Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgM)

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>REP</td>
<td>List Number</td>
</tr>
<tr>
<td>IVB</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>!</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Warning</td>
<td>Caution</td>
</tr>
<tr>
<td>Store at 2-8°C</td>
<td>Store at 15-30°C</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Activator Line Treatment</td>
</tr>
<tr>
<td>Assay Kit Card</td>
<td>Calibrators</td>
</tr>
<tr>
<td>CALIBRATORS</td>
<td>Contains Sodium Azide. Contact with acids liberates very toxic gas.</td>
</tr>
<tr>
<td>DANGEROUS REPRODUCTIVE HAZARD</td>
<td>Danger: Reproductive Hazard</td>
</tr>
<tr>
<td>DISTRIBUTED BY</td>
<td>Distributed by</td>
</tr>
<tr>
<td>LINE CLEANER</td>
<td>Line Cleaner</td>
</tr>
<tr>
<td>MASTER LOT</td>
<td>Master Lot</td>
</tr>
<tr>
<td>PIPETTE TIPS</td>
<td>Pipette Tips</td>
</tr>
<tr>
<td>PRIME/PURGE ACCESSORIES</td>
<td>Prime/Purge Accessories</td>
</tr>
<tr>
<td>PRODUCED FOR ABBOTT BY</td>
<td>Produced for Abbott by</td>
</tr>
<tr>
<td>PRODUCT OF USA</td>
<td>Product of USA</td>
</tr>
<tr>
<td>PURGE CONCENTRATE</td>
<td>Purge Concentrate</td>
</tr>
<tr>
<td>REACTION TRAYS</td>
<td>Reaction Trays</td>
</tr>
<tr>
<td>REAGENT COMPONENTS</td>
<td>Reagent Components</td>
</tr>
<tr>
<td>RUN CONTROL ADAPTERS</td>
<td>Run Control Adapters</td>
</tr>
<tr>
<td>SAMPLE CUPS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>WARNING</td>
<td>Warning: May cause an allergic reaction</td>
</tr>
<tr>
<td>SEVERE IRRITANT</td>
<td>Warning: Severe Irritant</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME AND INTENDED USE
The ABBOTT PRISM HBsAg assay is an in vitro chemiluminescent immunoassay (ChLIA) for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma specimens. The ABBOTT PRISM HBsAg (ChLIA) is intended to screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of HBsAg. It is also intended for use in testing blood and plasma specimens to screen organ donors when specimens are obtained while the donor’s heart is still beating, and in testing blood specimens to screen cadaveric (non-heart-beating) donors. It is not intended for use on cord blood specimens.

SUMMARY AND EXPLANATION OF THE TEST
Hepatitis B virus (HBV) is a small, partially double stranded, DNA virus and a member of the Hepadnavirus family. The HBV genome contains four overlapping reading frames representing the core, polymerase, surface, and X genes. This virus is responsible for infecting approximately one third of the global population.

HBV, unlike other DNA viruses, replicates through reverse transcription. The reverse transcription process lacks proofreading capability; therefore, HBV is prone to mutations that result in the generation of variants with altered biological properties.1 Some of these mutations may cause changes in the antigenic structure of the hepatitis B surface antigen (HBsAg), which is responsible for infection.2

BIOLICAL PRINCIPLES OF THE PROCEDURE
The ABBOTT PRISM HBsAg assay is a two-step sandwich ChLIA. The reactions occur within the ABBOTT PRISM System in the following sequence:

• Microparticles coated with mouse monoclonal anti-HBs are incubated with sample (either plasma, serum, calibrator, or control) in the incubation well of the reaction tray. Incubation of HBsAg present in the sample binds to the antibody on the Microparticles.
• After this incubation is complete, the reaction mixture is transferred to the glass fiber matrix (matrix) of the reaction tray using the Transfer Wash. The Microparticles are captured by the matrix while the remaining mixture flows through to the absorbent section of the reaction tray.
• The Acridinium-Labeled Goat Polyclonal Anti-HBs Conjugate is added to the Microparticles on the matrix and incubated. After this second incubation, the unbound Conjugate is washed into the blower with the Conjugate Wash.
• The chemiluminescent signal is generated by addition of an alkaline hydrogen peroxide solution. The resultant photons are counted.

The amount of light emitted is proportional to the amount of HBsAg in the sample. The presence or absence of HBsAg in the sample is determined by comparing the number of photons collected from the sample to a cutoff value determined from a calibration performed in the same batch. If the number of photons collected from a test sample is less than the cutoff value, the sample is considered nonreactive for HBsAg, hepatitis B surface antigen, in the first viral antigen to circulate in the infected individual.

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NOTE: Each specific component description that follows is accompanied by a unique symbol. These symbols appear on both the component labels and on corresponding instrument tubing identifier labels. They are meant to facilitate identification and installation of reagent bottles within the ABBOTT PRISM System ambient reagent bay and refrigerator.

REAGENTS
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This product contains sodium azide; for a specific listing, refer to the REAGENTS section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

The following warnings and precautions apply to the Purge Concentrate:

**WARNING:** Contains methylisothiazolones.

**H317** May cause an allergic skin reaction.

**P261** Avoid breathing mist / vapours / spray.

**P272** Contaminated work clothing should not be allowed out of the workplace.

**P280** Wear protective gloves / protective clothing / eye protection.

**Response**

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice / attention.

