Dignity Health Laboratories	iFOB TEST OC-Auto SENSOR io
Arroyo Grande Community Hospital French Hospital Medical Center Marian Regional Medical Center	Procedure: 7500-H-72 Origin: Hematology

Applies to:		
☒ Santa Maria Campus, Marian Regional Medical Center	☐ Arroyo Grande Campus, Marian Regional Medical Center	☐ French Hospital Medical Center
☐ St. John's Pleasant Valley Hospital	☐ St. John's Regional Medical Center	

I. Principle:

The iFOB Test is an immunoassay utilizing rabbit polyclonal antibodies to specifically detect the presence of hemoglobin in feces. The immunological test is performed on the OC-Auto SENSOR io which provides qualitative results.

II. Clinical utility:

The iFOB test is an immunoassay test system performed on the OC-Auto SENSOR io. The test system is intended for the qualitative detection of fecal occult blood in feces. The automated test is used as an aid to detect blood in stool when lower gastrointestinal bleeding is suspected. The presence of fecal occult blood in stool is associated with a number of gastrointestinal disorders such as colitis, polyps, and colorectal cancer.

III. Specimen Collection:

Sample Type	Container	Minimum Volume	Storage Temperature	Stability
Inoculated Stool Sample	Must be collected at site using OC-Auto Sample Probe and Bottle	N/A	2-8 ºC 15-30 ºC	≤30 Days ≤15 Days
Fresh Stool	Must be inoculated using OC-Auto Sample Probe and Bottle within 4 hours of defecation	N/A	2-8 ºC 15-30 ºC	≤30 Days ≤15 Days

IV. Materials and Reagents:

Supplies/Materials	Equipment
OC-Auto SENSOR io Cuvettes (OC80CUV)	OC-Auto SENSOR io Analyzer
OC-Auto SENSOR io Sample Cups	

Reagent/Supply	Storage	Open Stability
Sampling Bottle (OCIOS1/2)	2-30°C	Expiration date on Bottle
Latex Reagent (OCIOL)	2-8°C	14 Days
Buffer (OCIOB)	2-8°C	On board 30 days
Wash Concentrate (OCIOW)	2-30°C	Expiration date on bottle
Calibration Kit (OCIOC)	2-8°C	Expiration date on bottle
Negative Control (OCQN)	2-8°C	Expiration date on bottle
Positive Control (OCQP)	2-8°C	Expiration date on bottle

V. Preparation of Reagents

A. Latex Reagent Kit (OCIOL)

1. Take the reagent out of the refrigerator and incubate at room temperature for 15 minutes.
2. Gently invert the bottle several times
3. After opening wipe rim of bottle, the reagent stability is 14 days when stored at 2-8 C after end of each day of use

B. Buffer Kit (OCIOB)

1. Incubate for 30 min in the buffer bottle cradle before use.
2. After opening, the ‘onboard’ reagent stability is 1 month

C. Calibrator Kit (OCIOC)

1. Ready to use and stable until expiration date when stored at 2-8 C even when opened.
2. Calibrate when LOT# of latex reagent is changed
3. Calibrate every 14 days if latex is refrigerated every night

D. Wash Concentrate (OCIOW)

1. Mix 15 ml of wash concentrate with 485 ml of DI water

VI. Maintenance

A. Daily

1. Check the level and expiration of the buffer (left position), wash solution (middle position) and DI water (right position). If needed, change buffer, refill wash solution and/or DI water
   a) If changing bottles select [MENU]-->[PRIME]-->[START]
   b) Select the bottle that was replaced or select ALL and press [START]
2. Check that the drain tank is not full. If full empty the tank as medical waste.
3. Check the thermo-sensitive paper. Replace the paper if needed.
4. Turn on the system power switch (on left side). After initializing the 'Sample' screen in the 'Analyze' screen will be displayed.
5. Open the reagent compartment cover (right cover)
6. Set Latex reagent on the reagent cradle with cap off
7. Close the reagent cover
8. Open the cell compartment cover (middle cover)
   a) Place up to 2 new DISPO-Cell segments in position S16 and S17
   b) Close the cell cover

B. End of the Day

1. Remove latex reagent, recap, and place it back in the refrigerator
2. Remove any patient samples and discard used DISPO-Cells
3. Close all covers
4. Press [MENU] →[CLOSE] →[START]
5. Turn off the system power switch (left side)
   NOTE: Do not turn off the main power switch on the back
6. Check the level of the buffer and replace if needed.
7. Empty drain tank as medical waste if needed.

