PROCEDURE
Corewell Health East - Fecal Occult Blood, Polymedco OC-SENSOR DIANA

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

Reference #: 34280

Version #: 2

Effective Date: 09/25/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Chemistry

1. Principle

A. The OC-Auto SENSOR DIANA Fecal Occult Blood (iFOB) Test is intended for the qualitative detection of fecal occult blood in feces. This test is an immunoassay utilizing rabbit polyclonal antibodies to specifically detect the presence of human hemoglobin (hHb) in feces.

B. The OC-Auto SENSOR DIANA iFOB Test uses an optical measurement method utilizing the OC-Auto SENSOR DIANA iFOB analyzer and a latex agglutination reaction. A latex reagent is prepared by sensitizing anti-human HbA_0 antibodies to polystyrene latex particles. When this reagent is mixed with the sample, the anti- human HbA_0 antibodies that were sensitized to latex react with the hemoglobin in the sample, resulting in a latex agglutination reaction. This reaction is then analyzed for changes in optical density, with the amount of the change increasing in proportion to higher concentrations of HbA_0 in the sample. The sample absorbance is compared to a stored calibration curve and qualitative results are reported.

C. The presence of fecal occult blood in the stool is associated with gastrointestinal disorders such as diverticulitis, polyps and Crohn's disease, that may lead to colorectal cancer if not treated. Early diagnosis by fecal occult blood screening and treatment of these problems has been shown to significantly reduce mortality from colorectal cancer.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. Specimen

A. Refer to the Instructions for Use provided with each Personal Use Collection Kit. Read all package insert directions carefully before sample collection. Test results may be invalid if test is not collected properly.

1. Do not reopen sampling bottle after fecal sample has been inserted.
2. No special dietary restrictions are required. Results of this test are not affected by dietary peroxidase or animal blood.
3. The specimen is stable in the Polymedco sampling bottle for 30 days refrigerated and 15 days at room temperature. Do not freeze.
4. Bring sample to room temperature prior to assaying and mix well before sampling.

B. Rejection Criteria
1. Collection tube or sampling device other than Polymedco OC-Auto sampling bottle.
2. Unlabeled specimens.
3. Specimens without a collection date.
4. Specimens received after a prolonged delay (more than 15 days at room temperature since collection).
5. Leaking sampling bottle or sampling bottle without adequate liquid.
6. Frozen specimens.

4. Reagent/Equipment Needed

A. **OC-Auto SENSOR DIANA Analyzer**
1. Racks for analyzer
   a. Sample rack is Light Blue
   b. Retest rack is Green
   c. Standard and QC rack is Blue
   d. Dilute test rack is Orange

B. **OCDL OC-Auto SENSOR DIANA Latex Reagent**
1. Stable until expiration date when stored unopened at 2-8º C.
   a. Open vial stability: 14 days when stored at 2-8 º C.
      1) Calibration stable for 2 weeks when latex reagent is stored at 2-8 º C.
   b. Alternative Open Vial Stability: 10 days when stored at 25 º C. (Left onboard analyzer)
      1) Calibration stable for 1 week when latex reagent is stored at 25 º C. (Left onboard analyzer)

C. **OCDB OC-Auto SENSOR DIANA Buffer**
1. Stable until expiration date when stored unopened at 2-8 º C.
   a. Open bottle stable for 30 days onboard analyzer.
      1) For optimal usage, do not remove from analyzer.

D. **OCDW OC-Auto SENSOR DIANA Wash Concentrate**
1. Stable until expiration date when stored unopened at 2 -30 º C.

E. **OC80C Calibrator**
1. Stable until expiration date when stored unopened at 2 -8 º C.

F. **OCQN –Negative Control**
1. The Negative Control is liquid ready. Store the Negative Control at 2 -8 º C. It will remain stable through the labeled expiration date in the absence of contamination.

G. **OCQP – Positive Control**
1. Bring the Positive Control vial to room temperature.
   a. Gently remove the rubber stopper from the vial.
   b. Add 1.0 mL of deionized water.
      1) Stable for 1 day at 2-8 ° or
      2) 30 days if aliquoted and stored at -20 ° C or below.

H. **OCS1, OCS2, & OCPU Sampling Bottle**
1. Stable until expiration date: prior to addition of sample to sampling bottle.
2. Stability of the specimen within the sampling bottle when stored at ambient temperature: 15 days.
3. Stability of the specimen within the sampling bottle when stored at 2-8 º C: 30 days. Do not freeze.