**P362+P364** Take off contaminated clothing and wash it before reuse.

**Disposal**

P501 Dispose of contents/container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

Handling Precautions

- Do not use kits beyond the expiration date.
- Gently invert each component several times prior to loading the original container on the ABBOTT PRISM System to ensure a homogenous solution. Additional gentle inversion may be required to thoroughly resuspend microparticles. Avoid foaming.
- Gently invert calibrators in the calibrator pack several times prior to each use.
- Each component of the ABBOTT PRISM HBsAg Wash Kit should be at room temperature (15 - 30°C) and then mixed before loading onto the ABBOTT PRISM System.
- Do not mix reagents or calibrators from different bottles. Do not mix or interchange reagents from different ABBOTT PRISM HBsAg Assay Kits.
- Any lot of ABBOTT PRISM HBsAg Wash Kit can be used with any lot of ABBOTT PRISM HBsAg Assay Kit.
- Any lot of ABBOTT PRISM Activator Concentrate, ABBOTT PRISM Activator Diluent, and Control from ABBOTT PRISM Run Control Kit or ABBOTT PRISM Positive Run Control Kit may be used with any lot of any ABBOTT PRISM Assay Kit.
- Treat Negative and Positive Calibrators and Controls as specimens.
- Avoid microbial and chemical contamination of samples, reagents and equipment. The use of disposable pipette tips is recommended for any preliminary sample transfer.
- Use accurately calibrated equipment.
- Do not freeze reagents.
- Failure to adhere to instructions in the ABBOTT PRISM Operations Manual or package insert may result in erroneous test results.
- Use caution when handling samples, reagent bottles, and reagent caps to prevent cross contamination.

Additional safety and handling precautions and limitations for the assay kit, calibrators, specimens, controls, and other reagents are described in the ABBOTT PRISM Operations Manual, Sections 7 and 8.

Preparation of Activator Solution

Activator solution must be prepared by mixing equal parts of ABBOTT PRISM Activator Concentrate and ABBOTT PRISM Activator Diluent. The activator solution expires 24 hours from preparation. The ABBOTT PRISM Activator Concentrate may be used immediately after removing from the refrigerator. The volume of activator solution required for multiple tests is calculated by the following formula:

\[ \text{Volume of Activator Solution} = \text{Volume of Activator Concentrate} \times \text{Number of Tests} \]

Storage Instructions

- Store the ABBOTT PRISM HBsAg Assay Kit, ABBOTT PRISM Run Control Kit, ABBOTT PRISM Positive Run Control Kit, and ABBOTT PRISM Activator Concentrate at 2 - 8°C.
- Store the ABBOTT PRISM HBsAg Wash Kit and ABBOTT PRISM Activator Diluent at room temperature (15 - 30°C).
- Store ABBOTT PRISM Pipette Tips and ABBOTT PRISM Reaction Trays in their original packaging until use.
- The activator solution must be stored at 15 - 30°C and used within 24 hours of preparation.

Indications of Instability or Deterioration of Reagents

The ABBOTT PRISM System will not continue to process samples when calibrator values do not meet specifications. This may indicate either deterioration or contamination of reagents, or instrument failure. Refer to the ABBOTT PRISM Operations Manual, Section 10, for additional information.

INSTRUMENT PROCEDURE

- For the software versions that may be used to perform the assay, refer to the ABBOTT PRISM Assay / Software Version Matrix located in the Supplemental Information tab of the ABBOTT PRISM Operations Manual.
- Refer to the ABBOTT PRISM Operations Manual for a detailed description of Instrument Procedures.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ABBOTT PRISM Operations Manual, Section 9.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Serum (including serum collected in serum separator tubes), plasma collected in EDTA, potassium oxalate, sodium citrate, ACD-A, ACD-B, CP2D, CPD, or CPDA-1 anticoagulants, or plasma collected from segmented tubing may be used with the ABBOTT PRISM HBsAg assay. Follow the manufacturer’s processing instructions for serum and plasma collection tubes.

CAUTION: Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in Sample Net Counts and in Sample Net Counts/Cutoff Value.

- This assay was designed and validated for use with individual human serum and plasma specimens. This assay has not been validated for use with pooled specimens.
- Do not use cadaveric plasma specimens.
- Do not use heat-inactivated specimens.
- Do not use specimens with obvious microbial contamination.
- When shipped, specimens must be packaged and labeled in compliance with applicable regulations covering the transport of clinical specimens and infectious substances. Specimens may be shipped at 30°C or colder for a period not to exceed 7 days. Prior to freezing, the serum or plasma should be removed from the clot or red blood cells.
- Failure to follow the specified centrifugation procedure on specimens tested with the ABBOTT PRISM HBsAg assay may cause a reduction in Sample Net Counts and in Sample Net Counts/Cutoff Value (S/CO) for ABBOTT PRISM HCV; therefore, heparin is not recommended for any ABBOTT PRISM assay.
- Indications of Instability or Deterioration of Reagents

Concentrate may be used immediately after removing from the refrigerator. Do not freeze reagents.

- Do not mix reagents or calibrators from different bottles.
- Do not mix or interchange reagents from different ABBOTT PRISM HBsAg Assay Kits.
- Any lot of ABBOTT PRISM HBsAg Wash Kit can be used with any lot of ABBOTT PRISM HBsAg Assay Kit.
- Any lot of ABBOTT PRISM Activator Concentrate, ABBOTT PRISM Activator Diluent, and Control from ABBOTT PRISM Run Control Kit or ABBOTT PRISM Positive Run Control Kit may be used with any lot of any ABBOTT PRISM Assay Kit.
- Treat Negative and Positive Calibrators and Controls as specimens.
- Avoid microbial and chemical contamination of samples, reagents and equipment. The use of disposable pipette tips is recommended for any preliminary sample transfer.
- Use accurately calibrated equipment.
- Do not freeze reagents.
- Failure to adhere to instructions in the ABBOTT PRISM Operations Manual or package insert may result in erroneous test results.
- Use caution when handling samples, reagent bottles, and reagent caps to prevent cross contamination.

Additional safety and handling precautions and limitations for the assay kit, calibrators, specimens, controls, and other reagents are described in the ABBOTT PRISM Operations Manual, Sections 7 and 8.

