Title:	HemaPrompt – Fecal and Gastric Occult Blood		
Department/Service Line:	Laboratory		
Approver(s):	CLIA Director		
Location/Region/Division:	NTX		
Document Number:	NTX.LAB.POC.403.R_V4		
Last Review/Revision Date:	See Signatures	**Origination Date:**	6/2012

SCOPE

This document applies to staff that perform occult blood testing using HemaPrompt.

DEFINITIONS

When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document.

EHR - Electronic Health Record

EHS – Employee Health Services

FOB - Fecal Occult Blood

HIS – Hospital Information System

LIS – Laboratory Information System

METHOD/UTILITY

Blood in the feces is often the first and only sign of colonic or rectal malignancy. Blood found in gastric contents may be used for early detection of conditions such as gastritis, ulcers or cancer.
The HemaPrompt FG test is based on the oxidation of phenolic compounds present in guaiac to quinones, resulting in the production of a blue color. If blood is present in the fecal or gastric sample, the heme portion of the hemoglobin molecule can function in a pseudoenzymatic manner, catalyzing the release of oxygen from the hydrogen peroxide, which in turn causes the oxidation of guaiac. HemaPrompt FG is composed of guaiac-impregnated paper mounted on a cardboard frame that permits sample applications to one side with development and interpretation from the reverse side. A buffer has been added to the paper to increase the pH of the gastric specimen, thus decreasing the likelihood of false negative test results, which may be seen with low pH gastric specimens. The stool or gastric aspirate specimen containing occult blood contacts the guaiac-impregnated paper and a pseudo-peroxidase reaction occurs when developing solution is brought into contact with the guaiac paper, by pulling the tab. The test paper will turn blue within 30 to 60 seconds in the presence of more than 2 mg hemoglobin per gram feces / 100 mcg hemoglobin per ml gastric juice.

PROCEDURE

SPECIMEN

Fecal

Feces can be obtained by direct rectal exam, but for screening purposes stool samples should not be collected if the patient is experiencing menstrual bleeding, constipation bleeding, bleeding hemorrhoids, or when rectal suppositories or medication is being used or if there are cuts on the hand. A specimen can be taken from stool smeared on the toilet bowl and above the toilet water level, from the toilet paper used following defecation, or from a specimen caught in a clean cup. Application to the slide may be performed from the gloved finger (as after a rectal exam), applicator, or by use of the toilet paper described above. It is important that the stool specimen is applied as a thin smear to each of the slide windows. It is recommended by the manufacturer to use non-refrigerated, fresh stool specimens. If there is a delay in testing, it is recommended to apply fresh stool to slide. No more than 5 days (at 10-24°C) should elapse between specimen application and testing.

Gastric

Gastric contents obtained from the naso-gastric tube or vomitus can be applied directly from the naso-gastric tube or by means of cotton tipped swab. In each case, only a thin smear of material should be applied to the test area on the slide and developed (by pulling the tab as described on each slide) immediately and read within one minute. The specimen by itself maybe be stored up to 10 days at 5°C before testing or after application to the slide may be stored up to 24 hours at 10-24°C. Occasionally gastric samples applied to the slide may appear green in which circumstances only the formation of blue can be regarded as positive. Patient specimens and all materials that come in contact with them are to be handled as potentially infectious and disposed of with proper precaution. Do not allow contact with skin or mucous membranes.

Note: Point of care testing sites must be approved to perform testing for each specimen type.

PATIENT PREPARATION

For Fecal Occult Blood (FOB) testing, in the acute situation, no particular preparation is possible.

- Gastric Occult Blood elective collection of gastric juice is rarely conducted. False positive and false negative reactions can be caused by medications and foods.
- See Interfering Substances.

SUPPLIES AND REAGENTS

- HemaPrompt FG test cards
- Applicator sticks

STORAGE

- Store HemaPrompt FG test slides at room temperature (10-24ºC or 50-75ºF) in original packaging.
- Protect slides from heat, sunlight, fluorescent light, UV radiation, humidity, volatile chemicals and gases.
- Do not refrigerate or freeze.
- Test cards are stable until expiration date stamped on each test card label.

