CA 19-9™

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 used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td></td>
<td>Expiration Date</td>
</tr>
<tr>
<td>2°C</td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td>15°C</td>
<td>Store at 15-30°C</td>
</tr>
<tr>
<td>Caution</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
<tr>
<td>CAL'A</td>
<td>Calibrator (A-F)</td>
</tr>
<tr>
<td>CONTROL'L</td>
<td>Control Low, Medium, High (L, M, H)</td>
</tr>
<tr>
<td>REAGENT PACK</td>
<td>Reagent Pack</td>
</tr>
<tr>
<td>REACTION VESSELS</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>MATRIX CELLS</td>
<td>Matrix Cells</td>
</tr>
<tr>
<td>SAMPLE CUPS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>ASSAY NO.</td>
<td>Assay Number</td>
</tr>
<tr>
<td>CHECKSUM</td>
<td>Checksum</td>
</tr>
<tr>
<td>CONTAINS: AZIDE</td>
<td>Contains Sodium Azide. Contact with acids liberates very toxic gas.</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
### PROCEDURE

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies. These specimens should not be assayed with the AxSYM CA 19-9 assay. Refer to the **LIMITATIONS OF THE PROCEDURE** section in this insert.

### NAME

AxSYM CA 19-9: Carbohydrate Antigen 19-9

### INTENDED USE

The AxSYM CA 19-9 assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative measurement of 1116-NS-19-9 reactive determinants in human serum.

### BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The AxSYM CA 19-9 assay is based on the Microparticle Enzyme Immunoassay (MEIA) technology.

The AxSYM CA 19-9 Reagents and sample are pipetted in the following sequence:

- Sample, 1116-NS-19-9 reactive determinants (human) prepared in TRIS buffer with protein stabilizers at the stock concentration level.
- An aliquot 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.

The results of published research studies indicate that the CA 19-9 assay value is frequently elevated in the serum of subjects with various gastrointestinal malignancies, such as pancreatic, colorectal, gastric and hepatic carcinomas. Increased serum CA 19-9 assay values have also been observed in patients with metastases and in nonmalignant conditions such as hepatitis, cirrhosis, pancreatitis and nonmalignant gastrointestinal disease. Elevated levels have also been seen in cystic fibrosis.

Research studies demonstrate that CA 19-9 assay values may have utility in monitoring subjects with the above-mentioned diagnosed malignancies. It has been shown that a persistent elevation in CA 19-9 assay value following treatment may be indicative of occult metastatic and/or residual disease. A persistently rising CA 19-9 assay value may be associated with progressive malignant disease and poor therapeutic response. A declining CA 19-9 assay value may be indicative of a favorable prognosis and good response to treatment.

### REAGENTS

**AxSYM CA 19-9 Reagents and Sample**

- **AxSYM CA 19-9 Reagent Pack (7A50-21)**
  - 1 Bottle (15.1 mL) 1116-NS-19-9 (Mouse, Monoclonal): Alkaline Phosphatase Conjugate in TRIS buffer with protein stabilizers. Minimum concentration: 0.1 µg/mL. Preservatives: Sodium Azide and Antimicrobial Agents. (Reagent Bottle 3)
  - 6 Bottles (4 mL each) of AxSYM CA 19-9 Calibrators. Calibrator A is TRIS buffer with protein stabilizers. Calibrators B-F contain 1116-NS-19-9 reactive determinants (human) in TRIS buffer with protein stabilizers at the following assay values:
    - **CAL A**: 0
    - **CAL B**: 30
    - **CAL C**: 90
    - **CAL D**: 180
    - **CAL E**: 320
    - **CAL F**: 500
  - Preservatives: Sodium Azide and Antimicrobial Agents.

**AxSYM CA 19-9 Specimen Diluent (7A50-38)**

- **Solution 1 (MUP)** (230 mL each) Solution 1 (MUP) containing 4-Methylumbelliferyl Phosphate, 1.2 mM, in AMP buffer. Preservative: Sodium Azide.

