HCV version 3.0

Hepatitis C Virus Encoded Antigen
(Recombinant HCr43, c200, c100-3, NS5)

Customer Service
For additional product information, please contact your local customer service organization.

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.

Key to symbols used

- **REF** List Number
- **IVD** In Vitro Diagnostic Medical Device
- **LOT** Lot Number
- **2°C/8°C** Store at 2-8°C
- **CAUTION** Consult accompanying documents.
- **Consult instructions for use**
- **Manufacturer**

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
AxSYM HCV version 3.0

INTENDED USE
AxSYM HCV version 3.0 is a microparticle enzyme immunoassay (MEIA) for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST
MEIs are a variation of the enzyme immunoassay (EIA) principle. Solid phase EIs, first described in the early 1970s, use antigens and/or antibodies coated on a surface to bind complementary analytes. The bound analyte is detected by a series of antigen-antibody reactions. EIs are available to identify many antigens and antibodies related to viral hepatitis infection. In the AxSYM final reaction, an antibody coupled to an enzyme acts upon a substrate to produce a fluorescent end-product. The fluorescence produced by the enzyme reaction is measured and is proportional to the amount of bound antibody.

HCV is a bloodborne virus closely associated with blood transfusion. Serological studies employing EIs for detection of antibodies to HCV is a bloodborne virus closely associated with blood transfusion. 2,3 The presence and absence of anti-HCV is determined by comparing the rate of formation of fluorescent product to the cutoff rate which is calculated from a previous AxSYM HCV version 3.0 Index Calibration.

SAMPLING CENTER
• Sample and all AxSYM HCV version 3.0 reagents required for one test are pipetted by the Sampling Probe into various wells of a Reaction Vessel (RV).
• Sample is diluted with Specimen Diluent 1 in one RV well and then further diluted with Specimen Diluent 2 in a second RV well.
• Recombinant antigen coated microparticles are added to the diluted sample.

PROCESSING CENTER
• The reaction mixture is incubated. The anti-HCV antibody in the sample binds to the antigen coated microparticles forming an antibody-antigen complex.
• A portion of the reaction mixture is transferred to the matrix cell. The microparticles bind irreversibly to the glass fiber matrix.
• The matrix cell is washed to remove unbound materials.
• Goat anti-human IgG: alkaline phosphatase conjugate is dispensed into the matrix cell.
• The matrix cell is washed to remove unbound materials.
• 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-Methylumbelliferone. This fluorescent product is measured by the MEIA optical assembly.

The presence or absence of anti-HCV is determined by comparing the rate of formation of fluorescent product to the cutoff rate which is calculated from a previous AxSYM HCV version 3.0 Index Calibration. If the rate of formation of fluorescent product in the sample is greater than or equal to the cutoff rate, the sample is considered reactive for anti-HCV. For further information regarding MEIA technology, refer to the AxSYM System Operations Manual, Section 3.

* RCF = Relative Centrifugal Force
AxSYM HCV version 3.0 Reagent Pack (3B44-20)

**REAGENT PACK, 100 Tests**

- 1 Bottle (9.9 mL) HCV antigen coated microparticles in MES Buffer with protein stabilizers. Minimum concentration: 0.01% solids. Preservative: sodium azide. (Reagent Bottle 1)
- 1 Bottle (12.1 mL) goat anti-human IgG: alkaline phosphatase conjugate in TRIS Buffer with protein stabilizers. Minimum concentration: 0.01 μg/mL. Preservative: sodium azide. (Reagent Bottle 1)
- 1 Bottle (28.0 mL) Specimen Diluent 2 containing TRIS Buffer with proteins, detergents and lysates. Preservatives: antimicrobial agents. (Reagent Bottle 3)
- 1 Bottle (50.2 mL) Specimen Diluent 1 containing 0.3 M sodium chloride in TRIS Buffer. Preservatives: sodium azide and antimicrobial agents. (Reagent Bottle 4)

**CONTROLS**

- AxSYM HCV version 3.0 Controls (3B44-10)
- 1 Bottle (2.0 mL) AxSYM HCV version 3.0 Index Calibrator.
- 4 Bottles (220 mL each) AxSYM Probe Cleaning Solution containing 2% Tetraethylammoniumhydroxide in AMP buffer. Preservative: sodium azide.
- 4 Bottles (230 mL each) AxSYM Controls 3.0 Controls (3B44-10)

**WARNINGS AND PRECAUTIONS**

**CAUTION:** This product contains human sourced infectious and/or potentially infectious components. Refer to the **REAGENTS** section of this package insert. Positive Control and Index Calibrator have been tested and found to be reactive for anti-HCV. Remaining components have been tested and found to be nonreactive for antibodies to HCV, HIV-1/HIV-2 and nonreactive for HBsAg. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.

