HBsAg (V2)

This package insert must be read carefully prior to use. 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.

© 1998, 2005 Abbott / AxSYM HBsAg (V2)
August 2005

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
HBsAg - Hepatitis B Surface Antigen

INTENDED USE
AxSYM® HBsAg (V2) is a third generation microparticle enzyme immunoassay for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST
Enzyme immunoassays for the detection of HBsAg were first described by Engvall and Perlmann1-3 and VanWeemen and Schuurs4 in 1971. In 1976 and 1977, solid phase "sandwich" enzyme immunoassays were developed in which HBsAg was captured on a solid phase coated with polyclonal antibodies against HBsAg (anti-HBs) and then detected with anti-HBs conjugated to an enzyme.5,5 In the early 1980's, monoclonal anti-HBs based assays were developed for the detection of HBsAg.5,6,7 AxSYM HBsAg (V2) is an enzyme immunoassay which uses microparticles coated with monoclonal anti-HBs for the detection of HBsAg.

Assays for HBsAg are used to screen blood and blood products for the presence of HBsAg to prevent transmission of hepatitis B virus (HBV) to recipients of these products. HBsAg assays are also routinely used to diagnose suspected HBV infection and to monitor the status of infected individuals; i.e., whether the patient's infection has resolved or the patient has become a chronic carrier of the virus.14 In addition, these assays are used to evaluate the efficacy of anti-viral drugs by monitoring the levels of HBsAg in patient sera or plasma.15 The prenatal screening of all pregnant women has been recommended by the U.S. Centers for Disease Control so that newborns from HBV carrier mothers may obtain prophylactic treatment.16,17

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
AxSYM HBsAg (V2) is based on the Microparticle Enzyme Immunoassay (MEIA) technology. Sample and all AxSYM HBsAg (V2) reagents required for one test are pipetted into the Sampling Probe into various wells of a reaction vessel (RV) in the Sampling Center. The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe. The reactions occur in the following sequence:

1. Sample, Anti-HBs Coated Microparticles and Biotinylated Anti-HBs are combined in one RV well.
2. When HBsAg is present in the sample, it binds to the Anti-HBs Coated Microparticles and Biotinylated Anti-HBs, forming an antibody-antigen-antibody complex in the reaction mixture.
3. A portion of the reaction mixture is transferred to the matrix cell. The microparticles bind irreversibly to the glass fiber matrix.
4. The Anti-Biotin-Alkaline Phosphatase Conjugate is dispensed onto the matrix cell and binds with any microparticle-bound antibody-antigen-antibody complex.
5. The matrix cell is washed to remove materials not bound to the microparticles.
6. The substrate, 4-Methylumbelliferyl Phosphate, is added. The alkaline phosphatase-labeled conjugate catalyzes the removal of a phosphate group from the substrate, yielding the fluorescent product, 4-Methylumbelliferyl. This fluorescent product is measured by the MEIA optical assembly.

The presence or absence of HBsAg in the sample is determined by comparing the rate of formation of fluorescent product to a cutoff rate determined from a previous AxSYM HBsAg (V2) Index Calibration. If the rate of formation of fluorescent product in the test sample is greater than or equal to the cutoff rate, the sample is considered reactive for HBsAg.

For further information regarding MEIA technology, refer to the AxSYM System Operations Manual, Section 3.

REAGENTS
REAGENT PACK, 100 TESTS
AxSYM HBsAg (V2) Reagent Pack (7A40-22)

1. Bottle (5.1 mL) Anti-HBs (Mouse, Monoclonal, IgM) Coated Microparticles in Phosphate buffer with protein stabilizers. Minimum concentration: 0.15%. Preservative: Sodium Azide. (Reagent Bottle 2)
2. Bottle (15.5 mL) Anti-Biotin (Rabbit) Alkaline Phosphatase Conjugate in TRIS buffer (Rabbit) IgG. Minimum concentration: 0.03 µg/mL. Preservative: Sodium Azide. (Reagent Bottle 1)

**INDEX CAL**
1. Bottle (6 mL) AxSYM HBsAg (V2) Index Calibrator. Recalibrated human plasma nonreactive for HBsAg, HIV RNA or HIV-1 Ag and antibodies to HCV, and nonreactive for HIV-1/HIV-2. Preservative: Sodium Azide. Dye: Green (Acid Yellow No. 23 and Acid Blue No. 9).