SAFETY PRECAUTIONS

HemaPrompt FG is intended for in-vitro diagnostic use only. Skin or eye contact with developing pad that is exposed after pulling tab should be avoided; flush the affected area with water should contact occur. **Ingestion may be fatal or cause blindness.** Keep away from heat, sparks or open flame.

QUALITY CONTROL

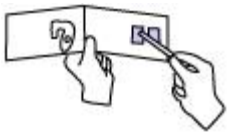
- Internal Quality Control is automatically performed on a test slide each time a patient sample is tested. When developer has been activated by pulling silver tab, a blue checkmark (internal positive control) appears on right side of the test card and the background behind the blue checkmark remains white (internal negative control). The on-board analyte control is Heme that is impregnated into test slide control area (Performance Control). Heme is analyte in blood, which is being detected by this test. Since this analyte control is developed with each test performed, it is unnecessary to run external controls for each test. Internal Controls verify that the test was performed correctly and card is functioning properly. Failure of the internal controls to produce the appropriate reactions is indicative of product deterioration and the test results are invalid. Internal control results are documented in EHR with patient result. When internal controls do not give expected results, patient results are not valid and should not be reported.

- External Quality Control: Lab performs external positive and negative controls with each new shipment/ kit lot number that is received, or more frequently as desired. Proficiency samples with known values are used as the positive and negative external QC. Both FOB and gastric proficiency specimens may be used for QC.

PROCEDURE

1. Identify the patient with two patient identifiers and properly label the test card with at least two patient identifiers.

2. Open HemaPrompt FG test card so both specimen windows are visible.

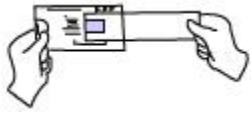


3. Apply the specimen to the test card windows

Fecal Specimen:
- Using Universal Precautions, collect small fecal sample on applicator stick provided in HemaPrompt FG kit.
- Apply a very thin smear of stool to the first window (do not completely cover window)
- Reuse applicator to obtain a second sample from a different part of specimen.
- Apply a thin smear to the second window (do not completely cover window).

Gastric Specimen:
- Using Universal Precautions collect and apply thin smear of specimen directly from NG tube or by means of cotton tipped applicator.
- Apply gastric specimen to both windows on the test card (do not completely cover window)

4. Close cover of test card, avoiding finger pressure to card.
5. Turn card over to the back.
6. Holding card facing you, gently lift silver tab so white developer pad is exposed.
7. While gripping the tab with thumb and finger of other hand, slowly and steadily pull long silver tab to the right and completely remove it from test card.



8. Wait one minute after pulling tab before interpreting test result. When internal QC is acceptable, patient testing results are valid. When internal QC is not acceptable, document the failure per facility protocol, notify Laboratory Leadership and repeat the test.
9. For both Gastric and Fecal samples, results are read from the reverse side of slide and through clear plastic window.
10. Dispose of test card and applicator stick in biohazard container.

RESULTS

- Interpretation
    - **Positive**: Valid internal control and any blue color in either specimen window. Any trace of blue coloration in the specimen window is regarded as positive for occult blood.

- **Negative**: Valid internal control and no detectable blue color on either window. Absence of blue in the specimen window indicates no detectable occult blood.
- **INVALID**: See Internal Quality Control Troubleshooting section below for details

- Results are read at 1 minute of pulling the tab. Interpret all results within 3 minutes of pulling tab. After 3 minutes, intensity of blue color may decrease or fade, and possibly appear negative.

- Within this time period, proper functioning of reagents is indicated by the positive internal control monitor turning blue and the background coloring remaining unchanged (internal negative control).

- Neither color intensity nor the shade of blue from the positive internal control monitor should be used as a reference for the appearance of positive test results.

- Follow facility protocol for result documentation.