**SAFETY PRECAUTIONS**

- 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.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.

**HANDLING PRECAUTIONS**

- Avoid neutralization of Conjugate due to contamination with human IgG during handling. Use clean gloves every time when handling the HCV reagent packs. Change gloves that have contacted human plasma/sera. Decontaminate instrument according to the AxSYM System Operations Manual, Section: 9: Service and Maintenance, Subsection: Daily Maintenance.
- AxSYM HCV 3.0 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: Maintenance.
- Do not use Solution 1 (MUP) beyond the expiration date or a maximum of fourteen days on-board the AxSYM System. When 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 reagents 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.

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- 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 reagents 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 specimens to prevent cross contamination.

Additional safety and handling precautions and limitations for the reagent packs, index calibrators, controls, patient specimens and other reagents are described in the AxSYM System Operations Manual, Sections 7 and 8.

STORAGE INSTRUCTIONS

- 2-8°C: The AxSYM HCV version 3.0 Reagent Pack, Index Calibrator and Controls must be stored at 2-8°C. The AxSYM HCV version 3.0 Reagent Pack, Index Calibrator and Controls may be used immediately after removal from the refrigerator.
- The AxSYM HCV version 3.0 Reagent Pack may be on-board the AxSYM System for a maximum of 112 cumulative hours. After 112 hours, the reagent pack and its associated index calibrator must be discarded. Refer to the AxSYM System Operations Manual, Sections 2 and 5 and Appendix C, for further information on tracking on-board time.
- 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.
- 15-30°C: 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 HCV version 3.0 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 the specimens must be retested. Assay recalibration may be necessary.

INSTRUMENT PROCEDURE

NOTE: AxSYM HCV version 3.0 must only be used with AxSYM System Software Version 3.60 or higher.

Assay File Installation

The AxSYM HCV version 3.0 Assay File must be installed on the AxSYM System from the software disk, 3C8-02 or higher, prior to performing the HCV version 3.0 assay. Refer to the AxSYM System Operations Manual, Section 2, for proper installation procedures.

AxSYM HCV version 3.0 Assay Parameters

The default assay parameters for the AxSYM HCV version 3.0 assay are listed below. These parameters can be printed, displayed and edited according to the procedure in the AxSYM System Operations Manual, Section 2. To print the displayed screen, press PRINT. Assay parameters that can be edited contain a (>) symbol.

Assay Parameters

<table>
<thead>
<tr>
<th>Assay Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay Name (English)</td>
<td>HCV_version_3</td>
</tr>
<tr>
<td>Abbrev Assay Name (English)</td>
<td>HCV_3</td>
</tr>
<tr>
<td>Assay Number</td>
<td>841</td>
</tr>
<tr>
<td>Assay Version</td>
<td>2</td>
</tr>
<tr>
<td>Calibration Version</td>
<td>00</td>
</tr>
<tr>
<td>Assay File Revision</td>
<td>100</td>
</tr>
<tr>
<td>Assay Enabled</td>
<td>ON</td>
</tr>
<tr>
<td>Assay Type</td>
<td>MEIA</td>
</tr>
</tbody>
</table>

