380070-C

Cat. No. OCDL, OCDB, OCDW, OC80C, OCS1, OCS2, OCPU

OC-Auto® SENSOR DIANA 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 DIANA 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 the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal disorders (GI), e.g. colitis, polyps, and colorectal cancer.

The OC-Auto SENSOR DIANA iFOB Test is recommended for use in:

1. Routine physical examinations
2. Monitoring for bleeding in patients
3. Screening for colorectal cancer or gastrointestinal bleeding

SUMMARY

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.

Conventional test methods used for the detection of fecal occult blood do not provide a high degree of accuracy. Immunological tests developed to detect human hemoglobin are more accurate and do not require special dietary restrictions for patients.

PRINCIPLE OF THE PROCEDURE

The OC-Auto SENSOR DIANA iFOB Test is an immunoassay utilizing rabbit polyclonal antibodies to specifically detect the presence of Hb 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 DIANA 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.

OCDL Latex Reagent for OC-Auto SENSOR DIANA iFOB

Stable until expiration date when stored unopened at 2-8°C.
Open vial Stability: 14 days when stored at 2-8°C. Calibration stable for 2 weeks when latex reagent is stored at 2-8°C.

Alternative Open Vial Stability: 10 days when stored at 25°C. Calibration stable for 1 week when latex reagent is stored at 25°C. (Left onboard analyzer)

OCDB Buffer for OC-Auto SENSOR DIANA iFOB

Stable until expiration date when stored unopened at 2-8°C.
Open vial stable for 30 days onboard analyzer. For optimal usage do not remove from analyzer.

OCDW Wash Concentrate for OC-Auto SENSOR DIANA iFOB

Stable until expiration date when stored unopened at 2-30°C

OC80C Calibrator for OC-Auto

Stable until expiration date when stored unopened at 2-8°C

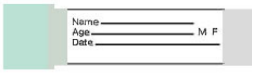
OCS1, OCS2 & OCPU Sampling Bottle for OC-Auto

Stable until expiration date: prior to addition of sample to sample 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.

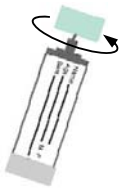
SPECIMEN COLLECTION, STORAGE AND PREPARATION

Collect feces from the sample collection paper or from specimen caught in a clean cup or collected during routine physical examinations during the visit. i.e. DRE. Contamination from toilet water should be avoided.

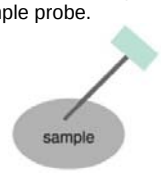
1. Fill in all required information on the sampling bottle.



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 sample device to your doctor or laboratory in envelope provided.

- Extracted feces 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 extractions to room temperature prior to assaying and mix well before sampling.

CONTENTS OF REAGENTS

- **OCDL** Latex Reagent for OC-Auto SENSOR DIANA iFOB - Store at 2-8°C (5 x 15 mL of latex-sensitized anti-human HbA_0 rabbit IgG solution.)
- **OCDB** Buffer for OC-Auto SENSOR DIANA iFOB - Store at 2-8°C (1 x 500 mL contains 5.95 g of N-2-Hydroxyethylpiperazine -N'-2-ethanesulfonic acid (HEPES)
- **OCDW** Wash Concentrate for OC-Auto SENSOR DIANA iFOB - Store at 2-30°C (1 x 150 mL contains 5% Sodium Hypochlorite solution. Dilute 150 mL with 4850 mL deionized water prior to use.)
- **OC80C** Calibrator for OC-Auto - Store at 2-8°C (10 x 1 mL, 2 x 45 mL Diluent)

ORDERING INFORMATION

Catalog	Name	Contents
OCDL	Latex Reagent	5 x 15 mL, Package Insert
OCDB	Buffer	1 x 500 mL, Package Insert
OCDW	Wash Concentrate	1 x 150 mL, Package Insert
OC80C	Calibrator	10 x 1 mL, 2 x 45 mL Diluent, Package Insert
OCS1/2	Sampling Bottle	4 x 50 / 20 x 50, Package Insert
OCPU	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
OCQP	Positive Control	5 x 1 mL, Package Insert
OCDIANA	OC-Auto SENSOR DIANA iFOB Test Analyzer	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. Reconstitute the calibrator according to the calibration kit instructions at least 15 minutes before calibration.
3. Verify that the OC-Auto SENSOR DIANA iFOB instrument is on and all reagents to be used are sufficient in quantity and within date.
4. Perform calibration on the OC-Auto SENSOR DIANA iFOB instrument according to the operator's manual.
5. 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.
6. 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.

