**UPMC ST MARGARET LABORATORY**

UPMC St Margaret Harmar Outpatient Center

Point of Care Testing

# PROVIDER-PERFORMED OCCULT BLOOD BY HEMAPROMPT FG METHOD

SMHPOCT-14

Effective Date: 6/2016

Reviewed/Revised:

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**INTENT OF DOCUMENT:** Describes all aspects of the approved testing process for occult blood testing by Hemaprompt FG method, including internal (procedural) quality control testing, in accordance with all regulatory guidelines and standards of good laboratory practice.

**RESPONSIBILITY/ACCESS/LOG-ON:** Results of stool occult blood testing by HemaPrompt FG performed by providers at UPMC St Margaret are accepted provided documentation is complete (including internal/procedural controls) per the results reporting guidelines of this policy. Competency as specified in the UPMC St Margaret POCT Competency Assessment Administrative Policy.

# Test Request: Test requests for provider-performed occult blood testing are initiated electronically in the hospital information system (HIS), Cerner PowerChart.

# Test Purpose/Clinical Significance:

HemaPrompt FG is a guaiac-based in-vitro slide method for the qualitative detection of occult blood in feces and gastric aspirate or vomitus by medical professionals only. It is not intended for home use, nor for patient self-application.

For fecal testing, it is a useful aid in the diagnosis of a number of gastro-intestinal disorders, and is recommended for use in clinical situations such as routine physical examinations , routine hospital testing and screening for colorectal cancer or gastro-intestinal bleeding from any other source.

For the testing of gastric contents it is used for the early detection of occult blood in conditions such as gastric trauma, gastric or duodenal ulceration, gastric cancer, esophageal varices, situations of likely exogenous or endogenous gastritis, leukemia, and hereditary telangiectasia.

HemaPrompt FG provides a method of testing for the presence of occult blood in which a thin smear of feces or gastric contents to be tested is applied to the guaiac paper window. The convenience of HemaPrompt FG is that the developing solution is contained on each individual test card in a pre-measured quantity, and is applied **automatically** to the buffered guaiac paper by pulling the tab on the card and unaffected by pH in the range of 1.0 - 7.0.

In addition, a monitor printed on the guaiac paper indicates if the chemicals are functioning correctly (positive and negative internal quality controls). HemaPrompt FG results cannot be considered conclusive evidence of the presence or absence of GI bleeding or pathology. False positive/negative reactions are known to be caused by a person's particular diet or medications (see Specimen/Sample Collection). The test is intended as a preliminary indicator and not as a replacement for other diagnostic procedures such as gastroscopy, sigmoidoscopy, barium enema, and x-ray studies.

## Test Principle:

The use of guaiac as a test for the presence of blood 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, the heme portion of the hemoglobin (Hgb) molecule can function in a pseudoenzymatic manner, catalyzing the release of oxygen from hydrogen peroxide, which in turn causes the oxidation of guaiac.

HemaPrompt FG is a version of the laboratory guaiac slide test for fecal or gastric occult blood, and is composed of guaiac-impregnated paper buffered and mounted on a cardboard frame which permits sample applications to one side with development and interpretation from the reverse side. Feces or gastric contents containing occult blood contacts the guaiac impregnated paper and a pseudoperoxidase reaction occurs when developing solution is brought into contact with the guaiac paper, by pulling the tab.

The test paper will turn blue in 60 seconds in the presence of more than 2 mg hemoglobin/ gram of feces, and will gradually fade in 5 - 15 minutes. It will also turn blue in the presence of more than 100 mcg Hgb/ ml of gastric fluid in 60 seconds, (Test Performance Characteristics). Positive and Negative Internal Quality Controls indicate if the chemicals are functioning correctly and in turn validate the patient test result.

## Test Performance Characteristics/Expected Results:

## Fecal - The use of guaiac impregnated paper for the detection of fecal occult blood has been extensively studied and these clinical studies indicate that guaiac impregnated slide tests yield a positive result 3-5% of the time in screening programs and the percent of false positive results lies in the range of 1-2% of persons on a controlled diet i.e. a diet excluding substances listed below under Specimen/Sample Collection, with the normal daily fecal blood loss in an adult lying in the range of 1-2 ml of blood per 100 gram of stool. Sensitivity (% of subjects with the condition being sought who test positive) is difficult to estimate, but in series of patients with known colorectal cancer, 50-87% have been reported to yield positive reactions. Estimates of positive reactions with adenomatous bleeding have varied widely, and appear dependant to a degree on the size of polyp, with polyps less than 2 cm yielding less than 5% positive reactions.

