**LOURDES HOSPITAL**

**169 Riverside Drive**

**Binghamton, New York 13905**

**LAB MANUAL**

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**SUBJECT: Occult Blood ORIGIN DATE: 11/05/97**

**REVIEWED: 6/1/2021 REVISED: 6/6/2017**

**REGULATORY REFERENCES: CROSS REFERENCES:**

**NYS, JACHO, CAP**

**POLICY**

 The Hemoccult® test is a rapid, convenient qualitative screening method for the detection of fecal occult blood. It is a simplified and standardized variation of the laboratory guaiac procedure for occult blood. The test contains a specially prepared, stabilized guaiac paper and is ready for use without additional preparation. The test is significant in giving information on the presence of occult blood in the stool and the integrity of the lower G.I. system. It is not a test for colorectal cancer or any other specific diseases.

The Hemoccult® test is based on the oxidation of guaiac by hydrogen peroxide to a blue-colored compound. The heme portion of hemoglobin, if present in the fecal specimen, has peroxidase activity, which catalyzes the oxidation of alpha guaiaconic acid by hydrogen peroxide to form a highly conjugated blue quinone compound.

Certification:

All Staff performing Occult Blood Testing will be certified by one of the designated trainers on initial hire, again at six months and then yearly during their annual competency with a written test and a hands on demonstration of their ability to run both QC and patients.

**PROCEDURE:**

SPECIMEN TYPE

 The Hemoccult® test requires only a small fecal sample. The sample is applied as a thin smear to the guaiac paper of the slide using the applicator stick provided.

 Hemoccult® slides may be prepared and **developed after 3-5 minutes following application of the specimen,** or prepared and stored for up to 14 days at room temperature.

 Hemoccult® slides present no hazard to the user.

IDENTIFICATION and LABELING The patient will be identified using 2 identifiers, patient name and date-of-birth. Specimen will be labeled with the 2 identifiers.

TEST PERFORMANCE

REAGENTS AND MATERIALS: only one lot # of slides and developer are to be in use at any time.

1. Hemoccult® slides – Test cards containing guaiac paper.
2. Hemoccult® developer – A developing solution containing a stabilized mixture of less than 5.0% hydrogen peroxide and 75% denatured ethyl alcohol in aqueous solution (See also Precautions)
3. Thermo Scientific Fecal Hemoglobin Controls- Positive and Negative

Supplies can be obtained via Sciquest ordering through Owens and Minor.

PROCEDURE:

1. Collect a small fecal sample. Apply a thin smear of fecal sample using applicator stick provided in kit to cover Box A. Reuse applicator to obtain second sample from a different part of the fecal sample. Apply a thin smear covering Box B. Close flap. Dispose of applicator in waste container.
2. **After waiting 3-5 minutes**, open the flap in the back of the slide and apply 2 drops of Hemoccult® Developer to the guaiac paper directly over each smear.
3. Read results within 60 seconds. Any trace of blue on or at the edge of the smear is positive for occult blood.
4. Apply 1 drop of Hemoccult® Developer between the positive and negative Performance Monitor® areas.
5. Read results within 10 seconds. If the slide and developer are functional, a blue color will appear on the positive area while no blue will appear in the negative area.

RESULT REPORTING

Patient results will be recorded on the log sheet which lists the slide and developer lot #’s and expiration date and in the patient's chart using a Laboratory Order/Result Form or documented by the provider in their dictation. The results of the internal control must also be documented with each patient result.

 POSITIVE: Any trace of blue on or at the edge of one or more of the smears indicates the test is positive for occult blood. A positive screening result may be used by the practitioner as a diagnostic tool for determining a treatment regimen.

 NEGATIVE: No detectable blue on or at the edge of the smears indicate the test is negative for occult blood.

 Record result as either Negative (neg) or Positive (pos.)

NORMAL:

 Negative

QUALITY CONTROL

 **External Controls**:

A positive and negative control is performed in the same manner as patient testing on each day of testing. The control results and lot #’s are recorded on the log sheet.

 **Internal controls:**

 The function and stability of the slides and developer can be tested using the on-slide Performance Monitor® feature. The positive (+) and negative (-) Performance Monitor® areas are located below the sample windows on the developing side of the slides.

 The positive Performance Monitor® area contains a hemoglobin - derived catalyst which will turn blue within 10 seconds after applying developer. The negative Performance Monitor® area contains no such catalyst and should not turn blue after applying developer.

 In the unlikely event that the Performance Monitor® areas do not react as expected after applying the developer, regard the test as invalid and repeat test. The acceptability of the internal control must be documented along with each patient on the log sheet.

**Individual patient results are not reported unless the quality control is acceptable.**

FOLLOW UP RECOMMENDATIONS

PRECAUTIONS:

1. For in vitro diagnostic use only
2. Do not use after expiration date, which appears on each test card.
3. Individuals should not interpret this test with blue color blindness.
4. Patient specimens and all materials that come in contact with them should be handled as potentially infectious.
5. Slides: Keep cover flap of slide sealed until ready to use.
6. Developer: Should be protected from heat and the bottle kept tightly capped when not in use.

 **The Developer is an irritant and should avoid contact with skin, DO NOT USE IN EYES. Should contact occur, rinse promptly with water.**

**Electronic Authorizations:**

Michael Zur, MD, Medical Director of Laboratory

Kelly Cwikla, MT(ASCP)SM, Clinical Manager of Microbiology