Assay Parameters

<table>
<thead>
<tr>
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<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Cal Reps</td>
<td>2</td>
</tr>
<tr>
<td>Default Calibration Method</td>
<td>Index Cal</td>
</tr>
<tr>
<td>Selected Result Concentration Units</td>
<td>S/CO</td>
</tr>
<tr>
<td>Selected Result Decimal Places</td>
<td>2</td>
</tr>
<tr>
<td>Max Intercept-Max MUP intercept</td>
<td>9000.0000</td>
</tr>
<tr>
<td>Min Intercept-Min MUP intercept</td>
<td>733.0000</td>
</tr>
<tr>
<td>Upper limit for NRMSE for low rates</td>
<td>9999.9900</td>
</tr>
<tr>
<td>Upper limit for NRMSE for high rates</td>
<td>1.4000</td>
</tr>
<tr>
<td>Max Rate-Max rate used to check Min MUP intercept</td>
<td>733.0000</td>
</tr>
<tr>
<td>Min Rate-Rate cutoff for NRMSE and Corr. Coef.</td>
<td>4.8000</td>
</tr>
<tr>
<td>Min correlation coefficient for low rates</td>
<td>0.0000</td>
</tr>
<tr>
<td>Min correlation coefficient for high rates</td>
<td>0.9700</td>
</tr>
<tr>
<td>MUP T Delay-Time delay following MUP</td>
<td>3.3000</td>
</tr>
<tr>
<td>Interpretation Option to use</td>
<td>1</td>
</tr>
<tr>
<td>Hold results with POS interpretation</td>
<td>ON</td>
</tr>
<tr>
<td>Hold results with NEG interpretation</td>
<td>OFF</td>
</tr>
<tr>
<td>Hold results with GRY interpretation</td>
<td>ON</td>
</tr>
<tr>
<td>Negative Interpretation Cutoff</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Refer to the AxSYM System Operations Manual for a detailed description of Instrument Procedures.

NOTE: Parameters 44, 45 and 80 cannot be edited.

NOTE: To utilize the grayzone option, parameter 117, Negative Interpretation Cutoff, can be edited. For details on configuring the AxSYM System to use grayzone interpretation, refer to the AxSYM System Operations Manual, Section 2: Installation Procedures and Special Requirements, Subsection: System Configuration.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- This assay was designed and validated for use with human serum or plasma from individual patient and donor specimens. Pooled specimens must not be used since the accuracy of their test results has not been validated.
- Serum (including serum collected in separator tubes) or plasma (collected in sodium citrate, potassium EDTA, sodium EDTA, sodium heparin, lithium heparin, potassium oxalate, ACD-A, ACD-B, CP2D, CPDA-1 and CPD) may be used. Use the ratio of anticoagulant (quantity) to sample (volume) that is recommended by the manufacturer.
- The AxSYM system does not provide the capability of verifying sample type. It is the responsibility of the operator to verify that the correct sample type(s) is (are) used in the HCV version 3.0 assay.
- Gravity separation is not sufficient for specimen preparation. Specimens must be separated from the clot or red cells by centrifugation.

- Specimens containing fibrin, red blood cells or particulate matter may give inconsistent or erroneous results and must be completely clotted and centrifuged prior to testing. Inspect all specimens 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.
- Centrifuged specimens with a lipid layer on the top of the liquid must be transferred to a sample cup. Care must be taken to transfer only the clarified specimen and not the lipemic material.
AxSYM HCV VERSION 3.0 PROCEDURE

Materials Required

- 3B44-20 AxSYM HCV version 3.0 Reagent Kit, containing:
  - 8A75-02 100 REAGENT PACK
  - 3B44-10 AxSYM HCV version 3.0 Controls
- 8A73-02 100 MATRIX CELLS
- 8A47-04 SOLUTION 1 MUP
- 8A81-04 SOLUTION 2 MATRIX CELL WASH
- 8A46 SOLUTION 4 LINE DIULSENT
- 8A35-05 AxSYM PROBE CLEANING SOLUTION
- 8A76-01 SAMPLE CUPS

Materials Required but Not Provided

- Pipettes and Pipette tips

CAUTION:

1. When manually dispensing samples, verify that dispensing equipment does not introduce cross contamination and that it delivers the specified sample volume. Use a separate pipette or pipette tip for each sample.
2. 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.
3. Order the HCV version 3.0 Index Calibrator, Controls, and/or patient specimens 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 HCV version 3.0 calibration by testing 2 replicates of the Index Calibrator. Dispense at least 4 drops of the Index Calibrator into a sample cup. Do not simultaneously calibrate more than one AxSYM HCV version 3.0 reagent lot.

Controls:

Perform quality control by testing Positive and Negative Controls (one test each). Dispense 4 drops each of the Positive and Negative Controls into individual sample cups.