CONTROL:
The Negative Control is nonreactive for HBsAg, HIV RNA or HIV-1 Ag and antibodies to HCV and nonreactive for HIV-1/HIV-2.

CONTROL:
The Positive Control is reactive for HBsAg and nonreactive for HIV RNA or HIV-1 Ag, anti-HBs, anti-HCV and antibodies to HIV-1/HIV-2.

Preservative: Sodium Azide.

The AxSYM HBsAg Controls have the following ranges:

<table>
<thead>
<tr>
<th>Control</th>
<th>Color</th>
<th>HBsAg Concentration</th>
<th>Control Range</th>
<th>Control Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Natural</td>
<td>0 ng/mL</td>
<td>0.70 - 1.30</td>
<td>0.35 - 0.65</td>
</tr>
<tr>
<td>Control</td>
<td>Blue*</td>
<td>4 - 15 ng/mL</td>
<td>7.00 - 63.00</td>
<td>3.50 - 31.50</td>
</tr>
</tbody>
</table>

* Dye: Bromophenol Blue.

CAUTION: This product contains human sourced and/or potentially infectious components. For a specific listing, refer to the Reagents section of this package insert. Components sourced from human blood present in the Positive Control have been tested and found to be reactive for HBsAg and nonreactive for HIV RNA or HIV-1 Ag and antibodies to HCV, HBs and HCV-1/HCV-2. Components sourced from human blood present in other kit components have been tested and found to be nonreactive for HBsAg and HIV RNA or HIV-1 Ag and antibodies to HBs, HCV and HIV-1/HIV-2. Components sourced from human blood present in other kit components have been tested and found to be nonreactive for HBsAg and HIV RNA or HIV-1 Ag and antibodies to HBs, HCV and HIV-1/HIV-2. Components sourced from human blood present in other kit components have been tested and found to be nonreactive for HBsAg and HIV RNA or HIV-1 Ag and antibodies to HBs, HCV and HIV-1/HIV-2.

For further information regarding MEIA technology, refer to the AxSYM System Operations Manual, Section 3.

**VIG**
For In Vitro Diagnostic Use.
SAFETY PRECAUTIONS

- The AxSYM Probe Cleaning Solution (2% TEAH) may cause mild eye irritation. If this solution comes in contact with eyes, rinse immediately with water. If irritation persists, seek medical attention.
- All components of this product contain Sodium Azide. For a specific listing refer to the Reagents section of this package insert. The components containing Sodium Azide are classified per the applicable European Community (EC) Directives as: Harmful (Xn).
- Additional safety and handling precautions and limitations for the reagent pack, Index Calibrator and Controls must be stored at 2-8°C. The AxSYM HBsAg (V2) Reagent Pack, Index Calibrator and Controls must be used immediately after removal from the refrigerator. Do not freeze the reagents.
- AxSYM HBsAg (V2) reagents are susceptible to splashes, air bubbles, foaming and require inspection and removal of bubbles before loading. If bubbles are present, refer to the AxSYM System Operations Manual, Section 9: Service and Maintenance, Subsection: Daily Maintenance.
- Do not use Solution 1 (MUP) beyond the expiration date. Loading new Solution 1 (MUP), it is important to immediately tighten the instrument cap for MUP to minimize exposure to air. Prolonged exposure to air may compromise performance.
- Do not use kits beyond the expiration date or a maximum of 112 cumulative hours on-board the AxSYM System.
- Do not mix reagents from different reagent packs. Do not mix reagent lots and index calibrators from different lots.
- Avoid microbial contamination of samples and reagents. Use of disposable pipettes or pipette tips is recommended.
- Avoid chemical contamination of reagents and equipment.
- Ensure that sufficient sample volume is present. If sample volume is insufficient, the AxSYM System will give an error code and no result will be reported. For a description of the System error codes, refer to the AxSYM System Operations Manual, Section 10.
- Inadequate adherence to package insert instructions may result in erroneous results.
- Use accurately calibrated equipment.
- Use caution in handling patient samples to prevent cross contamination.
- Transfer of as little as 1 µL from one HBsAg positive sample may contaminate an adjacent negative sample and result in a falsely reactive result.