Preparation of Activator Solution

Activator solution must be prepared by mixing equal parts of ABBOTT PRISM Activator Concentrate and ABBOTT PRISM Activator Diluent. The activator solution expires 24 hours from preparation. The ABBOTT PRISM Activator Concentrate may be used immediately after removing from the refrigerator. The volume of activator solution required for multiple tests is calculated by the ABBOTT PRISM System software. Refer to the ABBOTT PRISM Operations Manual, Section 5, PLAN WORK LOAD for additional information. Use clean pipettes and/or metal-free containers (such as plasticware or acid-washed and purified or equivalent water-rinsed glassware) to measure. Refer to the ABBOTT PRISM Operations Manual Glossary for the definition of purified water. Prepare the activator solution in the bottle provided in the ABBOTT PRISM Accessory Kit (NET 84365-60). Cover the bottle opening securely with the cap provided and invert gently five to ten times to mix. Load the activator solution on the ABBOTT PRISM System. Refer to the ABBOTT PRISM Operations Manual, Section 5, PREPARE AND LOAD ACTIVATOR SOLUTION, for additional information.

**NOTE:** The activator solution must be used within 24 hours of preparation.
No qualitative performance differences were observed when 20 nonreactive and 18 low-level reactive specimens were spiked with elevated levels of bilirubin (≤ 20 mg/dL), hemoglobin (≤ 500 mg/dL), red blood cells (≤ 0.4% v/v), triglycerides (≤ 3000 mg/dL), or protein (≤ 12 g/dL). However, specimens that contain greater concentrations of these potentially interfering substances have not been tested. The impact of greater concentrations of these potentially interfering substances on the ABBOTT PRISM HBsAg assay is unknown.

Performance has not been established using umbilical cord blood, or body fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or pleural fluid. These specimens should not be tested using the ABBOTT PRISM HBsAg assay.

Specimens collected by plasmapheresis, that have not been frozen, do not require centrifugation. All other specimens (including previously frozen plasmapheresis specimens) must be centrifuged as follows:

Non-frozen specimens (excluding non-frozen plasmapheresis specimens) must be centrifuged such that g-minutes is between 30,000 and 75,000. A refrigerated or non-refrigerated centrifuge is acceptable for use. The acceptable time and force ranges that meet this criterion are listed in Table I.

<table>
<thead>
<tr>
<th>Centrifugation Time (minutes)</th>
<th>RCF (x g)</th>
<th>g-minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>3,000</td>
<td>30,000</td>
</tr>
<tr>
<td>15</td>
<td>2,000 - 3,000</td>
<td>30,000 - 45,000</td>
</tr>
<tr>
<td>20</td>
<td>1,500 - 3,000</td>
<td>30,000 - 60,000</td>
</tr>
<tr>
<td>25</td>
<td>1,300 - 3,000</td>
<td>32,500 - 75,000</td>
</tr>
</tbody>
</table>

Convert rpm to RCF as follows: \[ RCF = \frac{1.12 \times (rpm/1000)^2}{r_{max}} \]

Convert RCF to rpm as follows: \[ rpm = \sqrt{\frac{1000 \times RCF}{1.12 \times r_{max}}} \]

NOTE: If custom tube adapters (i.e., adapters not defined by the centrifuge manufacturer) are used, then the radius \( r_{max} \) should be manually measured in millimeters and the RCF calculated.

NOTE: Filtered cadaveric serum specimens tested with ABBOTT PRISM HBsAg may be filtered using the instructions indicated below. If testing includes ABBOTT PRISM HIV O Plus, then the following instructions must be performed.

NOTE: Failure to adhere to the following instructions may result in erroneous or inconsistent test results for ABBOTT PRISM HIV O Plus.

Filtration of Centrifuged Cadaveric Serum Specimens

Wear personal protective equipment, including eyewear.

After centrifugation, filter each cadaveric specimen through a Millipore GV Filter as follows:

1. Label an empty tube with the specimen identification number matching the original tube.
2. Remove the plunger from a sterile 10 cc syringe.

NOTE: Do not use a syringe smaller than 10 cc because excess pressure may build up, potentially causing damage to the filter unit or personal injury.
3. Remove the sterile filter from the package.
4. Securely screw the syringe to the filter.
5. Pour a minimum of 1 mL of the centrifuged cadaveric serum into the syringe.

NOTE: Additional volume may be required based on the number of ABBOTT PRISM assays performed. Refer to the Specimen Volume section of this package insert.

6. While holding the filter syringe unit over the tube, insert the plunger and slowly apply pressure to deliver the filtered cadaveric serum.

NOTE: A clogged filter will resist pressure and no additional sample volume will pass through.

7. If necessary, replace the clogged filter as follows:
   a. Remove the sterile filter from the package.
   b. Carefully insert the syringe to a filter-side-up position with the syringe plunger intact to prevent sample leakage. Gently remove the clogged filter and dispose of it in a potentially infectious waste container.
   c. Securely screw the syringe to the filter.
   d. Slowly apply pressure on the plunger to deliver the filtered cadaveric serum into the tube.
   e. Repeat this step as needed to successfully complete the filtration process.

NOTE: Filtered cadaveric specimens that are not tested within 24 hours of initial centrifugation must be recentrifuged, but do not need to be refiltered.

Specimen Volume

The specimen volume required to perform a single assay on the ABBOTT PRISM System varies according to the number and type of assays, and the different specimen containers. The ABBOTT PRISM HBsAg assay requires 100 µL sample dispense. For ABBOTT PRISM Sample Cups, the minimum specimen volume required for one ABBOTT PRISM HBsAg assay is 400 µL. For either primary or aliquot tubes or additional assay volume requirements, refer to the ABBOTT PRISM Operations Manual, Section 5.