## Gastric - The significance of gastric occult blood has been less extensively studied than fecal occult blood. One study of 153 gastric aspirates from 50 intubated healthy adults indicated all aspirates with more than 50 micrograms of hemoglobin/ ml were positive. There was an apparent overall false positive rate of 25.5% in this study of normal intubated individuals, but even using less than 25 micrograms of hemoglobin / ml. as the test cut-off 11.8% showed a positive reaction. The positive rate will be affected by the method of collection. A traumatic intubation can be expected to produce some degree of bleeding. When gastric juice has been obtained immediately after intubation where some degree of bleeding is to be expected, a negative result is more important than a positive. In a similar study with HemaPrompt FG of 12 patient gastric samples obtained by gastroscopy, and 8 healthy volunteer gastric samples obtained by intubation, there was a pH range of 1.0-6.5, and blood was added to provide Hgb concentrations of 20 - 500 mcg/ml. above the baseline levels of blood detected (if any).

## It was found of the volunteer samples 37.5% (3/8) were positive with no added blood, 60% (3/5) were positive with 20 mcg/ml Hgb added, 87.5% (7/8) were positive with 50 mcg/ml Hgb added to the specimen, and 100% (8/8) were positive at concentrations of 100 mcg/ml Hgb added. All samples with blood added in concentrations of 200 mcg Hgb/ml or greater reacted positively, and all reacted in 60 seconds or less.

## Sensitivity:

1. **Fecal –** HemaPrompt FG has a sensitivity of 2 mg or greater of hemoglobin per gram of stool.
2. **Gastric –** HemaPrompt FG has a sensitivity of greater than 100 mcg hemoglobin per mL of gastric juice.

## Specimen/Sample Collection:

**NOTE:** All aspects of testing are considered Category 1 exposure. Adherence to Standard Precautions guidelines is required at all times. Items should be handled as potentially infectious and disposed of with proper precaution. Do not allow contact with skin or mucous membranes.

## 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, when rectal suppositories or medication is being used or if there are cuts on the hand. It is recommended that smears be collected from two different areas of each stool from three consecutive bowel movements as closely spaced in time as possible, or by the physician following a rectal exam. Using toilet paper, a specimen is taken from stool smeared on the 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. No more than 5 days (At 10-24°C (50-75°F) should elapse between specimen application and testing.

1. **Patient Preparation/Dietary Restrictions –** when Hemaprompt FG is used for screening purposes, the following guidelines should be observed:
   1. **Foods to be excluded (**may cause false positive results)
      1. Red and rare meats
      2. Horseradish
      3. Raw fruits and vegetables like broccoli, cauliflower, red radish, cantaloupe, parsnips and turnips
      4. Other high peroxidase containing vegetables, which can cause false positive results.
   2. **Acceptable diet**
      1. Cooked fruit and vegetables such as spinach and corn as well as lettuce, prunes, grapes, and apples
      2. Cereal, and well-cooked fish and fowl

**NOTE**: Because gastro-intestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, all patients who test positive regardless of diet should be followed up with additional diagnostic procedures.

* 1. **Medication Concerns** - Certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids and nonsteroidal anti-inflammatory drugs can cause gastro-intestinal bleeding and thus give positive reactions; dosages of greater than 250mg. of Vitamin C per day have been shown to cause false negative results, while iron containing compounds have been mentioned as a cause of false positive reactions. On the advice of the physician, these medications might be temporarily discontinued for 7 days prior to and during the test period.

1. **Gastric –** gastric contents obtained from the naso-gastric tube or vomitus can be applied directly from the naso-gastric tube or by means of a cotton-tipped swab. The specimen by itself may be stored up to 10 days at 5ºC before testing or after application to the slide may be stored up to 24 hours at room temperatures 10-24°C (50-75°F).
2. **Patient Preparation** - Elective collection of gastric juice is rarely conducted. False positive and false negative reactions can be caused by medications and foods, such as mentioned in the ‘fecal’ section, above. Unlike unbuffered guaiac methods (due to the buffering agent used in HemaPrompt FG) , interfering reactions (false positives and false negatives) at recommended dosage of ranitidine (Zantac 300mg), ferrous sulfate (USP 300mg), cimetidine (Tagamet 300mg), or antacids (Mylanta10-20 ml) have not been observed .

