For Reference Use Only

FOR REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each test kit.

A run is valid if the following criteria are met:

- The absorbance values of the Negative Controls are greater than 0.00 and less than or equal to 1.00 AU. One Negative Control value may be discarded. If two or more Negative Controls are out of limit, the run must be repeated.
- The absorbance value of the non-neutralized Positive Controls (PCX) must be greater than equal to 1.00 AU and the individual absorbance values must be within range of 0.65 to 1.35 times the PCX. No Positive Control value may be discarded.
- The absorbance value of the non-neutralized Low Positive Controls (LPX) must be greater (or equal to) the absorbance value of the Positive Control, neutralized.
- The % reduction of each neutralized Positive Control and Low Positive Control is ≥ 50%.

INTERPRETATION OF RESULTS

Note: If the absorbance value of patient samples is greater than the upper linear range of the reader, use the next upper cutoff as the absorbance value for the following calculations.

1. Determine the X_non-neutralized for the neutralized ("A") and non-neutralized specimen signals.
2. Calculate the cutoff value by adding 0.035 to the Non-reactive for HBsAg Low Positive Control (LPCX) values.
3. Calculate the cutoff value by adding 0.035 to the Non-reactive for HBsAg Low Positive Control (LPCX) values.
4. The % reduction of specimen X_non-neutralized sample – X_neutralized sample

A specimen is considered to be positive for HBsAg if the following criteria are met:

- The specimen is repeatedly reactive by the GS HBsAg EIA 3.0.
- The absorbance value of the non-neutralized specimen is greater than or equal to the calculated cutoff value of the GS HBsAg Confirmatory Assay 3.0.
- The % reduction of the specimen X_non-neutralized sample – X_neutralized sample

LIMITATIONS OF THE PROCEDURE

1. The GS HBsAg EIA 3.0 Procedure and GS HBsAg Confirmatory Assay 3.0 Procedure package insert recommendations must be followed when testing serum, plasma, or cadaveric serum specimens for the presence of HBsAg. The user of this kit is advised to read the package insert carefully prior to conducting the test. In particular, the test procedure must be carefully followed for specimen and reagent pipetting, plate washing and timing of the incubation steps.
2. False negative results can occur if the quantity of marker present in the sample is too low for the detection limits of the assay, or if the marker which is detected is not present during the stage of disease in which a sample is collected.
3. Failure to add specimen or reagent as instructed in the procedure could result in a falsely negative test. Repeat testing should be considered where there is clinical suspicion of infection or procedural error.
4. An absorbance value of 0.00 AU may indicate a procedural or instrument error which should be evaluated. This result is invalid and that specimen must be re-run.
5. Factors that can affect the validity of results include failure to add the specimen or reagent to the well, inadequate washing of microplate wells, failure to store the plate in refrigeration temperature, use of wrong reagents to wells, the presence of mites, or splashing of bleed into wells.

BIBLIOGRAPHY

If specimens are shipped, they should be packed in compliance with Federal Regulations covering the transportation of infectious agents. Studies have demonstrated that specimens may be shipped refrigerated (2-8°C) or at ambient temperatures for up to 7 days. For shipments that are in transit for more than 7 days, specimens should be kept frozen (-20°C or lower). Refrigerate samples at 2-8°C at receipt, or freeze for longer storage.

This kit is not intended for use with specimens other than serum, plasma, and urine specimens. This kit is not intended for use on saliva/oral fluids or urine samples.

**EIA Procedure**

The following procedures for the confirmation of HbsAg in human serum or plasma, procedures A and B. For the confirmation of HbsAg in cadaveric serum specimens, only procedure A can be used. The two procedures for the confirmation of HbsAg are described below:

1. **Materials Required**
   - GS HbsAg EIA 3.0
   - Plastic test tubes.
   - Precision pipettes to deliver volumes from 10 µL to 200 µL, 1 µL, 5 µL, and 10 µL (accuracy within ± 10%).
   - A multichannel pipettor capable of delivering 100 µL or 200 µL is optional.
   - Pipette tips.
   - Dry-heat static or shaker incubator capable of maintaining 37±1°C using a shaker incubator.

2. **Neutralization Procedure**
   - Neutralization Procedure for multiple specimens.
   - Use only adequately calibrated equipment with this assay.
   - Use of dedicated equipment is recommended if equipment performance validations have not precluded the possibility of cross-contamination.

3. **Disposal**
   - Neutralization Procedure for multiple specimens.
   - Use only adequately calibrated equipment with this assay.
   - Use of dedicated equipment is recommended if equipment performance validations have not precluded the possibility of cross-contamination.

4. **Confirmation of HbsAg**
   - Neutralization Procedure for multiple specimens.
   - Use only adequately calibrated equipment with this assay.
   - Use of dedicated equipment is recommended if equipment performance validations have not precluded the possibility of cross-contamination.