PROCEDURE

Materials Provided

- ABBOTT PRISM HBsAg Assay Kit

Materials Required but not Provided

- ABBOTT PRISM HBsAg Wash Kit
- ABBOTT PRISM Reactor Concentrate
- ABBOTT PRISM Reactor Diluent
- ABBOTT PRISM Reaction Trays
- ABBOTT PRISM Pipette Tips
- ABBOTT PRISM Accessory Kit
- ABBOTT PRISM Run Control Kit
- ABBOTT PRISM Positive Run Control Kit
- ABBOTT PRISM Run Control Adapters
- Protective Disposable Gloves
- Disinfectant
- Purified Water-rinsed or Clean Disposable Measuring Equipment

Additional Materials Available

- ABBOTT PRISM Sample Cups
- ABBOTT PRISM Reactor Line Treatment
- ABBOTT PRISM Primary/Secondary Accessories
- ABBOTT PRISM Purge Concentrate

For Cadaveric Specimens Only

- ABBOTT PRISM Line Cleaner
- Fire Bag
- Millipore GV Filters
- 10 cc Sterile Syringes

10 cc Sterile Syringes

Table I

<table>
<thead>
<tr>
<th>Time (minutes)</th>
<th>RCF (x g)</th>
<th>g-minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>12,000</td>
<td>180,000</td>
</tr>
<tr>
<td>20</td>
<td>9,000 - 12,000</td>
<td>180,000 - 240,000</td>
</tr>
<tr>
<td>25</td>
<td>7,200 - 12,000</td>
<td>180,000 - 300,000</td>
</tr>
</tbody>
</table>

ANY specimen (excluding non-frozen plasmapheresis) not tested within 24 hours of initial centrifugation, must be recentrifuged from 30,000 to 75,000 g-minutes as defined for non-frozen specimens.

NOTE: Specimens retested within 24 hours of initial centrifugation do not require recentrifugation.

FAILURE TO FOLLOW THE SPECIFIED CENTRIFUGATION PROCEDURE MAY GIVE ERRONEOUS OR INCONSISTENT TEST RESULTS.
ABBOTT PRISM HBsAg ASSAY PROCEDURE

Key procedures that require operator interaction for testing samples are listed below. For detailed information concerning batch time, maximum batch size, reagent handling and loading, and associated procedural steps, refer to the ABBOTT PRISM Operations Manuals, Sections 2, 5, and 7.

• Enter a Plan Work Load (refer to the ABBOTT PRISM Operations Manual, Section 5).
• Replace reagents as needed (refer to the ABBOTT PRISM Operations Manual, Sections 5 and 7).

NOTE: Gently invert each component several times prior to loading on the ABBOTT PRISM System to ensure a homogenous solution. Additional gentle inversion may be required to thoroughly resuspend microparticulates. Avoid foaming. Gently invert calibrators in the calibrator pack several times prior to each use. Each component of the ABBOTT PRISM HBsAg Wash Kit should be at room temperature (15 - 30°C) and then mixed before loading onto the ABBOTT PRISM System.
• Verify that all tubing label symbols match the symbols on each reagent label. (Refer to the symbol key in the REAGENTS section of this package insert, and the ambient reagent bay and refrigerator diagrams provided with the ABBOTT PRISM System).
• Verify that all tubing is securely fastened to the corresponding wash and reagent bobbins.
• Inspect the waste containers. Empty and clean as defined in the ABBOTT PRISM Operations Manual, Section 9, if necessary.
• Prepare activator solution (Refer to the Preparation of Activator Solution description of this package insert) and load onto the ABBOTT PRISM System.
• Verify that an adequate number of ABBOTT PRISM Reaction Trays are in the Tray Loader.
• Verify that an adequate number of ABBOTT PRISM Pipette Tips are in the Pipette Tip Racks.
• Perform the prime procedure (Refer to the ABBOTT PRISM Operations Manual, Section 5).
• Initiate sample processing. Gently invert calibrators in the calibrator pack several times. Open the bottles in the calibrator pack and place in the calibrator rack. Load the calibrator rack and sample racks, including the run controls. (Refer to the QUALITY CONTROL PROCEDURES, Controls, Control Handling Procedure, in this package insert.)
• After the calibrators have been automatically pipetted, remove the calibrator rack. Close the calibrator bobbins and return them to 2 - 8°C storage.
• Each specimen is initially tested once, unless the operator overrides this automatic function of the ABBOTT PRISM System.
• Sample racks may be removed after the samples have been pipetted.

NOTE: No operator interaction is required for the following steps, which are automatically carried out by the ABBOTT PRISM System: reaction tray transport, calibrator/sample/release control pipetting, incubation, reaction digestion, sample reading, data reduction, run validity and result determination.
• After specimen processing is complete, perform the purge procedure (Refer to the ABBOTT PRISM Operations Manual, Section 5).

Refer to the ABBOTT PRISM Operations Manual, Section 3, for a detailed description of ChLIA procedures. The ABBOTT PRISM HBsAg assay is a two-step ChLIA procedure.

QUALITY CONTROL PROCEDURES
Calibration
The ABBOTT PRISM HBsAg Negative and Positive Calibrators are automatically tested in triplicate at the beginning of each batch. The ABBOTT PRISM System will not generate test results when calibrator values do not meet specifications. This may indicate either deterioration or contamination of reagents, or instrument failure.

Controls
1. The ABBOTT PRISM Positive Control MUST be included as the last sample in each batch as a release control. The operator is prompted to include this control as the last sample in every batch, and the ABBOTT PRISM Positive Control is then automatically tested as a single replicate. This control must meet specifications defined in the ABBOTT PRISM Run Control Kit package insert or the ABBOTT PRISM Positive Control Kit package insert in order to validate the system functionality and release sample results. If this control does not meet specifications defined in the ABBOTT PRISM Run Control Kit package insert or the ABBOTT PRISM Positive Control Kit package insert, refer to the ABBOTT PRISM Operations Manual, Section 10, for additional information.