**AxSYM CA 19-9 Specimen Diluent (7A50-41)**

- **Solution 2 (MUP)** (230 mL each) Solution 2 (MUP) containing 4-Methylumbelliferyl Phosphate, 1.2 mM, in AMP buffer. Preservative: Sodium Azide.
Cleaning Solution containing 2% Tetraethylammoniumhydroxide (TEAH).

System operation.

Refer to the AxSYM System Operations Manual, Sections 7 and 8, for a more detailed discussion of the safety and handling precautions during system operation.

**WARNINGS AND PRECAUTIONS**

- **For In Vitro Diagnostic 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.

**Safety Precautions**

- CAUTION: This product contains human sourced and/or potentially infectious components. Calibrators B-F and the Controls contain antigen derived from a human sourced cell line. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens.17 Bioisafety Level 218 or other appropriate biosafety practices19, 20 should be used for materials that contain or are suspected of containing infectious agents.

Some components of this product contain Sodium Azide. For a specific listing, refer to the REAGENTS section of this package insert. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

**Handling Precautions**

- AxSYM CA 19-9 reagents are susceptible to bubbles/foaming and require inspection and removal of bubbles before loading. Refer to the AxSYM System Operations Manual, Section 9.
- Do not use Solution 1 (MUP) beyond the expiration date or a maximum of 14 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 of MUP 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.
- 1116-NS-19-9 reactive determinants are shed naturally in saliva and other body fluids.21 Contamination of the samples or the AxSYM disposables with saliva or aerosols (e.g. as a result of sneezing) may cause falsely elevated CA 19-9 values. It is recommended that all elevated values be reviewed and repeated as appropriate. Gloves should always be worn when handling samples, sample cups, reaction vessels and individual matrix cells. Talc from gloves is known to cause an increase in fluorescence, therefore, the use of talc-free gloves is recommended. Exposure of the reaction vessels to contamination can be reduced when the instrument is idle by utilizing the Reaction Vessel Carousel Cover provided with the AxSYM System.

Refer to the AxSYM System Operations Manual, Sections 7 and 8, for a more detailed discussion of the safety and handling precautions during system operation.

**Storage Instructions**

- The AxSYM CA 19-9 Reagent Pack, Specimen Diluent, Calibrators and Controls must be stored at 2-8°C. The AxSYM CA 19-9 Reagent Pack, Calibrators and Controls may be used immediately after removing them from the refrigerator. Calibrators and Controls should be returned to 2-8°C storage immediately after use. Do not freeze the AxSYM CA 19-9 Reagents. AxSYM CA 19-9 Reagents, Calibrators, and Controls are stable until the expiration date when stored and handled as directed.
- The AxSYM CA 19-9 Reagent Pack may be on board the AxSYM System for a maximum of 112 cumulative hours; for example 14 eight hour shifts. After 112 hours, the reagent pack must be discarded. Refer to the AxSYM System Operations Manual, Section 2, 5, and Appendix C, for further information on tracking onboard time.
- Solution 1 (MUP) must be stored at 2-8°C. It may be on board the AxSYM System for a maximum of 14 days. After 14 days, it must be discarded. It may be used immediately after removing it from the refrigerator. Do not freeze MUP.
- The AxSYM Probe Cleaning Solution, Solution 3 (Matrix Cell Wash) and Solution 4 (Line Diluent) must be stored at 15-30°C.

**INSTRUMENT PROCEDURE**

**Assay File Installation**

The AxSYM CA 19-9 Assay File must be installed on the AxSYM System from the following software disk, prior to performing CA 19-9 assays:

- 03D05-03, or higher (112 hours onboard Stability)

Refer to the AxSYM System Operations Manual, Section 2, for proper installation procedures.

**AxSYM CA 19-9 Assay Parameters**

The default values for the visible assay parameters used for the AxSYM CA 19-9 assay follow. These parameters can be displayed and edited according to the procedure in the AxSYM System Operations Manual, Section 2. Press PRINT to print the assay parameters. Assay parameters that can be edited contain a (>) symbol. In order to obtain values for the parameters with an asterisk (*), review the specific Assay Parameter screen.

