



PROCEDURE # 945.8022
FECAL & GASTRIC OCCULT BLOOD TEST

PREPARED BY	DATE ADOPTED	SUPERSEDES PROCEDURE #
Janet Swaim	1/2004	POC 3 and 5

REVIEW DATE	REVISION DATE	SIGNATURE

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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 quinines, resulting in the production of a blue color. If blood is present, the heme portion of the hemoglobin molecule can function in a pseudoenzymatic manner, catalyzing the release of oxygen from hydrogen peroxide, which in turn causes the oxidation of guaiac. HemaPrompt is a version of the laboratory guaiac slide test for fecal or gastric occult blood, and is composed of guaiac-impregnated paper mounted on a cardboard frame which permits sample applications to one side with development and interpretation from 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 less than 60 seconds in the presence of more than 2mg hemoglobin/gm of feces, and will gradually fade in 5-15 minutes. It will also turn blue in presence of more than 0.01 mg hemoglobin/ml of gastric fluid in less than 60 seconds. Monitors on the guaiac slide indicate if the chemicals are functioning correctly.

OPERATORS:

Testing is performed by physicians whose competency is accessed at the time of credentialing. Testing is also performed by registered nurses and licensed practical nurses who are properly trained in the procedure. They must demonstrate their proficiency in performing CAP surveys, quality control and patient testing activity in their annual skills lab competency or peer review.

SPECIMEN:

Patient Preparation:

1. Fecal Occult Blood: In the acute situation no particular preparation will be possible, but for screening purposes a special diet as described below is recommended to decrease the possibility of false positive results. On the one hand, dispensing with such a diet for initial screening purpose may increase patient compliance but a positive result under these circumstances would indicate the need to repeat the test in which a special diet two days prior to and during the three day test period is followed. This diet should EXCLUDE red and rare meats, horseradish, raw fruits and vegetables like broccoli, cauliflower, red radish, cantaloupe, parsnips and turnips, or other high peroxidase containing vegetables, which can cause false positive results. An acceptable diet could include cooked fruit and vegetables such as spinach and corn as well as lettuce, prunes, grapes, and apples. Cereal, and well cooked fish and fowl are also acceptable. If any of the recommended foods are known to cause discomfort, the patient should consult his or her physician. 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. 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 250 mg 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.
2. Gastric Occult Blood: Elective collection of gastric juice is rarely conducted. False positive and false negative reactions can be caused by medications and foods such as mentioned above. In addition, using a guaiac based test with an unbuffered developer, certain histamine (H2) antagonists such as cimetidine (Tagamet) have been shown to cause false positive reactions as with iron, and false negative reactions can result from low pH, but because of the buffering of the developer used in HemaPrompt, interfering reactions by recommended dosage of ranitidine (300mg), ferrous sulfate (300mg), cimetidine (300mg) or antacids (Mylanta 10-20 ml) have not been observed.

Type:

Stool and/or gastric juices.



PATIENT IDENTIFICATION:

The patient is identified using their identification band to verify name and date of birth. At the Health Center Clinic, the patient or patient's parent or legal guardian is asked to state the patient's name and date of birth. The HemaPrompt card is labeled with the name and date of birth immediately.

Handling Conditions:

Blood in bulk stool is unstable, so once it is collected, the sample is applied to the test card immediately. 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. 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. It is important that the stool specimen is applied as a thin smear to each of the slide windows and that no more than 4 days should elapse between preparation and testing, with patients being instructed to return all slides to the physician as soon as possible. Rehydration of the specimen is neither necessary nor recommended. Gastric contents obtained from the nasogastric tube or vomitus can be applied directly from the nasogastric tube or by means of a cotton tipped swab. In each case only a thin smear of material is 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 as applied to the slide or by itself may be stored up to 24 hours at room temperatures or up to 5 days at 15-30° C before developing. 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 should be handled as potentially infectious and disposed of with proper precaution. Do not allow contact with skin or mucous membranes.

EQUIPMENT AND MATERIALS

Equipment:

N/A

Materials:

Guaiac impregnated paper and developing solution are both mounted on each slide, as is a control monitor. The developing solution of 60-70% denatured ethyl alcohol and approximately 6% hydrogen peroxide diluted approximately 20% by a buffering mixture is contained within a developing pad and is exposed after pulling the tab. The positive monitor contains a hematoid equivalent to a minimum of 2.0 mg Hb per gram feces. The fecal specimen is usually applied directly by the gloved finger, from toilet paper or by applicator (as supplied). Gastric specimens can be applied directly from the nasogastric tube or by obtaining a specimen from the container of gastric juice by means of the applicator supplied or by a clean cotton tipped swab (not supplied). There are 50 slides with applicators in each box (Catalogue Number HPfg). Important Note: Current U.S. Postal Regulations prohibit mailing completed test slides in standard envelopes.

Performance Parameters:

Feces: Hemoglobin was diluted to the following concentrations: 1,2,4 and 6 mg/ml, equivalent to 0.1, 0.2, 0.4 and 0.6 grams hemoglobin per 100 grams of stool or approximately 1,2,4 and 6 mls. of blood per 100 grams of stool. These dilutions were used to test the sensitivity of HemaPrompt fg as well as to compare the reactions of one other commercially available guaiac slide test concurrently with HemaPrompt. In testing with blood-spiked normal stool, HemaPrompt fg reacted positively at hemoglobin concentrations of 2mg/ml or greater, in less than 60 seconds, with no reactions below this concentration. Hydrating stool (unless dried by age) by adding distilled water may produce reactions below this level by eluting blood out of the sample and onto the test paper and false positive reactions are possible.