2. Additional controls may be run at the operator’s discretion (refer to the ABBOTT PRISM Operations Manual, Section 3).

Non-validating controls: Additional controls may be run anywhere within a batch as a non-validating control. Specifications may be assigned to non-validating controls. A valid release control (ABBOTT PRISM Positive Control) result is required to release data. If the user-assigned specifications for the non-validating control(s) are not met and the release control specifications are met, there will be no effect on sample processing. In this case, reactive sample results must not be considered invalid.

3. Control Handling Procedure
a. Place run control adapters into the sample rack. The adapters can be placed in any rack position except 1, 2, 27, or 28.
b. Place each run control bottle into an adapter in the sample rack such that when the bottle flip-top cap is opened, it can be snapped into an open position within the adapter.
c. As mentioned above, place an ABBOTT PRISM Positive Control after the last sample tested in the batch. The controls can be placed in any rack position except 1, 2, 27, or 28.

Refer to the ABBOTT PRISM Operations Manual, Section 3, for additional information on calibrators, assay controls and run controls.

ASSAY PARAMETER SPECIFICATIONS

The ABBOTT PRISM HBsAg assay parameter specifications have been factory set. These parameters cannot be printed, displayed, or edited.

RESULTS

Calculation of Cutoff and S/CO Values
The ABBOTT PRISM System calculates the ABBOTT PRISM HBsAg assay cutoff value using the following formula:

\[
\text{Cutoff Value} = \frac{\text{Mean Negative Calibrator (NC) Net Counts} + \left(0.19 \times \text{Mean Positive Calibrator (PC) Net Counts}\right)}{100 + \left(0.19 \times 1,000\right)} = 290
\]

Example:

- Mean NC Net Counts = 100
- Mean PC Net Counts = 1,000
- Cutoff Value = 290

The ABBOTT PRISM System calculates the ABBOTT PRISM HBsAg assay S/CO for each sample and control using the following formula:

\[
\text{S/CO} = \frac{\text{Sample Net Counts} \times \text{Cutoff Value}}{\text{Sample Net Counts} - \text{Cutoff Value}}
\]

Example:

- Sample Net Counts = 580
- S/CO = 2.00
- Cutoff Value = 290

Interpretation of Results

• In the ABBOTT PRISM HBsAg assay, specimens with Net Counts less than the cutoff value are nonreactive and need not be tested further. Nonreactive specimens are considered negative for HBsAg by the criteria of ABBOTT PRISM HBsAg.

• Specimens with Net Counts greater than or equal to the cutoff value are considered initially reactive by the criteria of the ABBOTT PRISM HBsAg assay. All specimens (excluding non-frozen plasmapheresis specimens) that are reactive on initial testing must be centrifuged prior to retesting according to the table in the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section of this package insert. Initially reactive specimens must be retested in duplicate using the ABBOTT PRISM HBsAg Assay Kit.

- NOTE: Specimens retested within 24 hours of initial centrifugation do not require reconfiguration.

• If the sample Net Counts for both retests are less than the cutoff value, the specimen is nonreactive. Nonreactive specimens are considered negative for HBsAg by the criteria of ABBOTT PRISM HBsAg.

• If the sample Net Counts for either duplicate retest are greater than or equal to the cutoff value, the specimen is considered repeatedly reactive.

• Repeatedly reactive specimens must be tested by the ABBOTT PRISM HBsAg Confirmatory assay, a licensed neutralizing confirmatory test. Only the specimens which are confirmed by specific neutralization with anti-HBs are considered positive for HBsAg.

• Individuals who are repeatedly reactive may be referred for medical evaluation which may include additional testing.

• Although the association of infectivity of donated blood or plasma and the presence of HBsAg is strong, it is recognized that presently available methods for HBsAg detection are not sensitive enough to detect all potentially infectious units of blood, plasma or possible cases of HBV infection. A nonreactive test result does not exclude infection.
Reading Results

Some S/CO values may be flagged with "<" or ">") symbols. For more information on sample reports, refer to the ABBOTT PRISM Operations Manual, Section 5: Operating Instructions, Reports. The ABBOTT PRISM System reports sample results in Net Counts and S/CO. Net Counts are used by the ABBOTT PRISM System to interpret results. The S/CO value is provided in reports to show reactivity relative to the cutoff value. In the ABBOTT PRISM HBsAg assay, specimens with S/CO values of less than 1.00 are considered nonreactive. Specimens with an S/CO value of greater than or equal to 1.00 are considered reactive.

System Errors

For a description of the error codes that appear on ABBOTT PRISM System reports, refer to the ABBOTT PRISM Operations Manual, Section 10.

LIMITATIONS OF THE PROCEDURE

- This assay was designed and validated for use with individual human serum and plasma specimens. This assay has not been validated for use with pooled specimens.
- Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in Sample Net Counts and in S/CO for ABBOTT PRISM HBsAg; therefore, heparin is not recommended for any ABBOTT PRISM assay.
- Serum from heparinized patients may be incompletely coagulated. Erroneous or inconsistent test results may occur due to the presence of fibrin. To prevent this phenomenon, draw specimen prior to heparin therapy.
- False-reactive test results can be expected with any test kit. False-reactive test results have been observed due to nonspecific interactions. Refer to the SPECIFIC PERFORMANCE CHARACTERISTICS section of this package insert for assay performance characteristics.
- Some specimen that have undergone multiple freeze-thaw cycles or have been stored frozen for prolonged periods may result in erroneous or inconsistent test results.
- Previously frozen specimens must be centrifuged prior to running the assay.
- An increased occurrence of drain time errors may be observed for cadaveric specimens.
- Do not use cadaveric plasma specimens.
- Performance has not been established using umbilical cord blood, or body fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or pleural fluid. These specimens should not be tested using the ABBOTT PRISM HBsAg assay.
- Do not use heat-inactivated specimens.
- Do not use specimens with obvious microbial contamination, gross lipemia or gross hemolysis.