STORAGE INSTRUCTIONS

- The AxSYM HBsAg (V2) Reagent Pack, Index Calibrator and AxSYM HBsAg Controls must be stored at 2-8°C. The Reagent Pack, Index Calibrator and Controls may be used immediately after removal from the refrigerator. Do not freeze the reagents.

SOLUTION 1 (MUP) must be stored at 2-8°C. It may be on-board the AxSYM System for a maximum of fourteen days. After fourteen days it must be discarded.

The AxSYM Probe Cleaning Solution, Solution 3 (Matrix Cell Wash) and Solution 4 (Line Diluent) must be stored at 15-30°C.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

When an AxSYM HBsAg Positive or Negative Control value is out of the expected range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and must be retested. Assay recalibration may be necessary.

INSTRUMENT PROCEDURE

ASSAY FILE INSTALLATION

The AxSYM HBsAg Assay File must be installed on the AxSYM System from the software disk, 9A16-03, or higher, prior to performing the HBsAg (V2) assay. Refer to the AxSYM System Operations Manual, Section 2, for proper installation procedures.

NOTE: Parameters 18, 43, 44 cannot be edited to another value.

INSTUMENT PROCEDURE

ASSAY PARAMETERS

1. Long Assay Name (English): HBsAg
2. Abbrev Assay Name (English): HBsAg
3. Assay Number: 106
4. Assay Version: 2
5. Calibration Version: 00
6. Master Cal Reps: 0
7. Cal Adjust Reps: 0
8. Cal A Concentration: 1.00
9. Cal B Concentration: 0.00
10. Cal C Concentration: 0.00
11. Cal D Concentration: 0.00
12. Cal E Concentration: 0.00
13. Cal F Concentration: 0.00
14. Master Calibrator 1 Concentration: 0.00
15. Master Calibrator 2 Concentration: 0.00
16. Cal Adjust Concentration: 0.00
17. Default Dilution Protocol: UNDILUTED
18. Default Calibration Method: Index Cal
19. Selected Result Concentration Units: S/N
20. Selected Result Concentration Units: S/CO
21. Blank i-Max background intensity: 0.0000
22. Min Tracer-Min net intensity: 0.0000
23. Max Intercept-Max MUP intercept: 10000.0000
24. Min Intercept-MIN MUP intercept: 1200.0000
25. Upper limit for NRMSF for low rates: 19.999999
26. Upper limit for NRMSF for high rates: 0.5000
27. Max Rate-Max rate used to check Min MUP Intercept: 50.0000
28. Min Rate-Min rate cutoff for NRMSF and Conn. Coef.: 8.0000
29. Min correlation coefficient for low rates: 0.9500
30. Min correlation coefficient for high rates: 0.9700
31. MUP T Delay-Time delay following MUP: 2.6000
32. Low Limit-Normal/Therapeutic Range lower limit: 0.00
33. High Limit-Nnormal/Therapeutic Range upper limit: 0.00
34. Low Extreme Value: 0.00
35. High Extreme Value: 0.00
36. Lo Norm-% Uptake Normal Range Low: 0.0000
37. Hi Norm-% Uptake Normal Range High: 0.0000
38. Interpretation Option to use: > 1
39. Hold results with POS interpretation: ON
40. Hold results with NEG interpretation: OFF
41. Hold results with GRY interpretation: ON
42. Low Range Neat: 0.00
43. High Range DII: 0.00
44. High Range DII: 0.00
45. High Range DII: 0.00
46. High Range DII: 0.00
47. High Range DII: 0.00
48. Negative Interpretation Cutoff: 2.00

NOTE: Parameters 18, 43, 44 cannot be edited to another value.

NOTE: Parameter 45 can be edited to the alternate Result Unit S/CO. Refer to the AxSYM System Operations Manual for a detailed description of Instrument Procedures.

