

380324-A

Store at 2-8°C

For in vitro diagnostic use only

Positive Hemoglobin Control for use with OC-Auto SENSOR io iFOB Test

Caution: Contains human source material. Handle as potentially infectious.

INTENDED USE

OC-Auto SENSOR io FOBT-CHEK Positive Control is a hemoglobin control material designed to monitor iFOB (Fecal Occult Blood Test) procedures. The use of controls helps to monitor technique as well as environmental and physical factors.

SUMMARY AND PRINCIPLE

Good laboratory practices recommend the use of appropriate controls. Refer to the Quality Control section of the OC-Auto SENSOR io iFOB Test package insert for instructions.

REAGENTS

OC-Auto SENSOR io FOBT-CHEK Positive Control is an in vitro diagnostic control composed of stabilized hemoglobin suspended in a buffered, bacteriostatic and fungistatic fluid.

WARNINGS AND PRECAUTIONS

Warning: Potentially Biohazardous Material

Because no test method can offer complete assurance that HIV, HBsAg, or other infectious agents are absent, it is recommended that human blood based products be handled with the same precautions used for any potentially biohazardous patient specimens.

This product utilizes human hemoglobin which is derived from human blood. The blood is tested for HBs antigens and HIV (HIV-1 and HIV-2) antibodies, and only blood that tests negative is used. Other viruses of pathogens were not tested and may be present. Therefore, when using these reagents, handle them with the same degree of caution as patient samples.

OC-Auto SENSOR io FOBT-CHEK Positive Control is intended solely for in vitro diagnostic use for the purpose described on the labeling. Polymedco Cancer Diagnostic Products shall not be liable for any claimed damages arising from other usage.

STORAGE AND STABILITY

Upon receipt, store OC-Auto SENSOR io FOBT-CHEK Positive Control at 2-8°C. This product is stable until the expiration date on the vial label.

PROCEDURE

1. The Positive Control is liquid ready. Store the control at 2-8°C. It will remain stable through the labeled expiration date in the absence of contamination.
2. Add Positive Control into sample cups. One drop of Positive Control is approximately 50 µL in volume. For one measurement, it takes about 150 µL (3 drops) of control, taking into consideration of dead volume of a sample cup being 100 µL. For a measurement in duplicates, 200 µL (4 drops) is required.

- Following the instructions in the OC-Auto SENSOR io iFOB Test package insert, perform measurement using the same procedure as is used for samples of unknown concentration.

EXPECTED VALUES

If the control fails to perform consistently, patient results should be considered invalid. Contact Polymedco Technical Services for assistance at (800) 431-2123.

LIMITATIONS OF THE PROCEDURE

OC-Auto SENSOR io FOBT-CHEK Positive Control is not designed to be used as a control for any other systems than OC-Auto SENSOR io iFOB Test. Do not use this Positive Control with OC-Auto SENSOR DIANA or OC-Auto Micro 80 iFOB Test.

External controls are used to assure the operator that the capture and conjugated antibodies are present and reactive. External controls will not detect an error in performing the patient test procedure.

ORDERING INFORMATION

Catalog Number	Product Description	Volume	Product Packaging
OCQN	OC-Auto® FOBT-CHEK® Negative Control	1 mL	5 x 1 mL
OCIOQP	OC-Auto® SENSOR io FOBT-CHEK® Positive Control	5 mL	2 x 5 mL

INDEX OF SYMBOLS

	Batch code		Manufacturer		Consult instructions for use
	Use by date		<i>In vitro</i> diagnostic medical device		Biological risks
	Catalog number		Temperature limitation		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/>

Distributed by

 **Polymedco**
Cancer Diagnostic Products, LLC

510 Furnace Dock Rd
Cortlandt Manor, NY 10567
800-431-2123 914-739-5400
FAX: 914-739-5890
www.polymedco.com
info@polymedco.com
www.fobt-tests.com

Date of Issuance: 2019-12-31
380324-A
PN 52741-00