SPECIFIC PERFORMANCE CHARACTERISTICS

ASSAY REPRODUCIBILITY

Assay reproducibility was determined by testing a seven-member panel consisting of three diluted specimens reactive for HBsAg ad subtype (panel members 1, 2, and 3), three diluted specimens reactive for HBsAg ad subtype (panel members 4, 5, and 6) and one specimen nonreactive for HBsAg (panel member 7). Panel members were prepared in recalculated human plasma. Each panel member was tested in replicates of four in five runs over five days with each of the three reagent lots at six sites. In addition, each panel member was tested in replicates of four in five runs over five days with one of the three reagent lots at four of the six sites. The Negative and Positive Controls were tested once at the beginning and end of each run on each subchannel. The Negative and Positive Calibrators were automatically tested in triplicate at the beginning of each run on each subchannel. The intra-assay and inter-assay standard deviation (SD) and percent coefficient of variation (%CV) were determined with a variance component analysisa for a mixed modelb (Table III).

<table>
<thead>
<tr>
<th>Panel</th>
<th>Number of Replicates</th>
<th>Mean</th>
<th>Intra-assay SD</th>
<th>Inter-assay SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td></td>
<td>S/CO*</td>
<td>%CV</td>
<td>S/CO*</td>
</tr>
<tr>
<td>1</td>
<td>440</td>
<td>6.88</td>
<td>0.238</td>
<td>4.1</td>
</tr>
<tr>
<td>2</td>
<td>440</td>
<td>0.04</td>
<td>0.160</td>
<td>3.9</td>
</tr>
<tr>
<td>3</td>
<td>440</td>
<td>1.39</td>
<td>0.068</td>
<td>4.9</td>
</tr>
<tr>
<td>4</td>
<td>439a</td>
<td>8.66</td>
<td>0.513</td>
<td>5.8</td>
</tr>
<tr>
<td>5</td>
<td>439a</td>
<td>3.46</td>
<td>0.162</td>
<td>3.5</td>
</tr>
<tr>
<td>6</td>
<td>439a</td>
<td>1.37</td>
<td>0.078</td>
<td>5.7</td>
</tr>
<tr>
<td>7</td>
<td>440</td>
<td>0.34</td>
<td>0.036</td>
<td>10.6</td>
</tr>
<tr>
<td>Negative Control</td>
<td>439a</td>
<td>0.26</td>
<td>0.038</td>
<td>14.6</td>
</tr>
</tbody>
</table>

Cutoff Value = Mean Negative Calibrator Net Counts + (0.18 x Mean Positive Calibrator Net Counts)

<table>
<thead>
<tr>
<th>Category</th>
<th>Number Tested</th>
<th>IR (% of Total) [95% CI]</th>
<th>RR (% of Total) [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary Blood Donors</td>
<td>8,246</td>
<td>5 (0.06)</td>
<td>(0.02 - 0.14)</td>
</tr>
<tr>
<td>Plasma</td>
<td>13,911</td>
<td>8 (0.06)</td>
<td>(0.02 - 0.11)</td>
</tr>
<tr>
<td>Plasma/Plasmapheresis</td>
<td>3,081</td>
<td>1 (0.03)</td>
<td>(0.00 - 0.12)</td>
</tr>
<tr>
<td>Total Donors</td>
<td>25,238</td>
<td>14 (0.06)</td>
<td>(0.03 - 0.08)</td>
</tr>
</tbody>
</table>

Reactivity of the ABBOTT PRISM HBsAg Assay in Whole Blood and Plasmapheresis Donors, in Specimens from Individuals with Medical Conditions Unrelated to HBV Infection, and in Specimens Containing Potentially Interfering Substances

a A specimen was confirmed positive for HBsAg if the non-neutralized specimen (with ABBOTT PRISM HBsAg Confirmatory assay Reagent B added) exhibited a net count greater than or equal to the ABBOTT PRISM HBsAg Confirmatory assay cutoff value and if the neutralization with anti-HBs (Reagent A) was 50% or greater.

b Specimens from individuals with medical conditions unrelated to HBV infection and specimens containing potentially interfering substances included the following categories: anti-HIV positive (12), anti-HIV negative (12), anti-HIV-1 positive (12), anti-HIV-2 positive (5), -anti-HTLV-I positive (12), -anti-HTLV-II positive (12), non-viral liver diseases (42), rubella antibody positive (12), toxoplasma antibody positive (11), E.coli infections (5), syphilis serology positive (12), anti-nuclear antibody positive (12), rheumatoid factor positive (12), influenza vaccine recipients (52), elevated IgG (12), elevated IgM (12), elevated triglycerides (10), elevated bilirubin (12), elevated hemoglobin (11), and pregnant females (55).