Gastric juice: The reactions of HemaPrompt fg to the presence of blood in gastric juice were compared to one other commercial gastric occult blood test, and tested in the following manner. Twenty batches of gastric juice obtained by aspiration from different individuals, ten with gastric pathology and ten from healthy volunteers.



Each sample was divided into 5 further samples and the pH in each adjusted to produce samples at pH 1.0, 2.5, 4.0, 6.0 and 8.0 respectively (simulating the varying pHs likely to be encountered in gastric juices). Each of these samples had blood added so as to provide hemoglobin levels of 0.005, 0.01, 0.05, 0.1, 0.2, 0.5, and 1 mg hemoglobin / ml. A total of 35 samples were available for testing, reproducibility, and comparison to another commercially available product. These test results showed excellent precision and reproducibility at all pH and blood levels. They were performed 4 times the same day, and on three subsequent days on the same samples. Levels of hemoglobin above 0.02 mg/ml gastric juice always produced a reaction in less than 60 seconds and were negative below this level. Similar results were seen with another commercially available test designed for gastric occult blood and it was found that this product reacted in a like manner. Furthermore, concentrations of ranitidine, cimetidine, ferrous gluconate, and an antacid (Mylanta) to be expected in the stomach after a maximum recommended dose did not alter the results. All monitors reacted in the expected manner (positive control turned blue). Exposing the guaiac paper to UV light for ten minutes inactivated the expected reaction. It was concluded that with stool, HemaPrompt fg reacted positively and definitely to all hemoglobin levels above 2mg/g of stool at which level another commercially available guaiac slide test, when used in its indicated manner, reacted comparatively and similarly. It was further concluded that with gastric juice, HemaPrompt fg reacted positively and reliably to hemoglobin added to levels above 100mcg / ml of gastric juice.

Storage Requirements:

Each slide is equipped with controls to monitor the effectiveness of the chemicals and hence the test itself. The positive control must turn blue. Failure of the control to produce the appropriate color reaction is indicative of product deterioration and the test results are invalid. HemaPrompt slides should be stored at room temperature (15-30C) 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 is not to be used.

CALIBRATION:

None Required

QUALITY CONTROL:

Each shipment of Hemaprompt cards is tested with NERL controls upon arrival at the Torresdale campus. Two cards are pulled from every lot in the shipment, and negative and positive control are run on each lot and the results are recorded on the Hemaprompt QC log. SPD at Torresdale ships the tested Hemaprompt boxes to the Bucks and Frankford campuses. The records of the QC are stored in the Urinalysis department at the Torresdale campus. Each slide is equipped with controls to monitor the effectiveness of the chemicals and hence the test itself. The positive control must turn blue. The clear area surrounding the positive control functions as a negative control, (i.e., it should remain clear). Failure of the controls to produce the appropriate color reaction is indicative of product deterioration and the test results are invalid.

PROCEDURE – STEPWISE:

There are two windows on each test card to which a stool or gastric specimen can be applied. Attached to each card there is a liquid-containing pouch which is released by pulling the tab. After the tab is pulled, you will see a "+" control on the edge of each test card which must turn blue indicating the test has functioned correctly. A blue color in the window test areas is a positive result. No blue in the test areas means no blood was detected.

1. Open the front cover of one Hemaprompt card and spread a very thin smear of the specimen on one of the windows. When testing feces, from a different area of the stool, spread a second specimen thinly on the second window. Close the card cover.
2. After closing the card cover turn to the back of the card. Grip with the left thumb and finger at the point indicated and hold the foil tab with the right thumb and finger. Alternatively lay the closed card face down flat on a table and hold in place with your left thumb at the indicated grip point. Slowly and steadily pull the foil tab all the way out to the right and off. Wait one minute after pulling the tab before reading the test result.
3. Check that the "+" indicator marked "control" has turned blue. If it has not turned blue the test card is faulty and is discarded. After one minute, inspect the indicated window test areas. Any shade of blue no matter if it is faint or a small speck in either one of the test areas is a positive reaction and indicates that blood is



present. Do not read after 3 minutes as the blue color may fade. After noting the results, discard (do not flush) the card and applicator safely.

CALCULATIONS:

None required

REPORTING RESULTS:

Reference Range:

Negative.

Procedure for Abnormal Results:

No special handling pertains.

Reporting Format:

All results are recorded on the Point of Care Form in the clinic. Physicians use the sticker provided on the card to record lot numbers and results. All recorded results must be checked against the visual results prior to discarding slide.

PROCEDURE NOTES:

1. Any trace of blue coloration is to be regarded as a positive for occult blood. An absence of blue indicates no detectable occult blood. These results are read at room temperature (16-32C) after 30 seconds and before 1 minute of pulling the tab. Within this time period, the proper functioning of the reagents is indicated by the positive monitor turning blue; should the monitor reaction be different, the test result is invalid. Contact Aerscher at **800-474-4072** for assistance if an invalid test result occurs.
2. Colorblind persons can not interpret the results.
3. Neither the intensity nor the shade of blue from the positive Control Monitor can be used as a reference for the appearance of positive test results.

LIMITATIONS OF THE PROCEDURE:

Gastrointestinal 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, medication, or traumatic use of a nasogastric tube (see Patient Preparation above). 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.

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