in stool, which may indicate bleeding from the loser gastrointestinal (GI) tract.

How does the hema-screen SPECIFIC GOLD iFOB differ from a guaiac-based test?

In comparison with guaiac-based testing, the hema-screen SPECIFIC GOLD test has a higher specificity due to its unique combination of monoclonal and polyclonal antibodies that are specific to human hemoglobin. A traditional guaiac test reacts with the peroxidase activity of heme protein in blood and is non-specific for human hemoglobin.

How is the hema-screen SPECIFIC GOLD iFOB different from other fecal occult blood tests (FOBTs)?

The hema-screen SPECIFIC GOLD iFOB test features a unique single-card, dual-specimen sampling method and a single immunochemical test cassette. This innovative approach offers several advantages, including 30-day sample stability and the ability to use the buffer tube and cassette even if the card is not returned. Additionally, replacing the DEVEL-A-TAB sampler and mailing costs is reduced compared to replacing the buffer tube.

38 Industrial Way East Ste.1, Eatontown, NJ 07724 • (732) 918-0770 • Fax (732) 918-0618

hema-screen SPECIFIC GOLD FAQ's

Is fecal immunochemical testing effective in detection of colorectal bleeds?

Since hema-screen SPECIFIC GOLD detects only blood from the lower GI tract where polyps and colorectal cancer develop, the test was found to be more accurate than a leading guaiac-based FOBT. In clinical studies, hema-screen SPECIFIC GOLD demonstrated a sensitivity of 98% and a specificity of 99%. When compared with a guaiac-based FOBT in clinical studies, hema-screen SPECIFIC GOLD demonstrated 33% greater sensitivity for occult blood.

Do patients need to go on a special diet before or during collecting the sample?

There are no dietary restrictions required in order to use the hema-screen SPECIFIC GOLD product offering.

Does the hema-screen SPECIFIC GOLD have any medication restrictions?

There are no medication restrictions required in order to use the hema-screen SPECIFIC GOLD product offering.

Should we run external controls with this kit?

Good laboratory practice recommends the use of external quality controls to assure the functionality of reagents and proper performance of the test procedure. For this purpose, we recommend using the hema-screen SPECIFIC GOLD iFOB Control Set (Cat. №: HSGDCON).

Does the hema-screen SPECIFIC GOLD require fecal handling?

No fecal handling is required when performing sample collections. Instead, samples are collected by defecating onto a tissue and using an applicator stick to collect stool from 4-6 different areas. Once the sample is collected on the applicator, lay the DEVEL-A-TAB sampler on a flat surface. Apply the sample to window #1 by pulling the applicator stick across the entire window, ensuring that the cavity is evenly filled and leveled. Close the flap. Release the tissue and flush it. Discard the applicator stick.

Can the test be read after the designated read time?

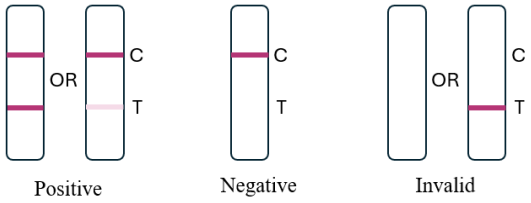
The test should be read at 5 minutes after the addition of specimen to the test cassette well. Do not read after the 5-minute read time.

38 Industrial Way East Ste.1, Eatontown, NJ 07724 • (732) 918-0770 • Fax (732) 918-0618

hema-screen SPECIFIC GOLD FAQ's

How is the hema-screen SPECIFIC GOLD test interpreted?

A positive result is indicated by the appearance of two lines, one in the test region and one in the control region. A single line in the control region indicates a negative result. An invalid test result is indicated by the absence of a control line, even if a test line is present.



I performed the test development procedure in accordance with the instructions, however the test has not developed. What should I do?

Check that there is not excess specimen in the tube. Use the stick attached to the tube cap to loosen feces from the sample strip if dispersion of the specimen seems inadequate. Shake the tube vigorously (or vortex or rotator mix) to ensure the feces is well mixed with the buffer. A small amount of fecal matter may remain undissolved. There should not be any significant amount of undissolved fecal matter in the preparation tube. If the buffer flow along the test cassette appears to have stopped, first tap the cassette lightly on a hard surface. If the flow does not continue, dispense one or more further drops into the test cassette well. If the test continues to not develop, the patient should be supplied another collection kit and instructed to perform sample collection in accordance with the instructions for use.

