

The Johns Hopkins Hospital Point-of-Care Testing Program
Self-Study Packet

FECAL OCCULT BLOOD
Hemoccult®

Operator Competency

Only operators who have completed a defined training program and can demonstrate competence will be able to perform fecal occult blood testing.

Operator competency will be assessed annually by two methods.

- a. Successful performance of quality control (Performance Monitor).
- b. One of the following:
 - Testing an unknown specimen
 - Having the supervisor or qualified delegate periodically observe routine work
 - Written test

Test Order

A physician's order, standard protocol, or order by other health professionals authorized to request laboratory tests is required for fecal occult blood testing.

Reagents and Storage

Slides and Developer are stable until the manufacturer's expiration date and are to be dated when opened.

1. Hemoccult® slides are stored in the original box/packaging at room temperature (15-30°C or 59-86°F).
2. Hemoccult® Developer is stored tightly capped at room temperature (15-30°C or 59-86°F).
3. Hemoccult® slides or Developer are not used after the expiration date.

Quality Control Label

A JHMI Quality Control Label should be affixed to the box of Hemoccult® slides when it is first opened. Record the open date at the top of the QC Label in the space below "Date Opened".

Quality Control Frequency

1. Weekly on each opened box of Hemoccult® slides and bottle of Developer.
2. Initially when opening a new box of slides or bottle of Developer.
3. Performance Monitor- After each patient test

Quality Control-Performance Monitor

1. Record the lot number and expiration dates of the Hemocult® slides and Developer on the Hemocult® QC Log Sheet, along with the date, time and operator initials.
2. Open the card and apply 1 drop of Hemocult® Developer to the area between the positive and negative Performance Monitor Areas on the card.
3. Interpret the result within 10 seconds
 - No color should appear in the “negative” location
 - A blue color should appear in the “positive” location
4. Document results on the Hemocult® QC Log Sheet. A positive result should be recorded as “Pos” or “Positive”. A negative result should be recorded as “Neg” or “Negative”.
Do not use (+) or (-) signs.
5. Place a check mark in the QC Pass/Fail Column on the QC Log Sheet to note whether QC passed or failed.
6. Document any QC failures and corrective actions in the Comment Section of the Hemocult® QC Log Sheet.
7. Record the date and operator initials on the JHMI QC Label affixed to the Hemocult® slide box to denote successful completion of quality control.

Quality Control – Results Documentation Summary

1. Record date, time, operator initials and lot numbers of slides and Developer on the Hemocult® QC Log Sheet.
2. Record the Performance Monitor results as “Pos/Positive” and “Neg/Negative”.
3. Place a √ mark in the QC Pass/Fail Column on the QC Log Sheet to note whether QC passed or failed.
4. Document any QC failures and corrective actions in the Comment Section of the Hemocult® QC Log Sheet.

Quality Control Failures and Corrective Actions

If the QC (Performance Monitor) results fail, i.e., the expected results are not obtained:

1. Check to make sure that the slides and Developer have not expired.
2. Repeat the test.
3. If repeat test fails, open a new bottle of Developer and repeat test.
4. If this test fails using the new Developer, open a new box of Hemocult® slides and retest using the new slides and new Developer.
5. If the repeat test fails using the new slides and Developer, STOP PATIENT TESTING AND REPORTING OF PATIENT RESULTS until the quality control issues are resolved and the expected results are obtained and recorded.
6. Document all steps taken in the Comment Section of the Hemocult® QC Log Sheet.
7. Contact the POCT Program Office for assistance.

Specimen Collection

1. Use at least 2 unique patient identifiers (neither to be the patient's room number) to verify a patient's identity when collecting samples for testing.
2. The Hemoccult® test requires only a small fecal sample.
3. Samples must be fresh (not refrigerated) and tested promptly.
4. Gloves must be worn during sample collection and testing (Standard Precautions)
5. Specimen should not be collected if hematuria, menstrual bleeding or obvious rectal bleeding are present.
6. Samples taken during a rectal examination may give misleading, positive results. Minimal occult rectal trauma could cause a positive result.
7. Because gastrointestinal bleeding may be intermittent, three samples from sequential bowel movements may be required to obtain an adequate screen for colon cancer.

Patient Testing

1. Check the JHMI QC Label on the box of slides or the Hemoccult® QC Log Sheet to make sure that quality control has been performed for the week. If not, stop and perform QC.
2. Check the expiration dates of the Hemoccult® slides and Developer.
3. Remove a slide from the box and label the front of the slide with the patient identifiers in the space provided.
4. Open the slide and apply a small amount of fecal sample to Box A and Box B, from two different areas of the fecal sample.
5. Close the cover and turn the card over.
6. Wait 3-5 minutes to allow the sample to mix with the test reagents on the card.
7. Open the flap at the back of the card and apply 2 drops of Hemoccult® Developer to the paper directly over each smear.
8. Read results within 60 seconds. Any trace of blue on or at the edge of the smear is positive for occult blood.
9. Apply 1 drop of Hemoccult® Developer between the positive and negative Performance Monitor Areas on the slide. Interpret results within 10 seconds.
10. Record the patient's result as "POS/Positive" for a positive result or "NEG/Negative" for a negative result in a dated, timed and signed admission/progress note, nursing flow sheet or EPR.
11. When documenting the result in the patient's chart, place a check mark (✓) or "Performance Monitor okay" next to the result to indicate that the Performance Monitor reacted correctly and that quality control has successfully been run within the week.
12. Results should be noted as Point-of-Care Testing results to distinguish them from laboratory results.
13. Discard used slides and materials in a JHMI-approved biohazard waste container.

Interferences

- A. **Foods:** Some foods (red or processed meat, some raw fruits and vegetables high in peroxidases such as melons, turnips, radishes) may interfere with test accuracy.
- B. **Medications:** Substances that can irritate the GI tract and cause bleeding (aspirin, alcohol, corticosteroids, anticoagulants) may produce positive test results.
- C. **Ascorbic Acid:** Ascorbic Acid (vitamin C) and iron supplements that contain quantities of vitamin C which exceed 250mg/day have been shown to cause false negative test results for occult blood.

Limitations

1. Hemocult® test results may be negative even when disease is present:
 - a. Bowel lesions may not bleed at all or may bleed intermittently.
 - b. Blood, if present, may not be distributed uniformly in the fecal sample.
2. Hemocult® test results may be positive on specimens from healthy patients:
 - a. May be due to interfering substances in the diet or to medications
 - b. May be due to low but detectable levels of blood loss common to both healthy adults and patients with gastrointestinal disease.
3. The Hemocult® test should not be used to test gastric samples.
4. Hemocult® results cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology.
5. For the most accurate results, patients should follow the Special Diagnostic Diet for at least 72 hours prior to and continuing through the sample collection procedure.