INTERNAL QUALITY CONTROL TROUBLESHOOTING

- The guaiac paper of the test card should be white or off-white in color prior to testing. Do not use cards if the guaiac paper is blue or gray.

- These are considered INVALID results:
  - Positive control area does not produce the blue checkmark
  - Background behind the blue checkmark does not remain white
  - Positive control area produces a pink checkmark

- When a patient result is INVALID:
  - Do NOT accept, report, or enter INVALID result in HIS or LIS
  - Check the expiration date on test card and repeat with a new card.
  - When repeat testing is invalid, deliver supplies Point of Care Coordinator or Laboratory designee, and notify of INVALID results. Obtain new test card supply for testing.

ENTERING RESULTS in EHR

Refer to your department training for result entry for HIS or LIS

LIMITATIONS

- Persons with color discrimination problems are not to interpret the results. Color Discrimination screening is performed by Employee Health upon employment within BSWH. Employees not passing colorblind screening are not permitted to interpret color dependent testing.

- EHS will inform the human resource department of employee who did not pass the test for color discrimination. Human Resources will notify department manager and Point of Care Coordinator as appropriate.

Interfering Substances

Fecal specimens

- Red and rare meats, horseradish, raw fruits and vegetables such as broccoli, cauliflower, red radish, cantaloupe, parsnips and turnips, other high peroxides containing vegetables, which can cause false positive results.
- Certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, orticosteroids and non-steroidal anti- inflammatory drugs can cause gastrointestinal bleeding and may give positive results. Iron containing compounds may cause false positive results.
- Vitamin C in dosages greater than 250 mg per day has been shown to cause false negative results.
- On the advice of the physician, these medications might be temporarily discontinued for 7 days prior to and during the test period and testing repeated.

Gastric specimens

- All foods and medications listed above may cause false positive (or negative) results in gastric specimens.
- Cimetidine (Tagamet) may cause false positive results.

HemaPrompt FG Retesting

After false positive results are obtained, discontinue food item believed to have caused false positive test for 2 days, then retest. Medications need to be discontinued at the advice of the physician for 7 days before and during the test period.

Gastro-intestinal cancers, adenomas and ulcerations do not always bleed. Also, blood if present, may not be distributed uniformly in the fecal specimen. Consequently, a test result may be negative even when disease is present.

ATTACHMENTS

HemaPrompt Occult Blood Testing Initial Training Form (NTX.LAB.POC.403.A1)
HemaPrompt Easy Instruction – Visual Aid (NTX.LAB.POC.403.A2)

RELATED DOCUMENTS

BHCS Color Discrimination Testing (BHCS.EH.12.P)
Functional Assessment for Color Blind Testing (BSWH.LAB.QM.0208.P)
Manual POC Test Result Entry in Epic for the Inpatient Setting (BSWH.LAB.POC.002.R)
Manual POC Test Result Entry in Epic for the Outpatient Setting (BSWH.LAB.POC.003.R)

REFERENCES

1. HemaPrompt FG Product Information. Aerscher Diagnostics, Chestertown, MD. 1-800-474-4072

REVISION HISTORY

Version #	Effective Date	Description of Change	Revised By	Removed Date
1	6/1/2012	New	POC sub council	NA
2	5/1/2013	Updated time for interpreting results	POC sub council	NA
3	2/6/2015	Updated storage temperature, added related Internal Document; Merged Lab and POC HemaPrompt Procedure	POC sub council	NA
4	01/04/2019	Storage Temperature corrected; added internal QC troubleshooting section; related documents, and attachments for initial training and easy instruction visual aid.	POC sub council	NA

Attachment Title:	HemaPrompt Occult Blood Testing Initial Training Form		
Attachment Number:	NTX.LAB.POC.403.A1_V1	**Last Review/Revision Date:**	See Signatures

Test: **HemaPrompt Occult Blood Testing**

Employee Name & Number: _____ **E**

UNIT: _____

Trainer _____

At conclusion of training, the employee understands and is able to do the following:

ON-LINE TRAINING			
Complete HemaPrompt online Lesson. Includes HemaPrompt Procedure Review & acknowledgement of understanding	Completion Date:		
	Date	**Employee's Initials**	**Trainer's Initials**
TEST CARD FEATURES			
Describe / demonstrate use of test card Locate expiration date, lot number, sample application area, silver tab for activating developer, and location for internal control.			
SAFETY			
Describe personal protective equipment. Always wear gloves when performing test			
TEST CARD STORAGE AND STABILITY			
Acknowledge Test Cards are stored at room temperature in appropriate areas (10-24°C or 50-75°F) avoiding heat, light, and humidity.			
Acknowledge Test cards are obtained from the Lab. Test cards are stable until expiration date on the card. Outdated test cards are discarded.			
INTERNAL QUALITY CONTROL			
Describe expected result for internal control (Blue Checkmark/ white background)			
Acknowledge proper interpretation on internal control Internal control is evaluated and documented with each patient test.			
PATIENT TESTING			
Acknowledge specimen requirements: Fecal sample may be collected from patient in a sample cup, bed pan, or with a gloved finger.			
Verbalize/demonstrate proper application of sample to test card. Thin smear applied to each window that does NOT cover entire window.			
Perform Patient test: Slowly pull tab, start timer, and interpret result between 1-3 minutes			
REPORTING/DOWNLOADING			
Describe or demonstrate how results are documented Enter lot number, expiration date, internal control, result, & performed by. Must enter full name or e-number in 'performed by' field.			
TROUBLESHOOTING			
Verbalize / demonstrate response to errors A pink check mark is an INVALID result. Check expiration dates, notify POCC or lab designee and repeat with new test card. Do NOT record invalid results in EHR.			

I have had an opportunity to review and ask questions about policies and procedures related to testing above. I feel proficient about performing testing documented above.

Employee Signature Date

Following successful completion of this training checklist, the employee is deemed competent to perform patient testing unsupervised.

Trainer Signature Date

Attachment Title:	HemaPrompt Easy Instruction – Visual Aid		
Attachment Number:	NTX.LAB.POC.403.A2_V1	**Last Review/Revision Date:**	See Signatures

HemaPrompt™ FG Easy Instructions

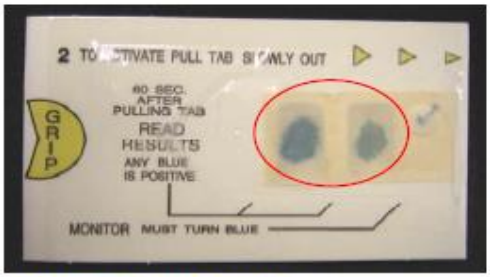
Fecal & Gastric Occult Blood Test

1. **Open the card so specimen windows are visible.**

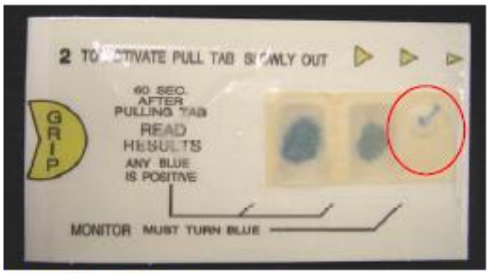
2. **Apply a thin smear of specimen to each window. *Do not cover entire window* (See insert) - Leave an outer periphery of white for contrast. Close card & turn over.**

3. **Grip where indicated. Lift up silver tab so that white developer pad is visible.**

4. **Pull silver tab *SLOWLY* all the way to the right and completely remove it. Developer pad will "flip over" as the tab is pulled.**



5. **Interpret patient results after 60 seconds, but before 3 minutes** (circled area shown above)
   Positive = Any shade of blue* (* in either or both windows)
   Negative = No blue



Internal Controls (circled area shown above):
Positive Control: Appearance of Blue Checkmark
Negative Control: White Background behind Blue Checkmark
Note: Controls must appear for valid results

www.hemaprompt.com Aerscher Diagnostics 1-866-425-7468 (toll-free)