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| Title: | HemaPrompt FG – Occult Blood |
| Department/Service Line: | Laboratory |
| Approver(s): | CLIA Director |
| Location/Region/Division: | Central Texas |
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# sCOPE

This document applies to employees that perform occult blood testing using the Hemaprompt FG card within the Central Division of Baylor Scott & White Health.

# DEFINITIONS

None.

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| 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. |

# PROCEDURE

**Specimen**

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.*

**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.
* A specimen can be taken from a diaper, or 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.
* Fecal specimens may be applied to the test slide and developed up to five days post-application when stored at room temperature (10-24ºC or 50-75ºF).

**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.
* Occasionally gastric samples applied to the slide may appear green in which circumstances only the formation of blue can be regarded as positive.

**Labeling**

Ensure adequate patient specimen integrity and positive identification throughout the pre-testing, testing, and post-testing process. Each card used for testing is labeled, where applicable, in the presence of the patient with the date and time of collection and at least two unique patient identifiers. Acceptable patient identifiers are dictated by location but are limited to:

* Patient’s First and Last Name
* Date of Birth
* Medical Record Number
* CSN/Visit/Encounter/Account Number

*Note:* Samples submitted to the laboratory for additional testing may require additional labeling requirements such as collector’s initials.

**Patient Preparation**

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

* See Interfering Substances.

**Reagents/Equipment**

* HemaPrompt FG Test Cards
* Timer

**Reagent Storage and Handling**

* 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.
* Appropriate PPE such as gloves should be worn during testing or when handling specimens.

**Quality Control**

Quality Control is automatically performed on a test card each time a patient sample is tested. After the tab is pulled and developer has been released, a blue checkmark (internal positive control) will appear at the right side of the test card and the background behind the blue checkmark will remain white (internal negative control). These controls verify that the test has been performed correctly and the card is functioning properly.

**Testing Procedures**

**Patient Testing Procedure**

1. Open the Hemaprompt FG test card so both specimen windows are visible.
2. Apply the specimen to the test card windows using Universal Precautions.
3. Apply a very thin smear of specimen to the first window (do not completely cover window).
4. Apply an additional thin smear to the second window (do not completely cover window).
5. Close the cover of the test card, avoiding finger pressure to card.
6. Turn the card over to the back. Holding the card facing you, gently lift up the silver tab so that the white developer pad is exposed.
7. While gripping the tab with thumb and finger of other hand, slowly and steadily pull the long silver tab all the way to the right and completely remove it from the test card.
8. Wait one minute after pulling tab before interpreting the test result. (Note: Interpret all results before 3 minutes.)

See HemaPrompt FG Easy Instructions attachment (CTX.LAB.POC.101.A2) for pictorial view.

**Interpretation of Test Results**

***Internal QC***

* A blue checkmark (positive control) will appear through the clear plastic window within 60

seconds after pulling the tab.

* The background behind the blue checkmark should remain white, which serves as the

negative control.

***Positive Result:*** Any blue color in either specimen window along with a blue checkmark (positive internal control) and a white background (negative internal control) in the control area. Look for any shade of blue, even if only a faint tinge.

*Note: Occasionally gastric samples applied to the slide may appear green in which circumstances only the formation of blue can be regarded as positive.*

***Negative Result:*** No detectable blue color in either specimen window along with a blue checkmark (positive internal control) and a white background (negative internal control) in the control area.

***Invalid Result:*** The test result is invalid if a blue checkmark is not visible and/or the background is not white in the control area.

**Reporting Results**

All testing and results should be documented in the EHR.

**Retesting**

If clinically a false positive is suspected, discontinue food item believed to have caused the false positive test for two days, then retest. Medications need to be discontinued at the advice of the physician for seven days before and during the test period.

**Color Discrimination**

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

**Limitations**

* 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.
* 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.
* HemaPrompt test cards are designed for preliminary screening as an aid to diagnosis. They are not intended as a replacement for other diagnostic procedures. Further testing and examination by the physician such as gastroscopy, sigmoidoscopy, barium enema, and xray studies need to be performed to determine the exact cause and source of the occult blood in the stool/gastric specimen.
* HemaPrompt test results are to be read 1 minute after pulling the silver tab, but before 3 minutes. After 3 minutes, intensity of blue color may decrease or fade, and possibly appear negative.

**Interfering Substances**

* Red and rare meats, horseradish, raw fruits and vegetables such as broccoli, cauliflower, red radish, cantaloupe, parsnips and turnips, or other high peroxidase containing vegetables, can cause false positive results.
* Certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids and non-steroidal anti-inflammatory drugs can cause gastrointestinal bleeding and give false 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.
* Cimetidine (Tagamet) may cause false positive results in gastric specimens.

**Principle of the Test**

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.

# ATTACHMENTS

Hemaprompt FG Training Form (CTX.LAB.POC.101.A1)

Hemaprompt FG Easy Instructions (CTX.LAB.POC.101.A2)

# RELATED DOCUMENTS

None.

# REFERENCES

1. Hemaprompt FG (package insert). Chestertown, MD: Aerscher Diagnostics; 2014

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| Revision History |

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