External Controls
External controls are used to assure the operator that the test system is performing accurately. iFOBT Positive (OCQP) 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 DIANA 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 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.
- 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 DIANA 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 (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.
- The test has not been validated for testing of patients with hemoglobinopathies.

EXPECTED VALUES
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.

Results for the OC-Auto SENSOR DIANA iFOB Test greater than 20 µg hHb/g stool or 100 ng hHb/mL buffer are associated with positive test results. However, the expected value/reference values may vary from laboratory to laboratory and depending on various factors such as population and frequency of screening. It is therefore recommendable for each institution to establish corresponding reference values.

PERFORMANCE CHARACTERISTICS
A comparison of the OC-Auto SENSOR DIANA iFOB with the predicate device at 2 clinical sites (Site 1, n = 967; Site 2, n = 6584) on samples submitted from an average risk population for colorectal cancer screening demonstrates the substantial equivalence of the OC-Auto SENSOR DIANA to the predicate device.

The overall percent agreement (OPA), positive percent agreement (PPA), negative percent agreement (NPA) and confidence intervals are present for each site and combined.

Site 1 Long Island City, NY

	OC Micro		n = 967	CI
OC Diana	Positive	Negative	99.48% OPA	98.79-99.78
Positive	80	4		
Negative	1	882	98.77% PPA	93.34-99.78
Total	81	886	99.55% NPA	98.85-99.83

Site 2 Concord, CA

	OC Micro		n = 6584	CI
OC Diana	Positive	Negative	99.57% OPA	99.38-99.70
Positive	632	21		
Negative	7	5924	98.90% PPA	97.75-99.47
Total	639	5945	99.65% NPA	99.46-99.77

Combined Sites 1 and 2 NY+CA

	OC Micro		n = 7551	CI
OC Diana	Positive	Negative	99.56% OPA	99.38-99.69
Positive	712	25		
Negative	8	6806	98.89% PPA	97.82-99.44
Total	720	6831	99.63% NPA	99.46-99.75

OPA=100% x(a+b)/(a+b+c+d), PPA=100% x a/(a+c), NPA=100% x d/(b+d)

Precision
Between run precision was performed on the OC-Auto SENSOR DIANA iFOB Test using pools of specimens. Twenty replicates were performed over twenty days at three levels, 50, 135 and 880 ng/mL. All the 50 ng/mL replicates were negative and all the 135 and 880 ng/mL replicates were positive.

Prozone Effect
To determine the maximum hemoglobin concentration affecting test effectiveness (Prozone effect), 820,000 ng/mL of internal human hemoglobin Ao standard is used. The specimens at more than 12,000 ng/mL are indicated "PRC", which means "prozone", on the screen of the analyzer.

INTERFERENCE TESTING
Cross reactivity studies were completed to investigate the cross reactivity with hemoglobin (Hb) and tissue extracts of other species on the OC-Auto SENSOR DIANA iFOB Test. Hb of bovine, equine, pig, rabbit, sheep, fish, chicken 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 was added to normal stool extracts at both 0 and 105 ng/mL human hemoglobin (hHb). 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. The study was repeated with tissue extracts of beef, pig, rabbit, sheep, fish, chicken and no cross reactivity was evident.

DIETARY TESTING
A potential interference of dietary substances on the OC-Auto SENSOR DIANA iFOB Test was assessed. Aqueous extracts of raw broccoli, cauliflower, cantaloupe, horseradish, red radish, parsnip, and turnip were added to the test device to determine if vegetable extracts cross react 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. Dietary Iron and Vitamin C supplements and horseradish peroxidase were also tested. No cross reactivity was evident.

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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.
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