C. Weekly

1. Press the[MENU]→[MAINTENANCE]
2. Select [CLEAN UP S-PROBE]→[START]
3. Select [Clean UP R-Probe]→[START]
4. Clean reagent cradle back to front (open right cover)
5. Clean cuvette slot back to front (open middle cover)

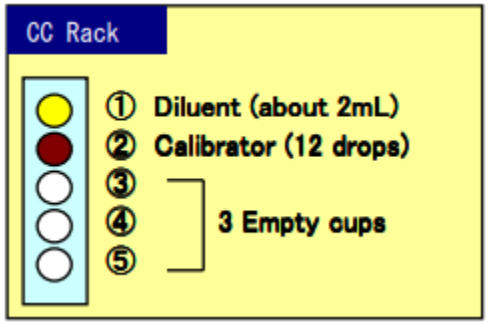
D. Monthly

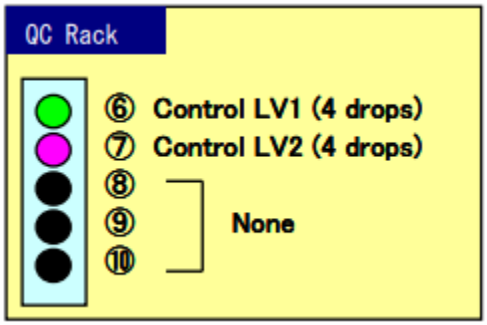
1. Refer to Instruction manual to clean sample racks

VII. Calibration: Calibration is required every 14 days, new lot of latex, or after major repair.

A. Prepare for calibration

1. Allow calibration kit to reach room temperature
2. Place 5 cups in a sample rack (CC Rack)
3. Place 2 cups in another sample rack (QC Rack)
4. Add the following to the cups:





Note: LV1=Neg and LV2=Positive

B. Load the racks

1. First set the CC Rack on the right (S10) and place the QC rack next to it in the second rack position (S11). First position towards the back.
2. Close the sample compartment cover.
3. Place a segment of Dispo-cells in the cell compartment (middle) in position S16
4. Close the cell compartment cover

C. Program the Calibration

1. In the analyze menu, press [CC] tab and select calibration curve number 1.
2. Set controls , for QC1 and QC2 select 'YES' for both levels
3. Enter the Latex reagent lot number by pressing the LOT No. button and entering the lot number
4. Enter the standard concentration by pressing the CAL. CONC. button and entering the concentration of the calibrator bottle.
5. Press [START]. The calibration will take about 7 minutes

D. Review Calibration and Control data

1. The screen will display 'Calibration has been finished' Check the printed data

   Upper conc.: Theoretical value (concentration of calibrator)
   Lower conc.: Application value (concentration recalculated based on OS value using specified calibration curve formula)
   OS value: Electrical value of the optical system

   STD2: Lower conc. should be +/-10% difference from upper conc.
   STD3-5: Lower conc. should be +/-5% difference from upper conc.

2. Verify the controls are within acceptable range. If the values meet the above criteria and both controls are within acceptable range, select [YES].

