



KAISER PERMANENTE®

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Fecal Occult Blood Using Beckman Coulter Card

Purpose This CLIA-waived procedure is to establish guidelines for performing fecal occult blood testing on feces at point-of-care using the Beckman Coulter Card, and to provide the patient early detection of abnormal bleeding associated with gastrointestinal disorders.

Scope This procedure may be performed by personnel who are trained and approved to perform POCT as defined in Chapter 510 of the California Business and Professional Code (CBPC) or per departmental policy (e.g., RN, LVN, CRNA, PA, DO, MD, CNM, & RNP) whichever is more restrictive..

Policy

- Fecal Occult Blood Test will be performed for screening purposes.
- Staff must be tested and evaluated for visual color discrimination and may not perform this test if the employee is unable to discriminate colors produced by this test.
- Based on the results of the Beckman Coulter Card test, the provider will determine whether a more definitive or laboratory test should be ordered.
- Testing reagents and slide cards are not to be interchanged between each kit or with components from any other manufacturer.
- Only testing on feces may be performed at point of care.
- External Quality Control (QC) checks should be performed in checking function and stability of Beckman Coulter Cards prior to use for each new lot number and/or shipment of kits.
- Performance Monitor (Quality Control) will be done and recorded with each patient test.
- If the Performance Monitor (Quality Control) does not perform as expected, the test will be repeated with another slide test card. If the Performance Monitor (Quality Control) still fails, the local laboratory Point of Care Coordinator will be contacted. **Patient results will not be reported. Patient specimens will be sent to the local laboratory.**
- Remedial action will be documented when expected Performance Monitor (Quality Control) results are not obtained.

Specimen source Fecal specimen

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Fecal Occult Blood Using Beckman Coulter Card, Continued

Specimen collection

- Fecal specimen should be collected preferably from bowel movement. A digital rectal exam may be performed but it is not recommended.
 - Specimen containers should be labeled with two unique patient identifiers (e.g. Patient Name and Medical Record Number) in a clean dry plastic or glass container if collected from a bowel movement.
 - The test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Beckman Coulter Card as a thin smear.
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Reagents and materials

- The Beckman Coulter Cards test consists of two main components that are stored at a controlled room temperature (15°C–30°C):
 - Beckman Coulter Cards (Test Cards) containing guaiac paper.
Note: Protect slides from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine, household cleaners).
 - Beckman Coulter Developer – a developing solution containing a stabilized mixture in an aqueous solution.
Note: Protect from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.
 - Commercial Controls or Diluted Whole Blood (1:5000 in distilled water) for checking function and stability of Beckman Coulter Cards.
 - Clock or timer
 - Sample collection cups
-

Safety

Refer to safety manual for general safety requirements and universal precautions.

Function and stability checks

Follow these steps to perform function and stability checks.

Step	Action
1	Perform function and stability checks using commercial controls or diluted whole blood (1:5000 in distilled water).
2	Verify the lot number and expiration date indicated on the commercial control bottle or diluted whole blood (1:5000 in distilled water).
3	Mix well and apply a drop in Box A and apply another drop in Box B.

Continued on next page

Fecal Occult Blood Using Beckman Coulter Card, Continued

Function and stability checks (continued)

Step	Action								
4	Close cover and wait 3-5 minutes after sample application before developing test.								
5	<ul style="list-style-type: none"> • On the develop test, open flap and apply two (2) drops of Beckman Coulter developer over each smear. • Interpret within 60 seconds. <table border="1" data-bbox="565 688 1388 1182"> <thead> <tr> <th data-bbox="565 688 979 726">If...</th> <th data-bbox="979 688 1388 726">Then...</th> </tr> </thead> <tbody> <tr> <td data-bbox="565 726 979 842">There is a presence of any trace of detectable blue color on or at the edge of the smear</td> <td data-bbox="979 726 1388 842">Result as POSITIVE.</td> </tr> <tr> <td data-bbox="565 842 979 957">There is no detectable blue color on or at the edge of the smear</td> <td data-bbox="979 842 1388 957">Result as NEGATIVE.</td> </tr> <tr> <td data-bbox="565 957 979 1182">Performance Monitor Controls fail to appear and/or background interferes with reading</td> <td data-bbox="979 957 1388 1182"> <ul style="list-style-type: none"> • Test is not valid. • Do not report patient results. • Follow procedure block Troubleshooting Failed Controls. </td> </tr> </tbody> </table>	If...	Then...	There is a presence of any trace of detectable blue color on or at the edge of the smear	Result as POSITIVE .	There is no detectable blue color on or at the edge of the smear	Result as NEGATIVE .	Performance Monitor Controls fail to appear and/or background interferes with reading	<ul style="list-style-type: none"> • Test is not valid. • Do not report patient results. • Follow procedure block Troubleshooting Failed Controls.
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Fecal Occult Blood Using Beckman Coulter Card, Continued

