REF 200020

Status iFOBT Control Set

For In Vitro Diagnostic Use

Intended Use

Status iFOBT Control includes a Positive Control containing stabilized human hemoglobin and a Negative Control containing a buffer. **Status iFOBT Controls** should only be used with **Status 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 **Status iFOBT** Positive and Negative Control Vials should be stored at 2°C- 30°C and can be used until the labeled expiration date.
- For in vitro diagnostics use for professional and Laboratory use only.
- Do not use the controls beyond the expiration dates.
- Handle as if capable of transmitting hepititis.For in vitro diagnostic use only. Not for internal use by humans or animals

Reagents

Status iFOBT Control Positive Control (1.0 ml) is liquid and ready to use. WARNING: Contains Human serum with 0.1% Sodium azide. For in vitro diagnostic use only. Contents sterile until opened.

Status iFOBT Control Negative Control (1.0 ml) is liquid and ready to use. WARNING: Contains Human serum with 0.1% Sodium azide. For in vitro diagnostic use only. 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 **Status iFOBT** test by tearing the pouch. Remove the test device from the pouch and use it as soon as possible.
- Squeeze 3 drops of the Positive Control into the sample well of the **Status iFOBT** device.
- Repeat the same procedure for 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 colored line appears in the test region, it should be considered a positive result

Negative Control Results:

Only one reddish line appears on the Control Position (C). No apparent line on the Test Position (T).

Positive Control Results:

Reddish lines appear on the Control and Test positions. Even if a very faint colored line appears in the Test position it should be considered as positive result.

Invalid

No line appears in the Control position "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 occured. The Control line serves as a built-in internal control and should always appear. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact LifeSign Technical Services at 1-800-526-2125.

Waste Disposal Method:

The **Status 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

MF Manufactured for:

lifeSign

A PBM Group Company
85 Orchard Road, Skillman, NJ 08558
Phone: 800.526.2125, 732.246.3366 Fax: 732.246.0570
www.lifesignmed.com

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