I. Supplies
1. Disposable Cells (Dispo-Cells)/ Reaction Cuvettes
2. Forceps
3. Methanol
4. Kim Wipes

5. Maintenance

A. Daily Maintenance “Beginning of the Day”

1. Turn on standby switch and select [START]
2. Set latex reagent and/or check current volume. Ensure that caps are removed from Latex Reagent bottles.
3. Check volumes in waste, DiH20 and wash solution tanks
4. Set buffer and/or check current volume.
5. Prime wash solution, DiH2O and buffer by selecting [MENU] [SUPPORT] [PREP FUNCTIONS] [NORMAL PRIME] [START] (Repeat this procedure once for a total of 2 primes)
6. If using frozen aliquots of Quality Control material, allow adequate time for thawing to room temperature. Gently remix prior to use.
7. When preparing fresh controls, allow positive control to come to room temperature and reconstitute with 1 ml DI water. Let reconstituted control sit at room temp for 15 minutes. The negative control is liquid-ready. Aliquot 250 µl of each control and store at -20º C for a four day supply.

B. Daily Maintenance “End of the Day”
   1. Remove sampling bottles on which analysis has been compl
   2. Recap the latex reagent bottles and either store in the refrigerator or on board the analyzer.
   3. Select [MENU] [MAINTENANCE] [CLOSE MODE] [CLOSE MODE]
   4. Select “YES” for Cell wash, “NO” for exchange buffer and wash solution to p. water (DiH20) and “YES” for Nozzle/Cell soak wash.
   5. Select [SETTINGS OF AUTO START UP], program days of the week and start up times and select C-blank and Test.
   6. Select [START]
   7. Empty waste/drain tank and ensure that DiH2O and wash solution tanks have adequate volume.
   8. Select [CONTINUE]
   9. After closing the instrument will turn off automatically.

C. Weekly Maintenance
   1. Perform Cell Blank
      a. Performed automatically if selected in Close mode.
   2. Clean Wash Nozzles
   3. Clean Sample and Reagent Nozzles
   4. Clean Sample and Reagent Probe Troughs
   5. Clean Rack Trays and Racks

D. Monthly Maintenance
   1. Clean Tanks
      a. Wash Solution
      b. DiH20

E. As Needed
   1. Replace Cells

6. Quality Control

A. Positive Control
   1. **Preparation:** Reconstitute the Positive Control with 1mL of deionized water and let sit at room temperature for 15 minutes. Invert to mix.
   2. Aliquot 200µL of control into 5 sample cups, label and freeze each aliquot at -20°C.
   3. **Storage:** 2-8°C – unopened.
   4. Once reconstituted, the controls are stable for 1 day when stored at 2-8°C.
   5. Aliquots stored at -20°C are stable for 30 days. When using frozen aliquotsthaw at room temperature for 15 minutes. Mix gently by inversion before use.

B. Negative Control
   1. **Preparation:** Ready to use.
   2. Remains stable through the labeled expiration date in the absence of contamination.

3. **Storage:** 2-8°C
4. **Expiration:** date printed on bottle label.

C. Running the QC
1. Place negative and positive controls into cups and place into positions 9 and 10 respectively in the blue STD/QC rack.
2. Select [MENU] [TEST] and press [START].
3. After analysis is complete, verify positive and negative control results and discard used cups.

7. Calibration

A. Frequency of Calibration
1. Once every 2 weeks
2. With a new lot of latex reagent.

B. Standard
1. **Preparation:** Reconstitute Standard with 1mL deionized water. Mix gently by inversion and let sit at room temperature for 15 minutes. Pipette 400µL into a sample cup for use.
   a. Concentration is kit specific and labeled on each vial.
   b. **Storage:** 2-8°C – unopened. Do not freeze.
   c. Once reconstituted, the calibrator is stable for one day. Store at 2-8°C.
2. Set up the blue STD/QC rack. Place 10 cups in the rack.
   a. Position #1 - 2.5 mL Calibrator Diluent Buffer (Ready to use) from Standard Kit.
   b. Position #2 – 500 µl of standard
   c. Position #3 thru #8 – EMPTY
   d. Position #9 – QC - 250 µl of negative control
   e. Position#10 – QC - 250 µl of positive control
3. Calibration Procedure
   a. Input the standard HbAo concentration (found on the front of the calibrator vial) by selecting [MENU] [SETTINGS] [PROTOCOL SETTINGS]
   b. Select the CC #
   c. Input the number of replicates (generally set to 1)
   d. Input the standard concentration
   e. Select [CONTINUE] [REGISTER]
   f. Select [MENU] [TEST]]SETTINGS] [SYSTEM SETTINGS] [STD/QC PROCESS], set “Operator’s Judgment” to YES and select [CONTINUE] [REGISTER]
   g. Select [MENU] [TEST] [PROTOCOL SETTINGS] [SAMP/QC PROTOCOL], set QC Replicate to 1 and select [CONTINUE] [REGISTER]
   h. Place blue STD/QC rack with barcode facing forward and to the left. Ensure that rack foot is seated underneath the rack feeder.
   i. Select [MENU] [TEST] and press [START]- Calibration takes approximately 13 minutes.
   j. After calibration is complete, [CHECK CC] screen will be displayed. Check the result and if acceptable (no red rectangle next to any of the STD #’s), press [REGISTER].
   k. Verify positive and negative control results and discard used cups.