Troubleshooting failed controls Follow these corrective action steps to troubleshoot failed controls.

Step	Action
1	Repeat the test using another card.
2	Repeat the test using a new kit.
3	<ul style="list-style-type: none">• If control results are still out of range, contact the local laboratory Point of Care Coordinator.• Do NOT perform patient testing until the problem is resolved.• Send patient specimens to the local laboratory.

Testing patient sample Follow these steps to test a patient sample.

Step	Action
1	Make a positive patient identification using two unique identifiers (patient name and MRN) prior to testing a patient's stool sample.
2	Collect a small stool sample and apply a thin smear in Box A and apply another thin smear in Box B.
3	Close cover and wait 3-5 minutes after sample application before developing test.

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Fecal Occult Blood Using Beckman Coulter Card, Continued

Testing patient sample (continued)

Step	Action								
4	<ul style="list-style-type: none"> • On the develop test, open flap and apply two (2) drops of Beckman Coulter developer over each smear. • Interpret within 60 seconds. <table border="1" data-bbox="560 617 1409 1255"> <thead> <tr> <th data-bbox="560 617 932 655">If...</th> <th data-bbox="932 617 1409 655">Then...</th> </tr> </thead> <tbody> <tr> <td data-bbox="560 655 932 804">There is a presence of any trace of detectable blue color on or at the edge of the smear</td> <td data-bbox="932 655 1409 804">Result as POSITIVE.</td> </tr> <tr> <td data-bbox="560 804 932 915">There is no detectable blue color on or at the edge of the smear</td> <td data-bbox="932 804 1409 915">Result as NEGATIVE.</td> </tr> <tr> <td data-bbox="560 915 932 1255">Performance Monitor Controls fail to appear and/or background interferes with reading</td> <td data-bbox="932 915 1409 1255"> <ul style="list-style-type: none"> • Test is not valid. • Do not report patient results. • Send patient specimens to the local laboratory. • Repeat with new specimen and/or a new Test Card. If the control fails to appear on repeat test, contact the local laboratory Point of Care Coordinator. </td> </tr> </tbody> </table>	If...	Then...	There is a presence of any trace of detectable blue color on or at the edge of the smear	Result as POSITIVE.	There is no detectable blue color on or at the edge of the smear	Result as NEGATIVE.	Performance Monitor Controls fail to appear and/or background interferes with reading	<ul style="list-style-type: none"> • Test is not valid. • Do not report patient results. • Send patient specimens to the local laboratory. • Repeat with new specimen and/or a new Test Card. If the control fails to appear on repeat test, contact the local laboratory Point of Care Coordinator.
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Fecal Occult Blood Using Beckman Coulter Card, Continued

Testing patient sample (continued)

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6	Document results directly into KP HealthConnect or use Manual Patient Logs/Forms.								

Expected results

Patient Test: Negative

- In a general screening population of highly compliant asymptomatic individuals, a positivity rate of approximately 3% was obtained; among a similar group of less compliant individuals, a positivity rate of about 7% was observed. The false-positivity rate for colorectal disease was 1 to 3% depending on the population studied.
- Positivity rates for fecal occult blood tests have been shown to vary in each patient population depending on diet, age, predisposition to colorectal disease, and other factors that may be associated with bleeding gastrointestinal lesions.