## Reagents: HemaPrompt FG Test Kit, obtained from main laboratory, containing:

1. Guaiac & buffer impregnated paper, with impregnated positive and negative internal quality control. The positive internal control monitor contains a hematoid equivalent to a minimum of 2.0 mg Hgb per gram feces, and the area surrounding this mark is a negative control area, which should remain unchanged in color.

##### Developing solution of 60-70% denatured ethyl alcohol and approximately 6% hydrogen peroxide is contained within a developing pad and is exposed after pulling the tab.

1. Wooden applicator sticks
2. **Storage and Stability:**

HemaPrompt FG slides should be stored at room temperature 10-24°C (50-75°F) and should be protected from heat, sunlight, fluorescent light, U-V radiation, humidity, volatile chemicals and gases. Do not refrigerate or freeze. They are stable until the expiration date indicated on each slide, after which time the slide should not be used.

NOTE: Prepared test cards (with sample applied) may be stored up to 24 hours at room temperature before test development.

1. **Additional Materials Required:**
   1. Gloves
   2. (POC Office only) CAMCO POSITIVE CONTROL SOLUTION for Fecal Occult Blood (CAT. No. 700-C-1)
      1. Single vial.
      2. Storage requirement = 15-30°C (59-86°F).
      3. Stable until printed expiration date.
2. **Test Limitations:**

Gastro-intestinal cancers, adenomas and ulcerations do not always bleed. Results cannot be considered conclusive evidence of the presence or absence of GI bleeding or pathology, and false positive or negative reactions are known to occur under certain circumstances such as a person's diet or medication (see Specimen/Patient Preparation, above). Hydrating stool by adding distilled water may produce false positive results and is not recommended.

In testing gastric juice in overdose situations, excessive iron compounds and certain H2 blockers (e.g. Tagamet) may produce false positive reactions, and excess antacids or ranitidine (e.g. Zantac) may also produce false negative reactions. The false positive rate may also be affected by the method of collection. Use of a large naso-gastric tube is often seen to cause bleeding initially; and in practically all clinical situations where gastric juice is obtained, some degree of bleeding might be expected. The false negative rate has not been established. The test is not intended as a replacement for other diagnostic procedures and further testing and examination by the physician such as esophago-gastroscopy, sigmoidoscopy, barium enema, and imaging studies needs to be performed to determine the exact cause and source of the occult blood.

1. **Precautions:** HemaPrompt FG is intended for in-vitro diagnostic use only. Skin or eye contact with the developing pad which is exposed after pulling the 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.
2. **Quality Control:**
3. Internal Quality Control - each slide is equipped with internal controls to monitor the effectiveness of the chemicals and hence the test itself.
4. Positive Internal Control - The positive internal control monitor appears as a blue checkmark and must turn blue after application of developer.
5. Negative Internal Control - The negative internal control is the background behind the positive control, which should remain unchanged in color.

**NOTE**: Failure of the controls to produce the appropriate reactions is indicative of product deterioration and the patient test results are therefore to be considered invalid.

1. External Quality Control: At the start of a new lot number of HemaPrompt FG test kits, acceptable performance is verified using the CAMCO POSITIVE CONTROL SOLUTION for Fecal Occult Blood (CAT. No. 700-C-1). This product is a single 7.5 mL vial. Procedure for testing:
   1. After receipt of a new lot of HemaPrompt FG Test cards, but prior to release for patient use, remove a testcard for testing from box.
2. Apply a single drop of sample from the CAMCO Positive Control vial to one side of the patient test areas on the card. Apply two drops of water to the other patient test area. Close cover and turn over.
3. Follow instructions under Patient Testing for exposure of the developer pad and result interpretation.
4. Record results in Hemoccult SENSA Supply Log Book. Acceptable performance of testcard lot number is indicated by CAMCO Positive Quality Control reacting as positive and water reacting as negative, with acceptable Internal Positive and Negative Control performance for both.