NOTE: A grayzone feature is available. To utilize the grayzone option, parameter 117, “Negative Interpretation Cutoff,” must be edited to desired value within the range of 1.60 to 1.99 S/N or 0.80 to 0.99 S/CO. Specifications with S/N values equal to the selected value and less than 2.00 or with S/CO values equal to the selected value and less than 1.00 are indicated as “GZ-NEGATIVE” or “GZ-NONREACTIVE” in the interpretation field. The report options are selected in parameter 80, “Interpretation Option to use.”
The AxSYM HBsAg (V2) values available for parameter #80 (Interpretation Option to use) are:

<table>
<thead>
<tr>
<th>POS Interp</th>
<th>NEG Interp</th>
<th>GRY Interp</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACTIVE</td>
<td>NEGATIVE</td>
<td>G2-NEGATIVE</td>
</tr>
<tr>
<td>REACTIVE</td>
<td>NONREACTIVE</td>
<td>G2-NONREACTIVE</td>
</tr>
<tr>
<td>REACTIVE</td>
<td>BLANK</td>
<td>BLANK</td>
</tr>
</tbody>
</table>

NOTE: Parameter 46 must be set to 3 in order to edit the alternate Result Unit S/CO grayzone value to 0.80.

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Serum (including serum collected in separator tubes) or plasma (collected in sodium heparin, sodium citrate, ACD, CPDA-1 or EDTA) may be used in the AxSYM HBsAg (V2) Assay. Use the ratio of anticoagulant (quantity) to sample (volume) that is recommended by the manufacturer.
- The AxSYM System does not have the capability to verify the sample type. It is the responsibility of the operator to verify the correct sample type(s) are used in the AxSYM HBsAg (V2) assay.
- Samples containing particulate matter or red blood cells may give inconsistent or erroneous results.
- Inspect all samples for splashing, air bubbles and foaming. If necessary remove bubbles prior to analysis using a new applicator stick for each sample. Refer to the AxSYM System Operations Manual, Section 7.
- Specimens with obvious microbial contamination should not be used.
- All patient samples to be tested in Primary Tubes must be centrifuged to remove red cells or particulate matter. Each sample that requires repeat or confirmatory testing, or that has been frozen and thawed, must be transferred to a centrifuge tube and centrifuged at an RCF* of at least 10,000 x g for 10 minutes. Transfer clarified sample to a sample cup for testing. WARNING: AxSYM System Software Version 3.0 and higher offers an Auto Retest/Auto Dilution feature. Due to requirements discussed above, this feature must not be used.
- Samples which contain fibrin may cause erroneous results. Serum samples must be completely clotted and centrifuged prior to testing to generate consistent results.
- Centrifuged specimens with a lipid layer on top of the liquid must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen and not the lipemic material.
- Samples from heparinized patients may be partially coagulated and erroneous results could occur due to the presence of fibrin. To prevent this phenomenon, draw the sample prior to heparin therapy.
- Samples may be stored on the clot or red blood cells for up to 14 days at 2-8°C prior to being tested.
- If the assay will be performed after 14 days, the sample must be removed from the clot or red blood cells and stored frozen (-10°C or colder).
- 15 nonreactive and 15 reactive samples showed no qualitative performance differences when subjected to 6 freeze-thaw cycles; however, multiple freeze-thaw cycles should be avoided. Samples must be mixed thoroughly after thawing and centrifuged prior to use, as described in this section, to remove particulate matter and to ensure consistency in the results.
- When shipped, samples must be packed and labeled in compliance with applicable federal and international regulations covering the transport of clinical samples and etiologic agents. Samples may be shipped under ambient conditions, refrigerated on wet ice (2-8°C) or frozen on dry ice (-10°C or colder).
- All samples (patient samples, controls and calibrators) should be tested within 3 hours of being placed on-board the AxSYM System. Refer to the AxSYM System Operations Manual, Section 5, for more detailed discussion of on-board sample storage constraints.
- Do not use heat-inactivated samples.
- Performance has not been established for cadaver samples or body fluids such as urine, saliva, semen or amniotic fluid.
- No qualitative performance differences were observed when HBsAg Negative and Positive Controls were tested with elevated levels of bilirubin (0-20 mg/dL), hemoglobin (0-250 mg/dL) or lipids (0-1000 mg/dL).
- The assay was designed and validated for use with human serum or plasma from individual patient and donor specimens. Pooled specimens should not be used since the accuracy of their test results has not been validated.

SAMPLE VOLUME

The sample volume required to perform a single HBsAg (V2) test on the AxSYM System varies according to the different sample containers. For sample cups, the minimum sample volume required is 190 µL. For every additional HBsAg (V2) test performed from the same sample container, an additional 140 µL of sample will be required.

