OC-Auto® SENSOR **io** iFOB Test

Caution: U.S.A. Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory and use is restricted to or on the order of a physician. For in vitro diagnostic use only.

INTENDED USE
"OC-Auto SENSOR io iFOB Test" is designed to be used together as an immunoassay test system. The test system is intended for the qualitative detection of fecal occult blood in feces by professional laboratories. The automated test is used for measurement of fecal occult blood and is useful as an aid to detect blood in stool when lower gastrointestinal bleeding may be suspected.

SUMMARY
The presence of fecal occult blood in the stool is associated with lower gastrointestinal disorders. Detection of fecal occult blood may lead to early diagnosis of these conditions and treatment.

iFOB, immunochemical fecal occult blood test (also known as FIT; fecal immunochemical test) has some advantages over conventional guaiac test. iFOB is more specific for human blood than guaiac tests, and it does not require special dietary restrictions prior to sample collection[1].

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

CONTRAINDICATIONS
Do not use beyond the labeled expiration date.

WARNINGS AND PRECAUTIONS
- For *in vitro* diagnostic use.
- The directions for use must be followed carefully for accurate results.
- Treat feces extraction samples as if they are potentially infectious.
- Do not use components beyond the labeled expiration date. The expiration date can be found on the carton and component labels.

STORAGE AND STABILITY
Store the OC-Auto SENSOR io iFOB Test reagents at 2-8°C. Do not freeze. Reagents are stable when stored at these temperatures until the expiration date printed on the labeling.

OCIOL Latex Reagent for OC-Auto SENSOR io
Stable until expiration date when stored unopened at 2-8°C.
Open Vial Stability: 7 days when stored at 25°C. Calibration stable for 1 week when latex reagent is stored at 25°C. (Left onboard analyzer)

OCIOB Buffer for OC-Auto SENSOR io
Stable until expiration date when stored unopened at 2-8°C.
For optimal usage do not remove from analyzer.

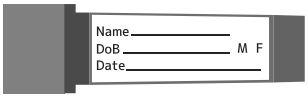
OCIOW Wash Concentrate for OC-Auto SENSOR io
Stable until expiration date when stored unopened at 2-30°C.

OCIOC Calibration Kit for OC-Auto SENSOR io
Stable until expiration date when stored unopened at 2-8°C.

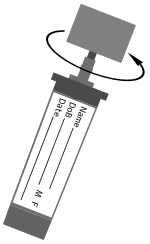
OCSIO1/OCSIO2 & OCPUIO Sampling Bottle for OC-Auto SENSOR io
Stable until expiration date: prior to addition of sample to sampling bottle. Stability of the specimen within the sampling bottle when stored at ambient temperature: 15 days. Stability of the specimen within the sampling bottle when stored at 2-8°C: 30 days. Do not freeze.

SPECIMEN COLLECTION, STORAGE AND PREPARATION
Collect feces from the sample collection paper or from specimen caught in a clean cup. Contamination from toilet water should be avoided.

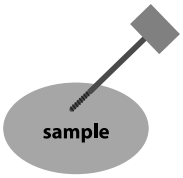
1. Fill in all required information on the sampling bottle.



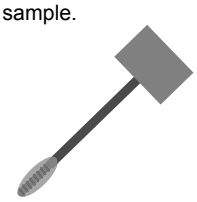
Open green cap by turning to the left and pulling upwards.



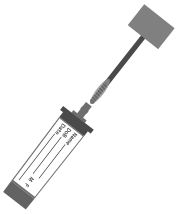
2. Randomly scrape the surface of the fecal sample with the sample probe.



Cover the grooved portion of the sample probe completely with stool sample.



3. Close sampling bottle by inserting the sample probe and screwing cap on tightly to the right. Do not reopen.



Return the sampling bottle to your doctor or laboratory in envelope provided.