* When more than one AxSYM HCV version 3.0 reagent lot is on-board the AxSYM System, multiply the control volume by the number of lots.
QUALITY CONTROL PROCEDURES

CALIBRATION

A minimum of two replicates of the HCV version 3.0 Index Calibrator must be tested for an AxSYM HCV version 3.0 calibration. A single sample of both the Positive and Negative Controls must be tested as a means of evaluating the assay calibration. Once an AxSYM HCV version 3.0 calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

• a reagent pack with a new lot number is used for an assay
• either of the AxSYM HCV version 3.0 Control values is out of its specified range

Refer to the AxSYM System Operations Manual, Section 6, for additional information.

The operator must verify that the AxSYM HCV version 3.0 Control values are within the acceptable ranges specified in this package insert (see Controls section). The AxSYM System verifies that the results of an assay calibration meet the specifications assigned to selected validity parameters. An error message occurs when the calibration fails to meet a specification. Refer to the AxSYM System Operations Manual, Section 10, for an explanation of the corrective actions for the error code. Refer to the AxSYM System Operations Manual, Appendix E, for an explanation of the calibration validity parameters that may be used by the AxSYM System.

QUALITY CONTROL

The minimum control requirement for an AxSYM HCV version 3.0 assay is a single sample of each of the Positive and Negative Controls tested once every 8 hours, each day of use. Controls may be placed in any position in the Sample Carousel.

The AxSYM HCV version 3.0 Control values must be within the acceptable ranges specified in the insert (see Controls section). If a control value is out of its specified range, the associated test results are invalid and the specimens must be retested. Recalibration may be indicated.

If the quality control procedures in your laboratory require more frequent use of controls, follow those procedures.

Fluorescence Background Acceptance Criteria

Quality control with regards to the MUP substrate blank is automatically determined by the instrument and checked under Assay Parameter 64, Max Intercept-Max MUP intercept, each time a test result is calculated. If the MUP intercept value is greater than the maximum allowable value, the result is invalid. The test request will be moved to the Exceptions List where it will appear with the message "1064 invalid test result, intercept too high" and the calculated intercept value. Refer to the AxSYM System Operations Manual, Section 10, when this error message is obtained. Refer to the AxSYM System Operations Manual, Section 2, for further information on parameter files.

RESULTS

CALCULATION

The AxSYM System calculates the cutoff rate from the mean rate of two Index Calibrator replicates and stores the result. The cutoff rate is determined by multiplying the Index Calibrator mean rate by 0.12.

Cutoff Rate (CO) = Index Calibrator mean x 0.12

The AxSYM HCV version 3.0 assay calculates a result based on the ratio of the sample rate to the cutoff rate (CO) for each sample and control.

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

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.

INTERPRETATION OF RESULTS

• Specimens with an S/CO value less than 1.00 are considered nonreactive.
• Specimens with an S/CO value equal to or greater than 1.00 are considered initially reactive.
• All specimens that are reactive on initial testing should be retested in duplicate using the AxSYM HCV version 3.0. If neither of the retests are reactive, the specimen must be considered nonreactive for HCV. If the specimen is reactive in either of the replicates, the specimen must be considered repeatedly reactive.
• Repeatedly reactive anti-HCV specimens should be investigated further in supplemental tests such as other HCV specific immunoassays and immunoblot assays or a combination thereof and/or NAT tests.

LIMITATIONS OF THE PROCEDURE

• It is recognized that currently available methods for the detection of antibody to HCV 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 HCV. Nonreactive test results in individuals with prior exposure to HCV may be due to antibody levels below the detection limit of this assay or lack of antibody reactivity to the antigens used in this assay. Vector and/or fusion protein antibody containing samples may demonstrate reactivity which is unrelated to HCV infection. For diagnostic purposes, the anti-HCV reactivity should be correlated with patient history and other hepatitis markers for diagnosis of acute or chronic infection.
- This assay was designed and validated for use with human plasma or serum from individual patient and donor specimens. Pooled specimens must not be used since the accuracy of their test results has not been validated.
- Specimens containing red blood cells may give inconsistent results, and therefore must be centrifuged prior to testing.
- Centrifuged specimens with a lipid layer on top of the liquid must be transferred to a sample cup. Care must be taken to transfer only the clarified specimen and not the lipemic material.
- Frozen specimens and those containing particulate matter must be centrifuged prior to running the assay.
- Do not use heat-inactivated specimens.
- Performance has not been established using cadaver specimens, or body fluids such as urine, saliva, semen, or amniotic fluid.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**PRECISION**