The sample cup minimum volume will be calculated by the AxSYM System. It will be displayed on the Order screen at the time the test(s) is(are) ordered and printed in the Orderlist Report. To obtain the recommended volume requirements for the AxSYM HBsAg (V2) Index Calibrator and AxSYM HBsAg Controls, hold the bottles vertically and dispense 15 drops of Index Calibrator or 5 drops of Positive or Negative Control into each respective sample cup.

For sample volume requirements in primary or aliquot tubes, and control volume requirements for multiple AxSYM HBsAg (V2) reagent lots, refer to the AxSYM System Operations Manual, Section 5.

AxSYM HBsAg (V2) PROCEDURE

Materials Required

<table>
<thead>
<tr>
<th>7A40-22</th>
<th>AxSYM HBsAg (V2) Reagent Kit, containing:</th>
</tr>
</thead>
<tbody>
<tr>
<td>AxSYM HBsAg (V2) REAGENT PACK</td>
<td></td>
</tr>
<tr>
<td>AxSYM HBsAg (V2) INDEX CAL</td>
<td></td>
</tr>
<tr>
<td>100 REACTION VESSELS</td>
<td></td>
</tr>
<tr>
<td>100 MATRIX CELLS</td>
<td></td>
</tr>
<tr>
<td>7A40-10</td>
<td>AxSYM HBsAg Controls</td>
</tr>
<tr>
<td>8A47-04</td>
<td>SOLUTION 1 MUP</td>
</tr>
<tr>
<td>8A81-04</td>
<td>SOLUTION 3 MATRIX CELL WASH</td>
</tr>
<tr>
<td>8A46</td>
<td>SOLUTION 4 LINE DILUENT</td>
</tr>
<tr>
<td>9A35-04/9A35-05</td>
<td>AxSYM PROBE CLEANING SOLUTION</td>
</tr>
<tr>
<td>8A76-01</td>
<td>SAMPLE CUPS</td>
</tr>
</tbody>
</table>

Materials Required But Not Provided

- Pipettes or pipette tips

CAUTION:

- When manually dispensing samples, verify that dispensing equipment does not introduce cross contamination and that it delivers the specified sample volume. Use a separate disposable pipette or pipette tip for each sample.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the AxSYM System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Assay Procedure

CAUTION: The System status must be WARMING, PAUSED, READY or STOPPED before adding or removing sample segments, reagent packs or reaction vessels.

1. Check for sufficient on-board inventory of matrix cells and bulk solutions, and for sample segment availability.
2. Check for sufficient waste collection capacity.

CAUTION: Do not open the Interior Waste Door or the AxSYM Processing Center Cover while any test is in progress. If opened, all processing will stop. All tests will be terminated and must be repeated.

3. Order the HBsAg (V2) Index Calibrator, HBsAg Controls, and/or patient samples as required. Assign or modify sample segment position (S/P) for each sample, as necessary. Refer to the Quality Control Procedures section in this package insert for calibration and control requirements.

Index Calibration:

Perform AxSYM HBsAg (V2) calibration by testing 5 replicates of the Index Calibrator. Dispense 15 drops of the Index Calibrator into a sample cup. Do not simultaneously calibrate more than one AxSYM HBsAg (V2) reagent lot.

Controls:

Perform quality control by testing the Positive and the Negative Control (one test each). Dispense 5 drops each of Positive and Negative Controls into individual sample cups.

* When more than one AxSYM HBsAg (V2) reagent lot is on-board the AxSYM System, multiply control volume by the number of lots.
CALCULATIONS
The AxSYM System calculates the Cutoff rate from the mean rate of five Index Calibrator replicates and stores the result. The AxSYM HBsAg (V2) assay has two selectable Result Units. One reports the result as S/N and the other reports the result as a ratio S/CO. These units can be selected in the assay parameters according to the procedure in the AxSYM System Operations Manual, Section 2.

The Cutoff rate is determined by multiplying the Index Calibrator mean rate by 2.

\[ \text{Cutoff Rate (CO)} = \text{Index Calibrator mean rate} \times 2 \]

\[ \text{S/N} = \frac{\text{Sample Rate}}{\text{Index Calibrator Mean Rate}} \]

\[ \text{S/CO} = \frac{\text{Sample Rate}}{\text{Cutoff Rate (CO)}} \]

FLAGS
Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the AxSYM System Operations Manual, Section 1 and 2.

