Quality Microbiological, Serological and Immunological Reagents

hema-screen SPECIFIC FAQ's

Why should patients take this test?

hema-screen SPECIFIC, a Fecal Immunochemical Test (FIT), is a rapid, convenient qualitative immunoassay for the determination of human hemoglobin in feces, a vital tool in the diagnosis and therapy 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 and low in fiber or high in red or processed meat);
- Obesity; Physical inactivity; Cigarette smoking; Heavy alcohol consumption;
- History or familial polyposis (parents, siblings, children;) and
- Persons having ulcerative colitis or crohn's disease.

The American Cancer Society and United States Preventative Services Task Force both recommend that average risk individuals from the age of 50 undergo some form of colorectal cancer screening.

What does the hema-screen SPECIFIC iFOB test detect?

The hema-screen SPECIFIC iFOB test detects human hemoglobin in stool resulting from lower GI bleeding.

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

In comparison with guaiac-based testing the hema-screen SPECIFIC test has a higher specificity due to its unique combination of monoclonal and polyclonal antibodies that are specific to human-globin. 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 iFOB different from other fecal occult blood tests (FOBTs)?

hema-screen™ SPECIFIC features an innovative sampling method that utilizes one card for collection of two (2) specimens of feces and ONLY one immunochemical specimen preparation tube/test cassette system for analysis. Advantages of utilizing the DEVEL-A-TAB sampler are as follows: thirty (30) days stability; and if the card is not returned the buffer tube and cassette are still useable. In addition, the replacement of the DEVEL-A-TAB sampler and mailing costs are reduced in comparison to the replacement of the buffer tube.

Is fecal immunochemical testing effective in detection of colorectal bleeds?

Since hema-screen™ SPECIFIC 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 demonstrated a sensitivity of 98% and a specificity of 99%. When compared with a guaiac-based FOBT, hema-screen™ SPECIFIC 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 product offering.

Does the hema-screen SPECIFIC have any medicinal restrictions?

There are no medicinal restrictions required in order to use the hema-screen SPECIFIC 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 performace of the test procedure. For this purpose, we recommend using the hema-screen SPECIFIC iFOB Control Set (Cat. №: HSSPCON).

Does the hema-screen SPECIFIC require fecal handling?

There is no fecal handling involved when performing sample collections. Rather, samples are taken by defecating onto a tissue and using an applicator stick to stab the stool in 4-6 different sites. Once the sample is collected on the applicator lay the DEVEL-A-TAB sampler on a flat surface and apply the sample to window #1 by pulling the applicator stick across the entire window, making sure that the cavity is evenly filled and leveled. Close flap. Release tissue and FLUSH tissue and discard 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.

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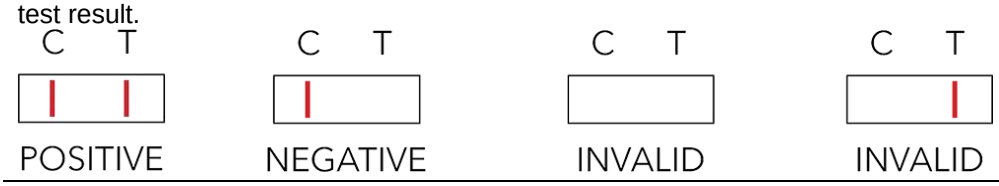
How is the hema-screen SPECIFIC test interpreted?

The appearance of two lines, one in the test region and one in the control region indicates a positive result. A single line in the control region indicates a negative result. No control line, even in the presence of a test line indicates an invalid test result.



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 stick attached to tube cap to loosen feces from sample strip if dispersion of specimen seems inadequate. Shake the tube vigorously (or vortex or rotator mix) to ensure the feces is well mixed with the buffer. Some small amount of fecal matter may not go into solution. 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 cassette lightly on a hard surface, if 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 mean that the patient has colorectal cancer?

hema-screen SPECIFIC detects human blood in stool. There are many gastrointestinal conditions that may cause blood in stool, aside from colorectal cancer. If a patient receives a positive test result, more testing and evaluation is necessary and the American Cancer Society recommends follow-up with a colonoscopy.

How many patient fecal specimens are recommended for iFOB testing?

Higher accuracy is achieved when testing is performed on two (2) consecutive fecal samples due to intermittent bleeding. The hema-screen SPECIFIC kit (Cat. №: HSSP-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 iFOB test?

50 ng hHb/mL buffer or 50 µg hHb/g feces.

What is the shelf life of the hema-screen SPECIFIC (HSSP-25 & HSSPCAS-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 (HSSP-25) or up to 14 days at 2-8°C in the specimen preparation tube.

Are there any times 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 prior to, during, and 3 days after a patient's menstrual period. Also, 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 may assist in assessing the severity of the disease.

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What is the liquid inside the buffer tube?

Phosphate Buffer Solution (PBS).

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?

Dilution of specimen, due to contact with urine or water from the toilet bowl, may render erroneous test results.

What kit options are available?

Cat. №: HSSP-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. №: HSSPENV-20:	(20) Patient Mailing Envelopes containing: (1) DEVEL-A-TAB Slide, (2) Collection Tissues, (2) Applicator Sticks & Patient Collection Instructions
Cat. №: HSSPCAS-10:	(10) Test Cassette, (10) Buffer Tubes (No patient mailers)
Cat. №: HSSPCAS-25:	(25) Test Cassette, (25) Buffer Tubes (No patient mailers)
Cat. №: HSSPCON:	External POS/NEG control set

What is the CMS suggested CPT code and National Limit amount for the hema-screen SPECIFIC iFOB test kit?

The Medicare National Limit Amount* is $21.70. The suggested* CPT codes are:

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

*Under Ferderal and State law, it is the individual provider's responsibility to determine the appropriate coding, charges and claims for a particular service. Policies regardaing appropriate coding and payment levels can vary greatly 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.