**Assay Parameters**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Long Assay Name (English): CA_19-9</td>
<td>452</td>
</tr>
<tr>
<td>2 Assay Version:</td>
<td>*</td>
</tr>
<tr>
<td>3 Assay Type:</td>
<td>MEIA</td>
</tr>
<tr>
<td>4 Standard Cal Reps</td>
<td>&gt; 2</td>
</tr>
<tr>
<td>5 Cal Adjust Reps:</td>
<td>0</td>
</tr>
<tr>
<td>6 Cal A Concentration:</td>
<td>0.00</td>
</tr>
<tr>
<td>7 Cal B Concentration:</td>
<td>30.00</td>
</tr>
<tr>
<td>8 Cal C Concentration:</td>
<td>90.00</td>
</tr>
<tr>
<td>9 Cal D Concentration:</td>
<td>180.00</td>
</tr>
<tr>
<td>10 Cal E Concentration:</td>
<td>320.00</td>
</tr>
<tr>
<td>11 Cal F Concentration:</td>
<td>500.00</td>
</tr>
<tr>
<td>12 Cal Adjust Concentration:</td>
<td>0.00</td>
</tr>
<tr>
<td>13 Default Calibration Method &gt; Standard Cal.</td>
<td>0.00</td>
</tr>
<tr>
<td>14 Selected Result Concentration Units &gt; U/mL</td>
<td>500.00</td>
</tr>
</tbody>
</table>

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

Note: Parameter 45 cannot be edited.
SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

• Serum only may be used with the AxSYM CA 19-9 assay.
• The AxSYM System does not provide the capability of verifying sample type. It is the responsibility of the operator to verify the correct sample type is used in the AxSYM CA 19-9 assay.
• Specimens with obvious microbial contamination should not be used.
• AxSYM CA 19-9 Calibrators and Controls should be mixed by gentle inversion prior to use.
• Ensure that complete clot formation has taken place prior to centrifugation. Some samples, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If a serum sample is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
• For optimal results, samples should be free of fibrin, red blood cells or other particulate matter.
• Patient samples should be mixed and centrifuged after any freeze/thaw cycle or to remove red cells or particulate matter.
• Multiple freeze/thaw cycles should be avoided. Samples must be mixed thoroughly after thawing, by LOW speed vortexing or by gently inverting, and centrifuged prior to use to remove particulate matter and to ensure consistency in the results.
• Samples may be stored for up to 24 hours at 2-8°C prior to being tested. If testing will be delayed more than 24 hours, the specimen should be stored at -20°C or colder. Samples that have been stored at -20°C or colder for 12 months have shown no performance differences.
• To minimize the effects of evaporation, 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 a more detailed discussion of onboard sample storage constraints.
• When shipped, samples must be packaged and labeled in compliance with applicable federal and international regulations covering the transport of clinical samples and etiologic agents.
• Inspect all samples for bubbles. Remove all bubbles prior to analysis.

Sample Volume

The sample volume required to perform a single undiluted CA 19-9 test on the AxSYM System varies depending on the type of sample container used. For sample cups, a ROUTINE test requires 150 µL and a STAT test requires 131 µL. For every additional test performed (ROUTINE or STAT) from the same container, an additional 81 µL of sample is required. The sample cup minimum volumes for STAT, ROUTINE, and diluted tests are calculated by the AxSYM System. They are displayed on the Order screen at the time the test(s) is (are) ordered, and printed in the Orderlist Report.

When using Host Order Query, the Order screen information and Orderlist Report are not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query option. If the assay is configured for auto retest, an additional 81 µL of sample will be required. Refer to the AxSYM System Operations Manual, Section 2, for details on Automatic Sample Retest Configuration.

To obtain the recommended volume requirements for the AxSYM CA 19-9 Calibrators and Controls, invert, hold the bottles vertically and dispense 5 drops of each Calibrator (replicates of 2) or 4 drops of the Control into each respective sample cup.