INTERPRETATION OF RESULTS
- Samples with S/N less than 2.00 are negative by the AxSYM HBsAg (V2) assay and need not be tested further.
- Samples with S/N values greater than or equal to 2.00 are considered reactive.
- Samples with S/CO values less than 1.00 are negative by the AxSYM HBsAg (V2) assay and need not be tested further.
- Samples with S/CO values greater than or equal to 1.00 are considered reactive.
- All samples that are reactive on initial testing should be retested in duplicate using the AxSYM HBsAg (V2) assay. If neither of the retests are reactive, the sample must be considered negative for HBsAg. If the sample is reactive in either of the repeated replicates, the sample must be considered repeatedly reactive.
- Repeatedly reactive samples should be tested by a neutralizing confirmatory test, such as the AxSYM HBsAg Confirmatory assay. Samples which are confirmed by neutralization with human anti-HBs must be considered positive for HBsAg.

False reactive results may be obtained with any diagnostic test. Two types of false reactive results may occur with AxSYM HBsAg (V2), nonrepeatable reactives and nonspecific reactives.

Nonrepeatable Reactives: Some samples which are reactive in the AxSYM HBsAg (V2) assay may not be reactive on retesting. The most common sources of nonrepeatable reactives are:
- particulate matter in the patient sample, particularly fibrin clots and cellular material,
- contamination of nonreactive samples caused by transfer of a high titer antigen sample.

Nonspecific Reactives: All highly sensitive immunoassay systems have a potential for nonspecific reactions. The specificity of a repeatedly reactive sample should be confirmed by a neutralizing confirmatory test, such as the AxSYM HBsAg Confirmatory assay. A nonspecific reactive sample will be repeatedly reactive but will not be confirmed by neutralization. Therefore, it is recommended that a specific antibody neutralization be performed prior to informing the donor/patient of their HBsAg carrier status. For additional information on neutralization testing, refer to the AxSYM System Operations Manual, Appendix C.

LIMITATIONS OF THE PROCEDURE
- For diagnostic purposes and in order to differentiate acute HBV infection from chronic HBV infection, the detection of HBsAg must be correlated with patient symptoms and other hepatitis B viral serological markers.
- It is recognized that presently available methods for the detection of hepatitis B surface antigen may not detect all potentially infectious units of blood or infected individuals. A nonreactive test result does not exclude the possibility of exposure to or infection with hepatitis B. Nonreactive test results in individuals with prior exposure to hepatitis B may be due to antigen levels below the detection limit of this assay or lack of antigen reactivity to the antibodies used in this assay.
• This assay was designed and validated for use with human plasma or serum from individual patient and donor specimens. Insufficient data are available to interpret tests performed on pooled blood or processed plasma and products made from such pools. Testing of these specimens is not recommended.
• Performance has not been established using cadaver samples or body fluids such as urine, saliva, semen or amniotic fluid.
• Do not use heat-inactivated samples.
• Frozen samples and those containing particulate matter or red blood cells must be centrifuged prior to running the assay.
• Samples which contain fibrin may cause erroneous results. Serum samples must be completely clotted to generate consistent results.
• Samples from heparinized patients may be partially coagulated. Erroneous results could occur due to the presence of fibrin. To prevent this phenomenon, draw the sample prior to heparin therapy.

EXPECTED VALUES
In random blood donor populations, the number of samples found repeatedly reactive for HBsAg by AxSYM HBsAg (V2) has typically been less than 0.20%. In a population reactive for HBsAg, AxSYM HBsAg (V2) detected HBsAg in 402/402 (100%) specimens.

SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION
Assay reproducibility was determined during the clinical evaluation of AxSYM HBsAg. The six member panel was run in replicates of three, four times per day, over two days on each of three clinical lots. Calculations were made with a variance components analysis, using a nested analysis of variance model. The results from these three clinical lots are summarized in Table 1.

DETECTABILITY
The ability of AxSYM HBsAg (V2) to detect HBsAg in specimens from blood donors, hospital patients (samples submitted to hospital laboratories for diagnostic testing) and hepatitis B patients is shown in Table 2. The data includes a total of 4940 serum and plasma specimens.