**NOTE**: Failure of the controls to produce the appropriate reactions is indicative of product deterioration and the patient test results are therefore to be considered invalid.

1. **Patient Testing Procedure:** 
   1. Identify patient to be tested by standard institutional procedure.
   2. Obtain patient sample (see Specimen/Sample Collection, above).
   3. Open front cover of HemaPrompt FG test card so that both specimen windows are visible. Apply a very thin smear of fecal sample to first specimen window of testcard. The specimen windows should not be completely covered with the specimen: an outer periphery of white should be left for contrasting background color.
   4. Obtain second fecal sample from different area of stool and apply a very thin smear to second specimen window of testcard. Close cover.
   5. The test card may be developed immediately (or **fecal specimens** may be developed for up to 5 days after specimen application when stored at room temperature 10-24°C (50-75°F), **gastric specimens** may be developed for up to 24 hours after specimen application when stored at room temperature 10-24°C (50-75°F).
   6. Turn the card over to the reverse side.
   7. Lift the silver tab, exposing the developer pad, and grip the card where indicated.
   8. **Slowly** pull the silver tab all the way to the right and completely remove it from the test card.
   9. Results should be interpreted after 60 seconds, but before 3 minutes (weak positive results may fade after that time).
   10. For both **Gastric and Fecal** samples, results are to be read from the card through the clear plastic window 60 seconds after developer is added. ANY shade of blue color in the patient test area is to be considered a positive occult blood result.
   11. **Neither the 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.**
   12. Positive results will begin to fade after 3 minutes.
   13. An absence of blue in the patient test areas indicates no detectable occult blood, and, thus a negative result.
   14. Occasionally gastric samples applied to the slide may appear green or blue prior to application to the test card. In such circumstances, only the additional formation of blue color can be regarded as positive; a second specimen or a second opinion may be helpful if difficulty with color differentiation is encountered.
   15. **Colorblind persons should not interpret the results**.
   16. The proper functioning of the test card is indicated by the positive internal control monitor turning blue (**not pink**) and the background color remaining unchanged (internal negative control); should the internal control monitor reactions be different, **the patient result is considered invalid and must be repeated using a test card where positive and negative internal controls perform as expected.** Contact POCT office at 412-784-4369 for further troubleshooting.
2. **Result Reporting:**

Online documentation of testing results is accomplished in the Cerner PowerChart HIS.

1. Verify patient name and medical record number and open appropriate patient eRecord chart.
2. Access *Ad-Hoc Charting*.
3. Access *Emergency Department* folder.
4. Select *Point of Care Testing Form*, then select *Chart*.
5. Select *POC Stool Occult Blood* or *POC Gastroccult* form.
6. In the *Patient Result* area, select the appropriate patient result (positive or negative).
7. The Internal Positive and Internal Negative Control result areas now become active. Select the appropriate control result for each area (Internal Positive control [blue checkmark] must perform as “positive” and Internal Negative control [clear background around blue checkmark] must perform as “negative” or patient test is considered invalid and must not be reported.)
8. If desired, a comment may be entered in the *Comment* area.
9. Select the *Hemaprompt* button to indicate the testing method.
10. Complete *Testing Personnel* area. The form will automatically default Testing Personnel name to the individual who is logged into the patient chart. If the staff member performing the occult blood testing is someone other than the person completing the POC form, click on the *Search* function (binoculars), or simply type over the displayed name to invoke a search for the performing staff member by name.
11. Complete the *Facility* area by clicking on the drop-down arrow. Select the appropriate facility (either UPMC St Margaret or UPMC St Margaret Harmar OP Center).
12. Complete the *Lot #(Slide 1)* area by typing in the test device lot number from the test card.
13. Complete the *Expiration Date* area by typing in the expiration date from the test card.
14. Test results will appear under the *All Data* or *Laboratory Data* section of the patient electronic medical record.

not pink)e repeated using a test card where positive and negative internal controls perform as expected.

1. **Reference Range:** Negative.
2. **References:** Aerscher Diagnostics HemaPrompt FG Product Insert, March 2014.

CAMCO Fecal Occult Blood Positive Control Solution Product Insert, Cambridge Diagnostic Products, CAT. NO. 700-C-1, March 2010.

**Authored by: James Beck, MT(ASCP), Point of Care Testing Coordinator, UPMC St Margaret.**

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