If there is no excess specimen and the test still does not develop within 5 minutes after the application of 2 additional drops of buffer, please contact Technical Services, Immunostics, Inc. in the US: 1-800-722-7505.

Does a positive result indicate that the patient has colorectal cancer?

Hema-screen SPECIFIC GOLD detects human blood in stool. Blood in stool can be caused by many gastrointestinal conditions, in addition to colorectal cancer. If a patient receives a positive test result, further testing and evaluation are necessary, and the American Cancer Society recommends follow-up with a colonoscopy.

hema-screen SPECIFIC GOLD FAQ's

How many patient fecal specimens are recommended for iFOB testing?

Higher accuracy can be achieved when testing is performed on two (2) consecutive fecal samples due to intermittent bleeding. The hema-screen SPECIFIC GOLD kit (Cat. №: HSGD-25) meets the American Cancer Society and the U.S. Task Force for Colorectal Cancer (CRC) Foundation recommendation of multiple-day testing.

What is the detection level of the hema-screen SPECIFIC GOLD iFOB test?

The detection level is 50 ng hHb/mL buffer or 50 µg hHb/g feces.

What is the shelf life of the hema-screen SPECIFIC GOLD (HSGD-25 & HSGDCAS-25) test kits?

24-months from the date of manufacture. The kits can be stored up to room temperature (4-30°C).

How long can fecal samples be stored before testing?

The collected fecal sample can be stored for up to 30 days at room temperature when utilizing our patented DEVEL-A-TAB system (HSGD-25) or up to 14 days at 2-8°C in the specimen preparation tube.

Are there any instances when the iFOB test should not be performed?

Yes, if blood is visible in stool or urine.

Can patients do the test if menstruating or have hemorrhoids that are bleeding?

No. The test should not be performed three days before, during, or three days after a patient's menstrual period. Additionally, hemorrhoids may interfere with test results. Testing may be performed after bleeding ceases.

Can patients do the test if they have a gastrointestinal illness i.e. diarrhea or liquid stool?

Conditions such as ulcerative colitis or certain types of relapsing infectious diarrhea can vary in severity over time, and FOBT can help assess the severity of the disease.

What is the liquid inside the buffer tube?

Phosphate Buffer Solution (PBS).

38 Industrial Way East Ste.1, Eatontown, NJ 07724 • (732) 918-0770 • Fax (732) 918-0618

hema-screen SPECIFIC GOLD FAQ's

Is the liquid inside the tube hazardous or toxic?

No.

Can the patient flush the collection paper in the toilet?

Yes, the collection paper is biodegradable and can be flushed in the toilet.

Is it acceptable to use a fecal specimen that has come in contact with urine and/or toilet bowl water?

Using a fecal specimen that has come in contact with urine or toilet bowl water can lead to erroneous test results due to dilution.

What kit options are available?

Cat. №: HSGD-25:	(25) Test Cassettes, (25) Buffer Tubes and (35) Patient Mailing Envelopes containing: (1) DEVEL-A-TAB Slide, (2) Collection Tissues, (2) Applicator Sticks & Patient Collection Instructions
Cat. №: HSGDENV-20:	(20) Patient Mailing Envelopes containing: (1) DEVEL-A-TAB Slide, (2) Collection Tissues, (2) Applicator Sticks & Patient Collection Instructions
Cat. №: HSGDCAS-25:	(25) Test Cassette, (25) Buffer Tubes (No patient mailers)
Cat. №: HSGDCON:	External POS/NEG control set

What is the CMS suggested CPT code for the hema-screen SPECIFIC GOLD iFOB test kit?

Medicare/Medicaid:

Medicare/Medicaid:		Private Insurance:	
Diagnostic	82274	Diagnostic	82274
Screening	G0328	Screening	82274

**Under Federal and State law, it is the individual provider's responsibility to determine the appropriate coding, charges, and claims for a particular service. Policies regarding appropriate coding and payment levels can vary significantly from payer to payer and change over time. Immunostics, Inc. strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.*

38 Industrial Way East Ste.1, Eatontown, NJ 07724 • (732) 918-0770 • Fax (732) 918-0618