- Inoculated sample may be stored at room temperature for up to 15 days or can be refrigerated at 2-8°C for up to 30 days.
- Bring inoculated sample to room temperature prior to assaying and mix well before sampling.

CONTENTS OF *REAGENTS*
- **OCIOL** Latex Reagent for OC-Auto SENSOR io - Store at 2-8°C
  (2 x 7 mL of latex coated with anti-human HbA_0 rabbit IgG solution.)
- **OCIOB** Buffer for OC-Auto SENSOR io – Store at 2-8°C
  (1 x 200 mL contains 2.38 g of N-2-Hydroxyethylpiperazine -N'-2-ethanesulfonic acid (HEPES)
- **OCIOW** Wash Concentrate for OC-Auto SENSOR io – Store at 2-30 °C
  (1 x 120 mL contains 5 % Sodium Hypochlorite solution. Dilute 15 mL with 485 mL deionized water prior to use.)
- **OCIOC** Calibration Kit for OC-SENSOR io - Store at 2-8 °C
  (1 x 3 mL Calibrator, 1 x 45 mL Diluent)
- **OCSIO1/OCSIO2 OCPUIO Sampling Bottle** for OC-Auto SENSOR io - Store at 2-30°C 1 x 2mL

ORDERING INFORMATION

Catalog No.	Name	Contents
OCIOL	Latex Reagent	2 x 7 mL, Package Insert
OCIOB	Buffer	1 x 200 mL, Package Insert
OCIOW	Wash Concentrate	1 x 120 mL, Package Insert
OCIOC	Calibration Kit	1 x 3 mL Calibrator, 1 x 45 mL Diluent, Package Insert
OCSIO1/ OCSIO2	Sampling Bottle	4 x 50 / 20 x 50, Package Insert
OCPUIO	Personal Use Kit	20 each of Mailing Envelope, Collection Paper, Sampling Bottle, Return Envelope, Educational Brochure
OCQN	Negative Control	5 x 1 mL, Package Insert
OCIOQP	Positive Control	2 x 5 mL, Package Insert
OC80CUV	10 Cuvettes	1 x 100
OCSIO	OC-SENSOR io	Analyzer, Operators Manual

TEST PROCEDURE

1. Bring test reagents and patient fecal extract to room temperature (15-30°C, 59-86°F). Shake the sampling bottle vigorously and thoroughly mix the fecal extract.
2. Verify that the OC-Auto instrument is on and all reagents to be used are sufficient in quantity and within date.
3. Perform calibration on the OC-Auto instrument according to the operator's manual.
4. Load the samples by placing sample bottles cap down in the sample rack, with foil seal on top. Alternatively, the samples can be pipetted into sample cups.
5. Analyze the samples according to the instructions in the operator's manual.

QUALITY CONTROL

Good laboratory practices recommend the use of appropriate controls. Follow your state and local guidelines.

Controls are used to assure the operator that the test system is performing accurately. FOBT-CHEK® Positive (OCIOQP) and Negative (OCQN) Controls are available separately.

If controls do not perform as expected, do not use the test results.
Repeat the test or call Polymedco Technical Services at 800-431-2123.

LIMITATIONS OF THE PROCEDURE

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

  However they may be tested after such bleeding ceases.
- 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.
- As with any occult blood test, results obtained with the OC-Auto SENSOR io iFOB Test should not be considered conclusive evidence of the presence or absence of GI bleeding or pathology. OC-Auto SENSOR io 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.
- Because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, a negative test result does not assure absence of lesion.
- A positive result should be followed up with further studies to establish the source of bleeding.
- Urine and excessive dilution of samples with water from the toilet bowl may cause erroneous test results. For best result, use the collection paper in the collection kit.
- OC-Auto SENSOR io iFOB Test is not for use in testing urine, gastric specimens or other body fluids.
- FOB testing is recommended annually by the American Cancer Society (2018) for average-risk women and men, 45 years of age and older[2], however, patients with significant risk factors such as family history of colorectal cancer should be screened earlier and more often[1].
- The test has not been validated for testing of patients with hemoglobinopathies.

