

REF 1000 **R_X ONLY**

INTENDED USE

OSOM iFOBT Control includes a Positive Control containing stabilized human hemoglobin and a Negative Control containing a buffer. OSOM iFOBT Controls should only be used with OSOM iFOBT tests.

WARNINGS AND PRECAUTIONS

- The Positive Control is the vial with the red cap and the Negative Control is the vial with white cap. Do not exchange the caps of the vials.
- The OSOM iFOBT Positive and Negative Control Vials should be stored at 2-30°C and can be used until the labeled expiration date.
- For *in vitro* diagnostics use and professional and laboratory use only.
- Do not use the controls beyond the expiration dates.
- Handle as if capable of transmitting hepatitis. Not for internal use by humans or animals.

REAGENTS

OSOM iFOBT Control Positive Control (1.0 ml) is liquid and ready to use.

WARNING: Contains Human serum with 0.1% Sodium azide. Contents sterile until opened.

OSOM iFOBT Control Negative Control (1.0 ml) is liquid and ready to use.

WARNING: Contains Human serum with 0.1% Sodium azide. Contents sterile until opened.

Directions for Use

- Allow the test and the controls to equilibrate room temperature 59-86°F (15-30°C) prior to testing.
- To begin the testing, open the sealed pouch of the OSOM iFOBT test by tearing the pouch. Remove the test cassette from the pouch and use it as soon as possible.
- Squeeze 3 drops of the Positive Control into the sample well of the OSOM iFOBT Cassette.
- With a new cassette, repeat the same procedure for the Negative Control.
- The results should be read at five minutes. **DO NOT INTERPRET RESULTS AFTER 10 MINUTES.**

EXPECTED RESULTS

- Read results at 5 minutes.
- Do not read results beyond 10 minutes.
- Even if a very faint color band appears in the test region, it should be considered a positive result.

Negative Control Results

Only one colored band appears on the control region. No apparent band on the test region.

Positive Control Results

Color bands appear on the control and test regions. Even if a very faint colored band appears in the test region it should be considered as positive result.

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Invalid

No line appears in the control region "C"; the test should be voided since an improper test procedure may have been performed or deterioration of positive or negative control reagents may have occurred. This is due to the internal control built in which a distinct control region (C) line should always appear. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact SEKISUI Diagnostics Technical Services at 800-332-1042 or techservices@sekisuidiagnostics.com.

WASTE DISPOSAL METHOD

The OSOM iFOBT Control contains sodium azide as a preservative. Best disposal method for biological material containing sodium azide is to wash it down the sewer with large excess of water. Disposal should be made in accordance with existing disposal practices. Observe all Federal, State and Local laws.

BIOHAZARD


Caution: Human source material used in the preparation has been found non reactive for HBsAg when tested by RIA, and also negative for HIV-1 antibody when tested by ELISA. However, no known test method can assure that a product derived from human sources does not contain hepatitis or HIV-1 viruses.

SYMBOLS

LOT Batch code

REF Catalog number


R_X ONLY Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

 Consult instructions for use

 Do Not Freeze

IVD *In Vitro* Diagnostic Medical Device

 Manufacturer

 Temperature limit

 Use by date

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