Refer to the AxSYM System Operations Manual, Section 5, for sample volume requirements in primary or aliquot tubes and calibrator/control requirements for multiple reagent lots.

AxSYM CA 19-9 PROCEDURE

Materials Provided
• 7A50-21 AxSYM CA 19-9 REAGENT PACK

Materials Required But Not Provided
• AxSYM System
• 9C20-11 AxSYM CA 19-9 Controls
• 9C20-04 AxSYM CA 19-9 Calibrators
• 7A50-38 AxSYM CA 19-9 SPECIMEN DILUENT
• 8A47-04 SOLUTION 1 MUP
• 8A81-04 SOLUTION 3 MATRIX CELL WASH
• 8A46 SOLUTION 4 LINE DILUENT
• 9A35-05 AxSYM PROBE CLEANING SOLUTION
• 8A76-01 SAMPLE CUPS
• Pipettes/pipette tips (optional) to deliver the volumes specified on the Order screen.

CAUTION:
When manually dispensing sample into sample cups, verify that dispensing equipment does not introduce cross-contamination and delivers specified sample volume. Use a separate pipette tip for each sample. Use accurately calibrated equipment.

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

Sections 5 and 6 of the AxSYM System Operations Manual contain detailed steps for performing assay Calibration and sample testing procedures. Prior to ordering tests, confirm that the system inventory of matrix cells, bulk solutions and waste levels are acceptable.

The Orderlist Report contains sample placement information, sample volume requirements and sample cup volume requirements for all ordered tests. It is recommended that this report be referenced when loading samples into sample segments.

When using Host Order Query, the Orderlist Report is not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query option.

CAUTION: When operating the AxSYM System, always observe the following:
• The System status must be WARMING, PAUSED, READY or STOPPED before adding or removing sample segments, reagent packs or reaction vessels.
• Do not open the Interior Waste Door or the AxSYM Processing Center Cover while any test is in process. If opened, all processing will stop. Any tests will be terminated and must be repeated.
• When testing is completed, it is recommended that samples and the AxSYM CA 19-9 Reagent Pack be removed from the Sampling Center to maximize the onboard reagent pack use. Store at 2-8°C.

SAMPLE DILUTION PROCEDURES

Patient samples with a CA 19-9 value exceeding 500 U/mL (HIGH RANGE, assay parameter 92), are flagged with the code “> 500”. To quantitate the concentration of these specimens, perform either the Automated Dilution Protocol or the Manual Dilution Protocol.

Automated Dilution Protocol

The Automated Dilution Protocol is provided to assist in quantitating test results greater than 500 U/mL. The AxSYM System performs a 1:10 dilution of the unknown sample using one reaction vessel. The AxSYM System automatically calculates the concentration of the diluted sample and reports the results.

Refer to the AxSYM System Operations Manual, Section 5, for additional information on ordering sample dilutions.

Manual Dilution Protocol

A manual dilution can be performed by making a dilution of the specimen with AxSYM CA 19-9 Specimen Diluent (7A50-38) before pipetting the sample into the sample cup. It is desirable to perform the dilution so that the diluted specimen reads above 30 U/mL on the calibration curve. Example: A twenty-fold dilution is prepared by adding 50 µL of the sample to 950 µL of AxSYM CA 19-9 Specimen Diluent. Mix thoroughly before assaying. To determine the concentration of CA 19-9 in the specimen, multiply the concentration of the diluted sample by the dilution factor.
QUALITY CONTROL PROCEDURES

Calibration

The AxSYM CA 19-9 assay must be calibrated using a Standard Calibration (6-point) procedure. The use of a particular calibration procedure is dependent upon individual laboratory policy.

Standard Calibration

To perform an AxSYM CA 19-9 Standard Calibration, test Calibrators A, B, C, D, E, and F in duplicate. A single sample of all levels of CA 19-9 Controls must be tested as a means of evaluating the assay calibration. Once the AxSYM CA 19-9 assay 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.
- Control values are out of their specified range.