ASSAY CUTOFF

Results for the OC-Auto SENSOR io iFOB Test greater than 20 µg hHb/g stool or 100 ng hHb/mL buffer are associated with positive test results.

Positive rates with immunochemical fecal occult blood tests have been shown to vary in each patient population depending on the test used, age and ethnicity of the patient and the predisposition to colorectal disease and other factors that may be associated with gastrointestinal bleeding[3].

PERFORMANCE CHARACTERISTICS

A method comparison of the OC-Auto SENSOR io iFOB Test with the predicate device at 3 clinical sites on total of 405 samples demonstrated the substantial equivalence to the predicate device.

The overall percent agreement (OPA), positive percent agreement (PPA), negative percent agreement (NPA) and 95 % confidence intervals for 3 sites combined were calculated.

		Predicate			OPA	PPA	NPA
		Positive	Negative	Total	(95 % CI)	(95 % CI)	(95 % CI)
OC-Auto SENSOR io	Positive	105	0	105	100% (99.1 % - 100 %)	100% (96.5 % - 100 %)	100% (98.7 % - 100 %)
	Negative	0	300	300			
	Total	105	300	405			

Precision

Repeatability and between site reproducibility tests were performed on the OC-Auto SENSOR io iFOB Test. For reproducibility study, twenty-one replicates of fecal samples were performed over twenty days at seven levels of hemoglobin concentrations at 3 clinical sites. For total of 17,640 tests in reproducibility study, OPA was 100 %; NPA of 0, 50, and 80 ng/mL (0, 10, and 16 µg/g stool) was 100 %; PPA of 120 ng/mL (24 µg/g stool) was 99.9% and of 450 and 700 ng/mL (90 and 140 µg/g stool) was 100 %.

CROSS REACTIVITY TESTING

Cross reactivity studies were completed to investigate the cross reactivity with hemoglobin (Hb) of other species on the OC-Auto SENSOR io iFOB Test. Hb of bovine, equine, pig, rabbit, sheep, fish, turkey and goat origin was added to the test device to determine the cross reactivity of the test with Hb of other species. Each Hb of other species (600 ng/mL) was added to 7 levels of human hemoglobin (hHb) in stool sample. The results were as expected. The negative results continued to be negative and the positive results continued to be positive after the addition of the animal hemoglobins.

DIETARY TESTING

Potential interferences of dietary substances on the OC-Auto SENSOR io iFOB Test were assessed. Aqueous extracts of raw broccoli (2.5%), cauliflower (3.3%), cantaloupe (2.5%), horseradish (2.5%), red radish (2.5%), parsnip (2.5%), and turnip (3.3%) were added to the test device to determine if vegetable extracts interfere with the test. The extracts were prepared by homogenizing raw vegetable in a food processor and then subsequently centrifuging the extract to separate the solid and liquid phases. The concentrations added are of the final volume in a sample. No interference was detected. The study was performed with tissue extracts of beef (2.0%), pig (2.0%), rabbit (2.5%), sheep (2.0%), fish (2.0%), and chicken (2.0%) and no interference was detected. Dietary Iron (3.1 µg/mL), Vitamin C supplements (2 µg/mL), and horseradish peroxidase (25 µg/mL) were also tested and no interference was detected.

REFERENCES

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INDEX OF SYMBOLS

LOT	Batch code		Manufacturer		Consult instructions for use
	Use by date	IVD	*In vitro* diagnostic medical device		Biological risks
REF	Catalog number		Temperature limitation	Σ	Contains sufficient for <n> tests

Manufactured by:

EIKEN CHEMICAL CO., LTD.
4-19-9 Taito, Taito-ku, Tokyo 110-8408, Japan
https://www.eiken.co.jp/en/

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