

380323-A

Store at 2-8°C

For in vitro diagnostic use only

For OC-Auto SENSOR io iFOB Test

KIT CONTENTS

Calibrator 3 mL, 1 vial

Diluent 45 mL, 1 bottle

INTENDED USE

OC-Auto SENSOR io Calibration Kit is hemoglobin calibration material (hemoglobin concentration of 1000 ng/mL) when using automated immunochemical analyzer, OC-Auto SENSOR io to measure fecal hemoglobin.

PROCEDURE FOR USE

Create the calibration curve, following the directions provided in the Operator's Manual. One drop is approximately 50 µL. Add about 600 µL (12 drops or more) of Calibrator into a sample cup. Add 2 mL or more of Diluent into another sample cup. Set the cups on a rack and measure to create calibration curve by the analyzer.

New calibration curve must be created under following conditions:

- When the lot of latex reagent is changed.
- When the value of OC-Auto SENSOR io FOBT-CHEK Positive Control is not within the indicated range.
- When opened latex reagent is left onboard for more than 7 days.
- After maintenance.

PRECAUTIONS FOR USE

1. For in vitro diagnostic use only.
2. Do not freeze the calibrator or diluent.
3. Do not use expired products.
4. Air bubbles on the surface after calibrator and diluent are in sample cups can result in erroneous measurement so that they should be removed.
5. The OC-Auto SENSOR io Calibration Kit utilizes human hemoglobin which is derived from human blood. The blood is tested for HBs antigens, HCV antibodies 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.
6. The Calibrator and Diluent contain less than 0.1% sodium azide in solution. If it enters the eyes or mouth, or contacts the skin, immediately and completely wash off with running water. If necessary, seek medical attention. In addition, sodium azide may react with lead and copper to form explosive metal azide. When disposing, drain together with large quantities of water.

STORAGE AND STABILITY

Upon receipt, store OC-Auto SENSOR io Calibration Kit at 2-8°C. This product is stable until the expiration date on the labels on vial and bottle.

INDEX OF SYMBOLS



Batch code



Use by date



Catalog number



Manufacturer



In vitro diagnostic medical device



Temperature limitation



Consult instructions for use



Biological risks



Contains sufficient for <n> tests

Manufactured by:



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