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Fecal Occult Blood Using Beckman Coulter Card, Continued

Limitations of procedure

- Bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently. 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.
- Conversely, a Beckman Coulter Card test result may be positive on specimens from healthy patients. This may be due to interfering substances in the diet or to medications. It may also be due to low but detectable levels of blood loss, common to both healthy adults and patients with gastrointestinal disease.
- Therefore, as with any occult blood test, results with the Beckman Coulter Card test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Beckman Coulter Card tests are designed for preliminary screening as an aid to diagnosis. They are not intended to replace other diagnostic procedures such as sigmoidoscopy, colonoscopy, barium enema, or other x-ray studies.
- The Beckman Coulter Card test, as well as other unmodified fecal occult blood tests, should not be used to test gastric specimens. Interfering factors, such as low pH, high drug concentrations, metal ions or plant peroxidase in food, may affect the function of guaiac-based occult blood tests. Gastrocult®, available from Beckman Coulter Primary Care Diagnostics, is specifically designed to detect occult blood in gastric specimens.
- Addition of a drop of water (rehydration) to the guaiac test card prior to the addition of the developer increases the sensitivity of the test, but also increases the number of false-positive test results. For this reason, **rehydration is not a recommended procedure** for the Beckman Coulter Card test.

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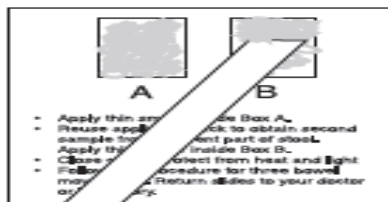
Fecal Occult Blood Using Beckman Coulter Card, Continued

Quick Reference of Beckman Coulter Card



A. Identification

Using a ball-point pen, write patient name,



B. Preparing the Test

- Using applicator provided, collect small fecal sample.
- Apply thin smear covering Box A.
- Reuse applicator to obtain second sample from a different part of feces. Apply thin smear covering Box B.
- Close cover flap. Dispose of applicator in waste container.



C. Developing the Test

- Slides are best developed no sooner than three days after sample application to allow for degradation of any fruit and vegetable peroxidases that may be present in the fecal sample. However, if immediate testing is required, wait 3 to 5 minutes before developing.
- Open back of slide and apply two drops of Hemocult® SENSE Developer to guaiac paper directly over each smear.
- **Read results within 60 seconds.** Any trace of blue on or at the edge of the smear is positive for occult blood.



D. Developing the Performance Monitor® Feature (Quality Control)

- The Performance Monitor® areas must be developed on every slide.
- Apply **one drop** of Hemocult® SENSE Developer between the positive and negative Performance Monitor® areas.
- **Read results within 10 seconds.** If the slide and developer are functional, a blue color will appear in the positive Performance Monitor® area and no blue will appear in the negative Performance Monitor® area.
- Neither the intensity nor the shade of the blue from the Positive Performance Monitor® area should be used as a reference for the appearance of positive test results.
- Any blue originating from the positive Performance Monitor® area should be ignored when reading the sample test results.

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Fecal Occult Blood Using Beckman Coulter Card, Continued

Non-Controlled documents The following non-controlled documents support this procedure.

- TJC, CAMH, Waived Testing, 2013.
 - College of American Pathologists, Point-of-Care Testing Checklist, July 29, 2013.
 - Commission on Office Laboratory Accreditation (COLA) Criteria.
 - Beckman Coulter FOBT Test Product Insert
 - BIO-RAD Quantify Control Package Insert
-

Controlled documents The following controlled document supports this procedure.


Regional Parent Document Reference Number: SCPMG-PPP-0179 Rev. 01

Reference
Regional Point-of-Care Quality Assurance Program

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Fecal Occult Blood Using Beckman Coulter Card, Continued

Reviewed and approved by:

Signature	Date
	10/23/14
Ji Yeon Kim, MD, MPH CLIA Laboratory Director SCPMG Target Laboratories	

Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name: _____ Operations Director, Area Laboratory	
Name: _____ CLIA Laboratory Director	

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Fecal Occult Blood Using Beckman Coulter Card, Continued

HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