Assay reproducibility was determined during the clinical evaluation of AxSYM HCV version 3.0 using three lots of reagents. A four member panel, the Index Calibrator and the assay Controls were tested. Four clinical sites tested 3 replicates of each specimen in 4 separate runs per day, on 2 consecutive days using one dedicated instrument per site. The coefficients of variation (CVs) were calculated based upon the variance components obtained by the Nested Procedure of SAS\(^{18}\). The combined coefficients of variation (CVs) were calculated based upon the variance components obtained by the Nested Procedure of SAS\(^{18}\). The combined coefficients of variation (CVs) were calculated based upon the variance components obtained by the Nested Procedure of SAS\(^{18}\). The combined coefficients of variation (CVs) were calculated based upon the variance components obtained by the Nested Procedure of SAS\(^{18}\).

**Sensitivity and Specificity**

A four member panel, the Index Calibrator and the assay Controls were tested. Four clinical sites tested 3 replicates of each specimen in 4 separate runs per day, on 2 consecutive days using one dedicated instrument per site. The coefficients of variation (CVs) were calculated based upon the variance components obtained by the Nested Procedure of SAS\(^{18}\). The combined results of three clinical lots are summarized in Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Mean</th>
<th>Intra-Run</th>
<th>Inter-Run(^{a})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>n</td>
<td>S/CO</td>
</tr>
<tr>
<td>1</td>
<td>216</td>
<td>12.235</td>
</tr>
<tr>
<td>2</td>
<td>216</td>
<td>7.309</td>
</tr>
<tr>
<td>3</td>
<td>216</td>
<td>3.110</td>
</tr>
<tr>
<td>4</td>
<td>216</td>
<td>0.225</td>
</tr>
<tr>
<td>Index Calibrator</td>
<td>216</td>
<td>8.878</td>
</tr>
<tr>
<td>Negative Control</td>
<td>216</td>
<td>0.237</td>
</tr>
<tr>
<td>Positive Control</td>
<td>216</td>
<td>4.208</td>
</tr>
</tbody>
</table>

\(^{a}\) This term includes Intra-Run variance components.

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

**Sensitivity and Specificity**

At present there is no recognized standard for establishing the presence or absence of antibody to HCV in human blood; therefore, sensitivity and specificity have been estimated as described below.

- Specificity was defined as the ability to detect specimens as nonreactive in populations at low risk for HCV infection. Specificity assessment is based upon testing random blood donors and hospitalized patients (serum and plasma specimens). It was calculated as follows:

  $$ \text{Specimens with nonreactive results} $$

  $$ \text{Total number of nonreactive specimens} - x \text{ = Specificity} $$

- Sensitivity was defined as the ability to detect as reactive those specimens from patients who were clinically and serologically diagnosed with acute or chronic HCV infection or to detect as reactive specimens with verified HCV serology.

The following results were obtained with the ABBOTT AxSYM HCV version 3.0 assay:

1. Specificity in random blood donors (n = 4383, “x” = 2) is calculated to be 99.84% (4374/4381) (Table 2). This term includes Intra-Run variance components.

2. Specificity in a collection of hospitalized patients (n = 1272, “x” = 12) is calculated to be 99.60% (1255/1260) (Table 2).

3. Sensitivity in a group of 596 specimens from patients with acute or chronic hepatitis C or with verified HCV serology was 100% (596/596) (Table 4).

4. Seroconversion Sensitivity

   The performance of the ABBOTT AxSYM HCV version 3.0 assay was compared to the ABBOTT HCV EIA 3.0 (7A16) in 20 seroconversion panels. Equivalent performance was observed with nine (9) panels. Ten (10) panels were detected at least one bleed earlier; one (1) seroconversion was identified one bleed later.

The data obtained for 4383 random blood donors and 1272 hospitalized patients from 3 geographically distinct regions is summarized in Table 2.