**TABLE IV**

<table>
<thead>
<tr>
<th>Category</th>
<th>Number Tested</th>
<th>IR (% of Total) [95% CI]</th>
<th>RR (% of Total) [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Conditions Unrelated to HBV Infection</td>
<td>870</td>
<td>59 (0.70)</td>
<td>50 (5.75)</td>
</tr>
</tbody>
</table>

IR = Initial Reactive; RR = Repeat Reactive; CI = Confidence Interval

**TABLE III**

<table>
<thead>
<tr>
<th>ABBOTT PRISM HBsAg Assay Reproducibility</th>
<th>Panel</th>
<th>Number of Replicates</th>
<th>Mean S/CO*</th>
<th>Intra-assay SD %CV</th>
<th>Inter-assay SD %CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>440</td>
<td>6.88</td>
<td>0.238</td>
<td>4.1</td>
<td>0.390</td>
</tr>
<tr>
<td>2</td>
<td>440</td>
<td>0.04</td>
<td>0.160</td>
<td>3.9</td>
<td>0.222</td>
</tr>
<tr>
<td>3</td>
<td>440</td>
<td>1.39</td>
<td>0.068</td>
<td>4.9</td>
<td>0.077</td>
</tr>
<tr>
<td>4</td>
<td>439a</td>
<td>8.66</td>
<td>0.513</td>
<td>5.8</td>
<td>0.596</td>
</tr>
<tr>
<td>5</td>
<td>439a</td>
<td>3.46</td>
<td>0.162</td>
<td>3.5</td>
<td>0.244</td>
</tr>
<tr>
<td>6</td>
<td>439a</td>
<td>1.37</td>
<td>0.078</td>
<td>5.7</td>
<td>0.083</td>
</tr>
<tr>
<td>7</td>
<td>440</td>
<td>0.34</td>
<td>0.036</td>
<td>10.6</td>
<td>0.039</td>
</tr>
<tr>
<td>Negative Control</td>
<td>439a</td>
<td>0.26</td>
<td>0.038</td>
<td>14.6</td>
<td>0.041</td>
</tr>
<tr>
<td>Positive Control</td>
<td>440</td>
<td>2.63</td>
<td>0.138</td>
<td>5.2</td>
<td>0.204</td>
</tr>
</tbody>
</table>
The 50 repeatedly reactive specimens included the following: anti-EBV positive (1), anti-HSV positive (1), anti-HCV positive (1), anti-HIV-1 positive (5), anti-HIV-2 positive (1), non-viral liver diseases (5), rubella antibody positive (1), anti-nuclear antibody positive (1), influenza vaccine recipients (1), elevated triglycerides (1), and pregnant females (32).

d) The following 40 specimens confirmed positive for HBsAg: anti-HCV positive (1), anti-HIV-1 positive (5), anti-HIV-2 positive (1), non-viral liver diseases (5), influenza vaccine recipients (1), and pregnant females (27).

ASSAY SENSITIVITY

A total of 1,212 serum and plasma specimens from 514 individuals known to be positive for HBsAg, 98 individuals with acute HBV infection, 101 individuals with chronic HBV infection, 47 individuals who have recovered from HBV infection, and 452 individuals at increased risk for HBV infection were tested with the ABBOTT PRISM HBsAg assay. A total of 767 specimens (63.28%) were repeatedly reactive, of which 754 (98.31%) were confirmed positive by specific antibody neutralization (Table VI). The overall sensitivity was estimated in these studies to be 100.00% (754/754) with a 95% CI of 99.51% to 100.00%.

TABLE V

Reactivity of the ABBOTT PRISM HBsAg Assay in Selected Populations with HBV Infection and at Increased Risk for HBV Infection

<table>
<thead>
<tr>
<th>Category</th>
<th>Number Tested</th>
<th>Number Repeatedly Reactive</th>
<th>Number Confirmed Positive</th>
<th>Number Confirmed Positive (% of Repeatedly Reactive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preselected HBsAg Positive</td>
<td>514</td>
<td>514* (100.00)</td>
<td>514* (100.00)</td>
<td></td>
</tr>
<tr>
<td>Acute HBV Infection</td>
<td>98</td>
<td>98 (100.00)</td>
<td>98 (100.00)</td>
<td></td>
</tr>
<tr>
<td>Chronic HBV Infection</td>
<td>101</td>
<td>101 (100.00)</td>
<td>101 (100.00)</td>
<td></td>
</tr>
<tr>
<td>Recovered HBV Infection</td>
<td>47</td>
<td>0 (0.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased Risk for HBV Infection</td>
<td>452</td>
<td>54* (11.93)</td>
<td>41* (75.93)</td>
<td></td>
</tr>
</tbody>
</table>

TABLE VI

Detection of Purified HBsAg ad by the ABBOTT PRISM HBsAg Assay

<table>
<thead>
<tr>
<th>HBsAg Concentration (ng/mL)</th>
<th>Mean S/CO Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.917</td>
<td>6.98</td>
<td>+</td>
</tr>
<tr>
<td>0.525</td>
<td>4.06</td>
<td>+</td>
</tr>
<tr>
<td>0.124</td>
<td>1.39</td>
<td>+</td>
</tr>
<tr>
<td>0.000</td>
<td>0.34</td>
<td>-</td>
</tr>
</tbody>
</table>

The ability of the ABBOTT PRISM HBsAg assay to detect HBsAg was evaluated by testing 12 HBV seroconversion panels from blood and plasmahepatitis donors who seroconverted over the course of their donation history. All specimens were also tested by a FDA licensed assay. The ABBOTT PRISM HBsAg assay detected HBsAg three to 13 days (one to three bleed) earlier in ten of the 12 panels and five to 48 days (one to three bleed) longer in four of the 12 panels when compared to the licensed assay. Both assays detected HBsAg in the first available bleed for two of the 12 panels.

PERFORMANCE CHARACTERISTICS OF CADAVERIC SERUM TESTING

Reproducibility

Inter-assay reproducibility of PRISM HBsAg was assessed using 10 postmortem donor sera. These sera specimens were spiked with human plasma positive for HBsAg to create low-level reactive specimens. Each of the specimens was tested in triplicate on three different days on each of three lots of PRISM HBsAg at one site for a total of 270 replicates. Three replicates generated dispense errors and 16 replicates generated drain time errors and were excluded from the analysis. For intra-assay reproducibility, the %CV ranged from 2.9 to 5.5 for the low level reactive specimens. For inter-assay reproducibility over all lots, the percent coefficient of variation (%CV) ranged from 4.4 to 8.7 for the low level reactive specimens. The total reproducibility ranged from 5.3 to 9.7 for the low level reactive specimens. Note: Inter-assay reproducibility includes intra-assay and inter-assay variation. Total reproducibility includes intra-assay, inter-assay and inter-lot variations.

