

OC-Auto® FOBT-CHEK® Controls

341656-D

Positive Hemoglobin Control
For use with OC-Auto Micro 80 iFOB and
OC-Auto SENSOR DIANA iFOB
Not for use with the OC-Auto SENSOR io iFOB

Negative Hemoglobin Control
For use with OC-Auto Micro 80 iFOB
For use with OC-Auto SENSOR DIANA iFOB
For use with OC-Auto SENSOR io iFOB

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

INTENDED USE

OC-Auto FOBT-CHEK Controls are hemoglobin control materials designed to monitor FOBT (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 Micro 80 iFOB, OC-Auto SENSOR DIANA iFOB or OC-Auto SENSOR io iFOB Test package insert for instructions.

REAGENTS

OC-Auto FOBT-CHEK controls are in vitro diagnostic controls composed of stabilized hemoglobin suspended in a buffered, bacteriostatic and fungistatic fluid.
Negative Hemoglobin Control contains buffer only.

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 A₀ 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 or 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 FOBT-CHEK controls are 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 FOBT-CHEK controls at 2-8°C. This product is stable until the expiration date on the vial label.

PROCEDURE

- Following the instructions in the OC-Auto Micro 80 iFOB or OC-Auto SENSOR DIANA iFOB or OC-Auto SENSOR io iFOB Test package insert, perform measurement using the same procedure as is used for samples of unknown concentration.
- OCQN Negative Control is liquid ready. Store the Negative Control at 2-8°C. It will remain stable through the labeled expiration date in the absence of contamination.
- OCIOQP Positive Control for OC-Auto SENSOR io iFOB is liquid ready. Refer to the OCIOQP Positive Control package insert for instruction.
- OCQP, bring the Positive Control vial for OC-Auto Micro 80 iFOB or OC-Auto SENSOR DIANA iFOB to room temperature. Gently remove the rubber stopper from the vial. Add 1.0 mL of deionized water.
- Seal the vial with the rubber stopper, allow it to sit for at least 15 minutes, and mix by gently inverting the vial several times before use.
- Use the OCQP Positive Control on the same day it is reconstituted. If necessary, the OCQP Positive Control may be dispensed into aliquots and stored frozen after reconstitution. It will remain stable for 1 month when stored at -20°C or below.

EXPECTED VALUES

If the controls fail 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 FOBT-CHEK controls are not designed to be used as a control for any procedure other than FOBT.

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
OCQP	OC-Auto® FOBT-CHEK® Positive 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		Temperature limitation
	Use by date		Consult instructions for use
	Catalog number		Biological risks
	Manufacturer		Contains sufficient for <n> tests
	In vitro diagnostic medical device		

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