SPECIFICITY
The percentage of samples found to be initially reactive with AxSYM HBsAg (V2) and the percentage of these samples found to be repeatedly reactive were determined by testing 4538 samples (plasma and sera) obtained from two blood banks and a hospital laboratory in a clinical evaluation. The presence of HBsAg in the repeatedly reactive specimens was confirmed by neutralization with anti-HBs using AxSYM HBsAg Confirmatory assay. The results of these tests are shown in Table 3.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Reproducibility of AxSYM HBsAg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panel</td>
<td>Member</td>
</tr>
<tr>
<td>---------</td>
<td>--------</td>
</tr>
<tr>
<td>1</td>
<td>72</td>
</tr>
<tr>
<td>2</td>
<td>72</td>
</tr>
<tr>
<td>3</td>
<td>72</td>
</tr>
<tr>
<td>4</td>
<td>72</td>
</tr>
<tr>
<td>5</td>
<td>72</td>
</tr>
<tr>
<td>6</td>
<td>72</td>
</tr>
<tr>
<td>Index</td>
<td>48</td>
</tr>
<tr>
<td>NC</td>
<td>48</td>
</tr>
<tr>
<td>PC</td>
<td>48</td>
</tr>
</tbody>
</table>

Index = Index Calibrator
NC = Negative Control
PC = Positive Control

* Representative performance data are shown. Results obtained at individual laboratories may vary.

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Detection of HBsAg in Serum and Plasma Specimens from Blood Donors, Hospital Patients and Hepatitis B Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>Number Tested</td>
</tr>
<tr>
<td>Blood Donors</td>
<td>4035</td>
</tr>
<tr>
<td>Hospital Patients</td>
<td>503</td>
</tr>
<tr>
<td>Hepatitis B Patients</td>
<td>402</td>
</tr>
</tbody>
</table>

* Representative performance data are shown. Results obtained at individual laboratories may vary.

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Number (%) of Reactive Samples Detected by AxSYM HBsAg (V2) and Confirmed as Positive for HBsAg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Number of samples tested</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Blood Donors</td>
<td>2033</td>
</tr>
<tr>
<td>Blood Donors (including 401 first donors)</td>
<td>2032</td>
</tr>
<tr>
<td>Hospital Patients</td>
<td>503</td>
</tr>
<tr>
<td>Medical Conditions</td>
<td>50</td>
</tr>
<tr>
<td>Potentially Interfering Substances (both unrelated to HBV infection)</td>
<td>57</td>
</tr>
</tbody>
</table>

* A confirmed positive result in these studies was defined as neutralization by AxSYM HBsAg Confirmatory Assay.

<table>
<thead>
<tr>
<th>TABLE 4</th>
<th>Detection of Purified HBsAg ad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration (ng/mL)</td>
<td>AxSYM HBsAg (V2)</td>
</tr>
<tr>
<td>0.721</td>
<td>4.35</td>
</tr>
<tr>
<td>0.496</td>
<td>3.57</td>
</tr>
<tr>
<td>0.229</td>
<td>2.26</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 5</th>
<th>Detection of Purified HBsAg ay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration (ng/mL)</td>
<td>AxSYM HBsAg (V2)</td>
</tr>
<tr>
<td>0.722</td>
<td>6.09</td>
</tr>
<tr>
<td>0.498</td>
<td>4.59</td>
</tr>
<tr>
<td>0.250</td>
<td>2.88</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 6</th>
<th>Sensitivity Calculated by Linear Regression Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg Subtype</td>
<td>Sensitivity (ng/mL)</td>
</tr>
<tr>
<td>ad</td>
<td>0.19</td>
</tr>
<tr>
<td>ay</td>
<td>0.14</td>
</tr>
</tbody>
</table>

* Representative performance data are shown. Results obtained at individual laboratories may vary.
Typically AxSYM HBsAg (V2) sensitivity results from clinical trials and studies done at Abbott Laboratories have ranged from 0.10 to 0.60 ng/mL. In studies performed at Abbott Laboratories using HBsAg as reference serum from Paul Ehrlich Institute (PEI), the AxSYM HBsAg (V2) assay calculated sensitivity was 0.031 PEI Units/mL.*

These are representative performance data. Results obtained at individual laboratories may vary.

BIBLIOGRAPHY