E. Remove all sample cups from the sample rack.

VIII. Quality Control (without performing new Calibration):

A. Quality Control Material: The positive and negative controls are liquid ready and must be run each day of patient testing or after calibration.
   1. Place 200µL or 4 drops negative (OCQN) and 200µL or 4 drops positive (OCQP) controls into cups in position 1 & 2 in a sample rack.
   2. Place the rack in the sample rack compartment in position S10 and close the sample cover.
   3. Place Dispo-cell in the cell compartment in position S16 and close the cell cover
   4. To program the QC, in the analyze menu, press the [QC] tab. Set controls for QC1 and QC2 select 'YES' for both levels. Press [START]
   5. Record lot number, expiration date and control results on manual log.
   6. If controls do not perform as expected, do not use test results. Repeat the test or call Polymedco Technical Services at 800-431-2123.

IX. Specimen Collection, Storage and Preparation

A. Collect feces from sample collection paper or from specimen caught in a clean cup.
B. All required information should be included on the sample bottle.
C. Open the green cap and scrape the surface of the fecal sample with the sample probe. The grooved portion of the sample probe should be completely covered with stool.
D. Close sampling bottle by inserting the sample probe and screwing cap on tightly.

X. Procedure:

A. Bring test reagents and patient fecal extract to room temperature. Shake the sampling bottle vigorously to mix the fecal extract.
B. Label the fecal sample(s) with barcodes and load the sample(s) by placing sample bottles' cap down in the sample rack, with foil seal on top. Alternatively, the samples can be pipetted into sample cups.
C. Place a sample rack in the sample compartment beginning in position S10. Position first sample towards the back of the unit.
D. If needed, place up to 2 new Dispo-cells into the cell compartment, one in position S16, and a second in position S17. Close the cell compartment cover.
E. A maximum of 4 samples racks (20 samples) can be set in the sample rack cradle.
F. To program in the analyze menu, press the sample tab. Press [START]
G. To adjust the Start Cell to the next available cell, select the desired button and input the new Start Cell number.
H. Press [START], the instrument will automatically progress to the next unused Dispo-cell.
I. To run a test that has already been punctured (if foil is pierced), change to retest mode.
   1. Select the mode button in the sample tab, select 'RETEST',
   2. Reinsert the sample rack with sampling bottles from the right side of the sample rack cradle partition in sequence.
   3. Press [START].
J. After finishing the analysis, results will be printed automatically.

XI. Interpretation of Results:

A. REFERENCE RANGES

1. POSITIVE: Results of iFOB Test greater than 20µL hHb/g stool or 100 ng hHb/mL buffer are associated with positive results.
2. NEGATIVE: Expected value for apparently normal individuals is a Negative result

B. CRITICAL VALUES: None

XII. Result Reporting:

A. In MANUAL MODE of ACCESSION RESULT ENTRY, scan the patient/QC barcode or manually enter the accession number.
B. Review results. If necessary, add a Result Comment or Result Note to document collection or processing problems and/or communications with nurses or physicians. Result either 'Positive' or 'Negative' under Occult Blood EIA. Enter latex lot number and expiration date.
C. Enter results for Pos and Neg QC. Result 'Not Applicable' for OccBL Internal Cntrl

XIII. Limitation of Procedure:

A. The iFOB Test is only for the detection of hemoglobin in feces.
B. Patients with the following conditions should not use this test due to interference with test results:
   1. Bleeding hemorrhoids
   2. Constipation bleeding
   3. Menstrual bleeding
   4. Urinary bleeding
C. Certain medications such as aspirin and non-steroidal anti-inflammatory drugs may cause gastrointestinal irritation and cause positive results.
D. The iFOB test is designed for preliminary screening and should not replace other diagnostic procedures. It is not intended for use in patients with upper GI bleeds.
E. Because gastrointestinal lesions may bleed intermittently, a negative test result does not assure the absence of lesion.
F. Urine and dilution of samples with toilet water may cause erroneous test results.
G. The test has not been validated for testing of patients with hemoglobinopathies.

XIV. References:

OC-Auto SENSOR io iFOB Test. Package Insert 380321-A. December 2019.

OC-SENSOR io Instruction Manual UL Rev.2. March 2021.

Approver	Status	Date
	Approved	
Kevin Ferguson, MD	Effective Date	

Review/Revised Date	By	Description of Changes