### Table 2

<table>
<thead>
<tr>
<th>Population</th>
<th>Specimens Tested</th>
<th>Initially Reactive</th>
<th>Repeatedly Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>n</td>
<td>(%)</td>
<td>n</td>
</tr>
<tr>
<td>BD Serum (Site 1)</td>
<td>2258</td>
<td>5 (0.22)</td>
<td>5 (0.22)</td>
</tr>
<tr>
<td>BD Plasma (Site 1)</td>
<td>1018</td>
<td>1 (0.10)</td>
<td>1 (0.10)</td>
</tr>
<tr>
<td>BD Plasma (Site 2)</td>
<td>1107</td>
<td>3 (0.27)</td>
<td>3 (0.27)</td>
</tr>
<tr>
<td>Blood Donors</td>
<td>4383</td>
<td>9 (0.21)</td>
<td>9 (0.21)</td>
</tr>
<tr>
<td>(Total)</td>
<td>1272</td>
<td>17 (1.34)</td>
<td>17 (1.34)</td>
</tr>
</tbody>
</table>

- Two (2) specimens were found reactive for ≥ two antigens by ABBOTT Matrix HCV 2.0; two (2) specimens were single-antigen reactive for NSS, and the remaining five (5) specimens were nonreactive.

- Twelve (12) specimens were found reactive for ≥ two antigens by ABBOTT Matrix HCV 2.0; four (4) specimens showed single-antigen reactive [two (2) specimens were NS5 reactive, one specimen was NS3/NS4 E. coli reactive and one (1) specimen was Core reactive] results and one specimen was nonreactive.

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

The AxSYM HCV version 3.0 assay was used to test specimens from individuals having an increased risk for HCV infection and from patients with diseases or infections which might interfere with the assay (Table 3).

### Table 3

<table>
<thead>
<tr>
<th>Population</th>
<th>Specimens Tested</th>
<th>Repeatedly Reactive</th>
<th>Supplimental Assay*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>n</td>
<td>(%)</td>
<td>n</td>
</tr>
<tr>
<td>Potentially Interfering Substances(^{a})</td>
<td>230</td>
<td>24 (10.43)</td>
<td>21 (8.75)</td>
</tr>
<tr>
<td>High Risk(^{c})</td>
<td>298</td>
<td>162 (54.36)</td>
<td>152 (51.30)</td>
</tr>
</tbody>
</table>

\(^{a}\) This term includes Intra-Run variance components.

\(^{c}\) This term includes Intra-Run variance components.
laboratories may vary. Representative performance data are shown. Results obtained at individual hospitals showed a repeated grayzone reactivity (0.86/1.12/0.88 S/CO), the other specimen (Elevated ALT) gave a nonreactive result by ABBOTT AxSYM HCV version 3.0.

c. This group contains specimens from intravenous drug users, hemophiliacs, homosexuals and dialysis patients.

t. The remaining ten (10) specimens gave the following results: five (5) were single-antigen reactive for Core, NS3 and NS4, and five (5) were nonreactive with ABBOTT Matrix HCV 2.0. * ABBOTT Matrix HCV 2.0 or Chiron RIBA HCV 3.0 were used as supplemental assays.

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

Table 4
Detection of Antibody to HCV in Serum or Plasma Specimens from Patients with Acute or Chronic Hepatitis C or Verified HCV Serology

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimens Tested</th>
<th>Specimens Reactive</th>
<th>% ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hepatitis</td>
<td>24</td>
<td>24</td>
<td>100.00</td>
</tr>
<tr>
<td>Chronic Hepatitis</td>
<td>105</td>
<td>105</td>
<td>100.00</td>
</tr>
<tr>
<td>Specimens with Verified HCV Serology</td>
<td>467</td>
<td>467</td>
<td>100.00</td>
</tr>
</tbody>
</table>

The ability to detect antibodies to HCV was evaluated by testing sequential specimens from 20 seroconversion panels; 18 of the panels were commercially available from Boston Biomedica Inc. (BBI, Massachusetts, USA), North American Biologicals Inc. (NABI, Florida, USA), Serologicals Inc. (Clarkston, USA) and BioClin. Partners (Boston, USA). The remaining two panels are not commercially available.

The performance was compared to the ABBOTT HCV EIA 3.0 (7A16). Equivalent performance was observed with nine (9) panels. Ten (10) were detected at least one bleed earlier; one (1) seroconversion was identified one bleed later.

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

BIBLIOGRAPHY


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