iStatis

Hepatitis B Surface Ag Test Controls

REF **90-1141**

Read this Instructions for Use and the iStatis Hepatitis B Surface Antigen (HBsAg) Test Instructions for Use before using this product. Conformance with the test procedure is necessary to ensure accurate results. Before performing the test, all operators must become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings[1].

NAME AND INTENDED USE

The iStatis Hepatitis B Surface Antigen Test Controls are intended to be used only with the iStatis *Hepatitis B Surface Antigen* Test.

SUMMARY

iStatis HBsAg Positive and Negative Control should be used in conjunction with Good Laboratory Procedures. It should be run under the following circumstances:

- for new iStatis operator verification prior to performing testing on patient specimens
- when switching to a new lot number of iStatis HBsAg test kits
- whenever a new shipment of kits is received
- when temperature during storage of the kit falls outside of 2° to 30°C (35.6°F to 86°F).
- when the temperature of the test area falls outside of 15°- 30°C (59°- 86°F)
- At regular intervals as determined by the user facility

PRINCIPLES OF THE PROCEDURE

The iStatis HBsAg Test Controls have been designed for use with the iStatis *Hepatitis B Surface Antigen* Test to validate the correct performance of the test procedure in the hands of the operator.

The iStatis HBsAg Positive Control is prepared from a purified antigen in PBS buffer. The Positive Control has been designed to produce an easily visible blue colour on both the test line and control line.

The iStatis HBsAg Negative Control is prepared from defibrinated human plasma or serum which is negative for Anti-HIV, HBsAg, Anti-HCV, and Anti-Syphilis. The Negative Control will produce a blue colour on the control line, but no colour on the test line.

REAGENTS

HBsAg POSITIVE CONTROL

1 vial containing 1.0 ml of diluted purified recombinant Hepatitis B surface antigen. Each vial is sufficient for 20 iStatis HBsAg tests.

NEGATIVE CONTROL

1 vial containing 1.0 ml of processed human plasma or serum substitute, non-reactive for antibodies to HIV and HCV and non-reactive for HBsAg and Syphilis. Each vial is sufficient for 20 iStatis HBsAg tests.

WARNINGS & PRECAUTIONS

For *in vitro* diagnostic use only. IVD

Safety Precautions:

1. All specimens should be handled as if capable of transmitting infectious agents.
2. Thoroughly wash hands after handling or performing this test.
3. Do not smoke, eat, or drink in areas where specimens or kit reagents are being handled.
4. Wear disposable gloves while handling kit reagents or specimens. Do not pipette by mouth.
5. Avoid contact with skin and eyes. If contact occurs, wash affected areas with water.
6. Avoid forming aerosols.
7. Dispose of all specimens and materials used to perform the test in a biohazard waste container. The preferred method of disposal is sterilization by autoclaving for a minimum of one hour at 121°C. Disposable materials may be incinerated. Liquid waste may be mixed with sodium hypochlorite (bleach) in volumes such that the final mixture contains 1.0% sodium hypochlorite (using a freshly prepared solution containing 10% household bleach). Allow at least 60 minutes for decontamination to be completed. **Do not autoclave solutions that contain bleach**.
8. Spills should be cleaned up and decontaminated in accordance with the user facility's established procedures for handling biohazardous spills.
9. For additional information on bio-safety refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health Care Settings"[1] and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis"[2].

Handling Precautions:

Do not use iStatis HBsAg Test Controls beyond the expiration date printed on the pouch.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Positive or Negative Controls that are visibly turbid and/or contain particulate matter should not be used and should be discarded in accordance with safety precautions.

STORAGE INSTRUCTIONS

1. The iStatis HBsAg Test Controls are shipped without temperature control. Upon receipt, store at -20°C (-4°F) or at 2 - 8°C (36 – 46°F) for up to 1 year.
2. It is recommended to store the vials in an upright position.
3. Fluctuations in temperature causing freeze-thaw cycles may affect the performance of the iStatis HBsAg Test Controls.

⚠ **NOTE**: Once the Positive controls are thawed following storage at -20°C (-4°F) or opened after storage from 2 - 8°C, they remain stable up to for 6 months at 2 - 8°C (36 – 46°F). Negative controls remain stable for 1 year at 2-8°C (36 – 46°F) after thawing or opening**.** Do not re-freeze once the vials have been opened.

PROCEDURE

Materials Required but not Provided

- Precision pipette capable of delivering 50µl of specimen.
- iStatis HBsAg Test Instructions for Use.

Instructions for use

1. Read the iStatis HBsAg Test Controls Instructions for Use prior to using the Positive and Negative Controls.
2. Remove from storage at 2 – 8°C (36 – 46°F) or -20 °C (-4°F) and allow the Controls to reach room temperature before testing with iStatis HBsAg. Return Controls to storage at 2-8°C after use. DO NOT RE-FREEZE.
3. Mix the Controls by swirling before use.
4. Uncap the iStatis HBsAg Positive Control or Negative Control vial. Using a 50µl pipette, collect 50µl of the Control. Do not use the disposable single-use pipette provided for fingerstick blood collection with the iStatis HBsAg Test.
5. Transfer the Control sample held in the pipette to the iStatis HBsAg cartridge sample well.
6. Follow the iStatis HBsAg test procedure as described in the TEST PROCEDURE section of the iStatis HBsAg Test Instructions for Use.
7. All Controls should be tested in the same manner as patient samples.
8. The HBsAg Positive Control and the Negative Control are to be run on separate test cartridges.

INTERPRETATION OF RESULTS

- Follow the interpretation guidelines provided in the INTERPRETATION OF RESULTS section of the iStatis HBsAg Test Instructions for Use.
- **Positive Result:** Both the control line and the HBsAg test line show blue colour development.
- **Negative Result**: Only the control line shows blue colour development.
- **Invalid Result**: The test is invalid if any of the following occurs:
  -There is no blue colour on both the control line and the test line
  -There is blue colour on the test line but not on the control line
  -The smearing background makes it impossible to read the result

LIMITATIONS OF THE PROCEDURE

The iStatis HBsAg Test Controls are only validated for use with the iStatis HBsAg Test.

1. The TEST PROCEDURE and INTERPRETATION OF RESULTS sections of the iStatis HBsAg Test instructions for use must be adhered to when testing the iStatis HBsAg Test Controls.
2. Deviations from the procedure outlined in the iStatis HBsAg Test Instructions for Use may produce unreliable results.
3. Do not dilute the iStatis HBsAg Test Controls. The iStatis HBsAg Positive and Negative Controls are intended for use in undiluted form.
4. Adverse shipping and storage conditions or use of expired reagents may produce erroneous results.

EXPECTED RESULTS

The iStatis HBsAg Positive Control must be Positive with iStatis HBsAg test.
Negative Control must be Negative with iStatis HBsAg test. Controls that produce incorrect or invalid results must be re-tested with iStatis HBsAg test.

Contact bioLytical Laboratories' Technical Support if the iStatis HBsAg Controls do not produce the expected results.

REFERENCES

1. CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health care settings. *MMWR* 1988; 37(24):377-388

2. CDC Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 2001; 50(RR-11):1-42.

GLOSSARY OF SYMBOLS

-20°C 8°C	Store at -20°C for up to one year Store at 2-8°C for up to one year		Manufacturer
IVD	*In Vitro* diagnostic medical device		Caution Harmful if swallowed
	Consult Instructions for use		Use By Date
REF	Catalogue Number	CONTROL	Control
LOT	Lot Number		Do not use if Damaged

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