Specificity

Specificity was evaluated using 51 postmortem donor specimens and 54 normal donor specimens. Each of the specimens was tested once on each of three lots of PRISM HBsAg. The mean sample to cutoff (S/CO) ratio for the 136 nonreactive postmortem replicates (51 specimens with three reagent lots; see Table VIII, footnotes a and b) was 0.37, and the mean S/CO for 162 normal donor replicates (54 specimens with three reagent lots) was 0.24. Results are presented in Table VIII.

TABLE VII

Detection of Purified HBsAg ad by the ABBOTT PRISM HBsAg Assay

<table>
<thead>
<tr>
<th>HBsAg Concentration (ng/mL)</th>
<th>Mean S/CO Value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.002</td>
<td>8.86</td>
<td>+</td>
</tr>
<tr>
<td>0.485</td>
<td>4.62</td>
<td>+</td>
</tr>
<tr>
<td>0.131</td>
<td>1.37</td>
<td>+</td>
</tr>
<tr>
<td>0.000</td>
<td>0.34</td>
<td>-</td>
</tr>
</tbody>
</table>

The ability of the ABBOTT PRISM HBsAg assay to detect HBsAg was evaluated by testing 12 HBV seroconversion panels from blood and plasmahepatitis donors who seroconverted over the course of their donation history. All specimens were also tested by a FDA licensed assay. The ABBOTT PRISM HBsAg assay detected HBsAg three to 13 days (one to three bleed) earlier in ten of the 12 panels and five to 48 days (one to three bleed) longer in four of the 12 panels when compared to the licensed assay. Both assays detected HBsAg in the first available bleed for two of the 12 panels.

PERFORMANCE CHARACTERISTICS OF CADAVERIC SERUM TESTING

Reproducibility

Inter-assay reproducibility of PRISM HBsAg was assessed using 10 postmortem donor sera. These sera specimens were spiked with human plasma positive for HBsAg to create low-level reactive specimens. Each of the specimens was tested in triplicate on three different days on each of three lots of PRISM HBsAg at one site for a total of 270 replicates. Three replicates generated dispense errors and 16 replicates generated drain time errors and were excluded from the analysis. For intra-assay reproducibility, the %CV ranged from 2.9 to 5.5 for the low level reactive specimens. For inter-assay reproducibility over all lots, the percent coefficient of variation (%CV) ranged from 4.4 to 8.7 for the low level reactive specimens. The total reproducibility ranged from 5.3 to 9.7 for the low level reactive specimens. Note: Inter-assay reproducibility includes intra-assay and inter-assay variation. Total reproducibility includes intra-assay, inter-assay and inter-lot variations.

Specificity

Specificity was evaluated using 51 postmortem donor specimens and 54 normal donor specimens. Each of the specimens was tested once on each of three lots of PRISM HBsAg. The mean sample to cutoff (S/CO) ratio for the 136 nonreactive postmortem replicates (51 specimens with three reagent lots; see Table VIII, footnotes a and b) was 0.37, and the mean S/CO for 162 normal donor replicates (54 specimens with three reagent lots) was 0.24. Results are presented in Table VIII.

TABLE VIII

Reactivity with PRISM HBsAg

<table>
<thead>
<tr>
<th>Population</th>
<th>No. of Specimens</th>
<th>No. of Replicates</th>
<th>Mean S/CO</th>
<th>Nonreactive</th>
<th>Initial Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postmortem</td>
<td>51</td>
<td>137</td>
<td>0.37</td>
<td>163</td>
<td>1*</td>
</tr>
<tr>
<td>Normal Donor</td>
<td>54</td>
<td>162</td>
<td>0.24</td>
<td>162</td>
<td>0</td>
</tr>
</tbody>
</table>

a) No results were obtained for 15 specimens on one lot due to drain time errors and one specimen on one lot due to an invalid result.

b) Specimen was not tested due to insufficient specimen volume.

Assuming the specimen with the initial reactive result would have a reactive result upon retest, the PRISM HBsAg assay has an estimated specificity of 99.27% (136/137) (binomial confidence interval = [96.00%, 99.98%]) in these studies of postmortem serum specimens collected up to 16.1 hours after death.

Sensitivity

Sensitivity was evaluated using 51 postmortem specimens and 54 normal donor specimens that were pre-screened for anti-HBs and HBsAg and found to be negative. The 105 specimens were spiked with human plasma positive for HBsAg to create low-level reactive specimens. Each of the specimens was tested once on each of three lots of PRISM HBsAg. The mean sample to cutoff (S/CO) for the 142 postmortem replicates (51 specimens, with three reagent lots; see Table IX, footnote a) was 2.05, and the mean S/CO ratio for the 162 normal donor replicates (54 specimens, with three reagent lots) was 2.07. Results are presented in Table IX.
Table IX
Reactivity with PRISM HBsAg

<table>
<thead>
<tr>
<th>Population</th>
<th>No. of Specimens</th>
<th>No. of Replicates</th>
<th>Mean S/CO</th>
<th>Nonreactive</th>
<th>Initial Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postmortem</td>
<td>51</td>
<td>142</td>
<td>2.05</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Normal Donor</td>
<td>54</td>
<td>162</td>
<td>2.07</td>
<td>0</td>
<td>162</td>
</tr>
</tbody>
</table>

* No results were obtained for 7 unique specimens, and 2 specimens using 2 reagent lots due to drain time errors.

The PRISM HBsAg assay has an estimated sensitivity of 100.00% (142/142) (binomial confidence interval = [97.44%, 100.00%]) in these studies of postmortem serum specimens collected up to 16.1 hours after death.

BIBLIOGRAPHY


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