Refer to the AxSYM System Operations Manual, Section 6, for:

- Setting up an assay calibration
- When recalibration may be necessary
- Calibration verification

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 an error code. Refer to the AxSYM System Operations Manual, Appendices, for an explanation of the calibration validity parameters that may be used by the AxSYM System.

Quality Control

The recommended control requirement for an AxSYM CA 19-9 assay is a single sample of all CA 19-9 control levels tested once every 24 hours each day of use. Controls may be placed in any segment position in the Sample Carousel.

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

Ensure that assay control values are within the concentration ranges specified in the package insert. Refer to the REAGENTS, CONTROLS section of this package insert for AxSYM CA 19-9 Control ranges.

Indications of Instability or Deterioration of Reagents

When a CA 19-9 Control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and require retesting. Assay recalibration may be indicated. Refer to the AxSYM System Operations Manual, Section 10, Subsection: Observed Problems, for further troubleshooting information.

The AxSYM System has a capability to generate a Levey-Jennings plot of each assay’s quality control performance. Refer to the AxSYM System Operations Manual, Section 5. At the discretion of the laboratory, selected quality control rules may be applied to the quality control data.

Fluorescence Background Acceptance Criteria

Quality control of 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 this parameter.

RESULTS

The AxSYM CA 19-9 assay utilizes a point-to-point data reduction method to generate a standard calibration curve. Refer to the AxSYM System Operations Manual, Appendix F, for further information.

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, Sections 1 and 2.

LIMITATIONS OF THE PROCEDURE

The measurement of 1116-NS-19-9 reactive determinants has been reported to be an aid in the management of patients with gastrointestinal cancer when used in conjunction with information available from clinical evaluation and other diagnostic procedures. Increased serum CA 19-9 assay values have also been observed in patients with metastasis and in nonmalignant conditions such as hepatitis, cirrhosis, pancreatitis, and nonmalignant gastrointestinal disease. Elevated levels have also been seen in cystic fibrosis.

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies. These specimens should not be assayed with the AxSYM CA 19-9 assay.

Patients with the LE(a-b-) phenotype may not express the 1116-NS-19-9 reactive determinant.

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert.

EXPECTED VALUES

The distribution of CA 19-9 assay values determined in 2017 specimens is shown in the following table:

<table>
<thead>
<tr>
<th>Distribution of AxSYM CA 19-9 Assay Values</th>
<th>Number of Subjects</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 37.0 U/mL</td>
<td>37.0-60.0 U/mL</td>
</tr>
<tr>
<td>HEALTHY SUBJECTS</td>
<td>592</td>
<td>96.6</td>
</tr>
<tr>
<td>MALIGNANT DISEASES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal</td>
<td>379</td>
<td>40.4</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>187</td>
<td>25.7</td>
</tr>
<tr>
<td>Gastric</td>
<td>106</td>
<td>50.9</td>
</tr>
<tr>
<td>Hepatic</td>
<td>60</td>
<td>33.3</td>
</tr>
<tr>
<td>Mammary</td>
<td>83</td>
<td>77.1</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>77</td>
<td>79.2</td>
</tr>
<tr>
<td>NONMALIGNANT DISEASES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>89</td>
<td>84.3</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>54</td>
<td>50.0</td>
</tr>
<tr>
<td>Diabetes</td>
<td>56</td>
<td>83.9</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>90</td>
<td>47.8</td>
</tr>
<tr>
<td>Hepatitis</td>
<td>59</td>
<td>64.4</td>
</tr>
<tr>
<td>Gallbladder</td>
<td>44</td>
<td>90.9</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>66</td>
<td>80.3</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>24</td>
<td>100.0</td>
</tr>
<tr>
<td>Renal</td>
<td>51</td>
<td>88.2</td>
</tr>
</tbody>
</table>

In this study of 592 healthy subjects, 96.6% of them had CA 19-9 assay values below 37 U/mL.

It is recommended that each laboratory establish its own reference range for the population of interest.