8. Procedure

A. Remove the Latex Reagent from the refrigerator and allow it to sit for 15 minutes at room temperature. Invert several times prior to use to assure a uniform suspension.
B. Turn on the standby switch and select [START].
C. Set latex reagent and/or check current volume. Ensure the caps are removed from the Latex Reagent bottles.
D. Check volumes in waste, DiH2O and wash solution tanks.
E. Set buffer and/or check current volume.
F. Prime wash solution, DiH2O and buffer by selecting [MENU] [SUPPORT] [PREP FUNCTIONS] [NORMAL PRIME] [START] (Repeat this procedure once for a total of 2 primes)
G. If using frozen aliquots of Quality Control material, allow adequate time for thawing to room

temperature. Gently remix prior to use.

H. When preparing fresh controls, allow positive control to come to room temperature and reconstitute with 1 ml DI water. Let reconstituted control sit at room temp for 15 minutes. The negative control is liquid-ready. Aliquot 250 µl of each control and store at -20º C for a four day supply.
I. If patient samples have been refrigerated, let sit for 15 minutes at room temperature. Shake the sampling bottles vigorously to thoroughly mix the fecal extract.
J. Loading of sample bottles:
   1. Place sampling bottles or cups with sample into the aqua sample racks.
   2. Ensure that sample rack barcodes are to the left and facing forward and that foot is seated underneath the rack feeder
   3. Foil seal facing up.
   4. Select [MENU] [TEST] and press [START].
   5. After analysis is complete, verify results and discard used cups.
K. Remove sampling bottles on which analysis has been completed
L. Recap the latex reagent bottles and either store in the refrigerator or on board the analyzer.
M. Select [MENU] [MAINTENANCE] [CLOSE MODE] [CLOSE MODE]
N. Select “YES” for Cell wash, “NO” for exchange buffer and wash solution to p. water (DiH20) and “YES” for Nozzle/Cell soak wash.
O. Select [SETTINGS OF AUTO START UP], program days of the week and start up times and select C-blank and Test.
P. Select [START]
Q. Empty waste/drain tank and ensure that DiH2O and wash solution tanks have adequate volume.
R. Select [CONTINUE].
S. After closing the instrument will turn off automatically.
T. Note: RETEST will not puncture foil on sample container.

9. Results/Interpretation

A. Qualitative results are displayed and printed automatically
B. The OC-Auto SENSOR DIANA iFOB test will detect a positive result if the sample contains greater than 100 ng hHb/mL.

10. Limitations

A. The OC-Auto SENSOR DIANA iFOB Test is intended only for the detection of hemoglobin in feces.
B. Patients with the following conditions should not be considered for testing, as these conditions may interfere with test results:
   1. Bleeding hemorrhoids
   2. Menstrual bleeding
   3. Constipation bleeding
   4. Urinary bleeding

   However they may be tested after such bleeding ceases.
C. Certain medications such as aspirin and non-steroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients and cause positive results.
D. As with any occult blood test, results obtained with the OC-Auto SENSOR DIANA iFOB Test should not be considered conclusive evidence of the presence or absence of GI bleeding or pathology. OC-Auto SENSOR DIANA iFOB Test is designed for preliminary screening. It is not intended to replace other diagnostic procedures such as colonoscopy or sigmoidoscopy in combination with double contrast barium x-ray. It is not intended for use in patients with upper GI bleeds.
E. Because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, a negative test result does not assure absence of lesion.
F. A positive result should be followed up with further studies to establish the source of bleeding.
G. Urine and excessive dilution of samples with water from the toilet bowl may cause erroneous test results. For best results, use the collection paper in the collection kit.

H. OC-Auto SENSOR DIANA iFOB Test is not for use in testing urine, gastric specimens or other body fluids.
I. FOB testing is recommended annually by the American Cancer Society (2008) for average-risk women and men, 50 years of age and older, however, patients with significant risk factors such as family history of colorectal cancer should be screened earlier and more often.
J. The test has not been validated for testing of patients with hemoglobinopathies.
K. Interfering Substances
    1. Cross reactivity with hemoglobin and tissue extracts of other species were performed with no cross reactivity being evident
    2. Potential interference with dietary substances were assessed with no cross reactivity being evident.

11. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

12. References

OC-Auto 80 Automated Fecal Occult Blood Analyzer Operation Manual, Polymedco, Inc., 2014

13. Procedure Development and Approval

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14. Keywords

Not Set