CA 19-9 assay values should not be interpreted as absolute evidence for the presence or absence of malignant disease. In patients with suspected or known cancer, other tests and procedures must also be considered for diagnosis and good patient management.
SPECIFIC PERFORMANCE CHARACTERISTICS

Precision
Reproducibility was determined as described in Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) protocol EP5-T2. A six member serum based panel was assayed, at 3 laboratories, in replicates of 2 at two separate times per day for twenty days (n=80 for each sample) using a single lot of reagents and a single calibration. Data from this study are summarized as follows.

Reproducibility of AxSYM CA 19-9

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Lab</th>
<th>Mean CA 19-9 (U/mL)</th>
<th>Within Run (%) CV</th>
<th>Between Run (%) CV</th>
<th>Between Day (%) CV</th>
<th>Total (%) CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>13.7</td>
<td>7.8</td>
<td>0.0</td>
<td>6.8</td>
<td>10.3</td>
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<tr>
<td>2</td>
<td>1</td>
<td>10.0</td>
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<td>16.4</td>
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</tr>
<tr>
<td>3</td>
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<td>6.9</td>
<td>3.1</td>
<td>8.0</td>
<td>11.1</td>
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<td>2</td>
<td>2</td>
<td>36.6</td>
<td>11.0</td>
<td>3.9</td>
<td>2.5</td>
<td>11.9</td>
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<td>3</td>
<td>2</td>
<td>36.7</td>
<td>7.1</td>
<td>3.2</td>
<td>3.3</td>
<td>8.5</td>
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<tr>
<td>4</td>
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<td>2.3</td>
<td>4.5</td>
<td>6.9</td>
</tr>
<tr>
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<td>61.9</td>
<td>6.0</td>
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<tr>
<td>3</td>
<td>3</td>
<td>63.2</td>
<td>4.5</td>
<td>2.2</td>
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<tr>
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<td>1</td>
<td>132.7</td>
<td>5.2</td>
<td>1.4</td>
<td>4.3</td>
<td>6.9</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
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<td>5.9</td>
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</table>

The standard deviation may be calculated by multiplying the mean CA 19-9 concentration by the percent CV and dividing by 100.

\[
SD = \frac{\text{Mean (U/mL)} \times (\% \text{ CV})}{100}
\]

Recovery
Known amounts of 1116-NS-19-9 reactive determinants were added to normal human serum. The concentration of reactive determinants was determined using the AxSYM CA 19-9 assay and the resulting percent recovery was calculated.

<table>
<thead>
<tr>
<th>Endogenous Level (U/mL)</th>
<th>1116-NS-19-9 Reactive Determinant Added (U/mL)</th>
<th>Assay Value Obtained (U/mL)</th>
<th>Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.2</td>
<td>39.6</td>
<td>59.8</td>
<td>105</td>
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<td></td>
<td>199.4</td>
<td>199.5</td>
<td>96</td>
</tr>
</tbody>
</table>

\[
\% \text{ Recovery} = \frac{\text{Assay Value Obtained (U/mL) - Endogenous Level (U/mL)}}{1116-NS-19-9 Reactive Determinants Added (U/mL)} \times 100
\]

Sensitivity
The sensitivity of the AxSYM CA 19-9 assay was calculated to be better than 2.0 U 1116-NS-19-9 reactive determinants/mL. This sensitivity is defined as the concentration at two standard deviations above the AxSYM CA 19-9 Calibrator A (0 U 1116-NS-19-9 reactive determinants/mL) and represents the lowest measurable concentration of 1116-NS-19-9 reactive determinants that can be distinguished from zero.

Specificity
Lipemic specimens with up to 3000 mg/dL triglycerides, icteric specimens with up to 50 mg/dL bilirubin and hemolyzed specimens with up to 1000 mg/dL hemoglobin were tested and did not interfere in the AxSYM CA 19-9 assay. Concentrations of IgG in specimens up to 32 mg/mL and human albumin up to 160 mg/mL showed no significant interference.

BIBLIOGRAPHY


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