This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. 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
- **Lot**: Lot Number
- **IVD**: In Vitro Diagnostic Medical Device
- **Store at**: Store at 2-8°C
- **Store at**: Store at 15-30°C
- **Caution**: Caution, consult accompanying documents
- **Expiration Date**: Expiration Date
- **Authorized Representative**: Authorized Representative
- **Stable Calibrator (A-F)**
- **Control Low, Medium, High (L, M, H)**
- **Reagent Pack**: Reagent Pack
- **Reaction Vessels**: Reaction Vessels
- **Sample Cups**: Sample Cups
- **Consult instructions for use**: Consult instructions for use
- **Manufacturer**: Manufacturer

See REAGENTS section for a full explanation of symbols used in reagent component naming.
in human serum to yield the following concentrations:

**AxSYM Gentamicin Standard Calibrators (7A65-01)**

- **STANDARD A**: 0.00 (μg/mL) 0.00 (μmol/L)
- **STANDARD B**: 0.50 (μg/mL) 1.05 (μmol/L)
- **STANDARD C**: 1.50 (μg/mL) 3.14 (μmol/L)
- **STANDARD D**: 3.00 (μg/mL) 6.27 (μmol/L)
- **STANDARD E**: 6.00 (μg/mL) 12.54 (μmol/L)
- **STANDARD F**: 10.00 (μg/mL) 20.30 (μmol/L)

Preservative: Sodium Azide

**AxSYM Gentamicin Controls (7A65-10)**

3 Bottles (8 mL each) of AxSYM Gentamicin Controls contain gentamicin prepared in human serum to yield the following concentration ranges:

<table>
<thead>
<tr>
<th>Concentration Range</th>
<th>Gentamicin Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0 - 16.0 μg/mL</strong></td>
<td><strong>1.5 - 20.0 μg/mL</strong></td>
</tr>
<tr>
<td><strong>1.5 - 16.0 μg/mL</strong></td>
<td><strong>2.0 - 25.0 μg/mL</strong></td>
</tr>
<tr>
<td><strong>2.0 - 20.0 μg/mL</strong></td>
<td><strong>2.5 - 30.0 μg/mL</strong></td>
</tr>
<tr>
<td><strong>2.5 - 15.0 μg/mL</strong></td>
<td><strong>3.0 - 40.0 μg/mL</strong></td>
</tr>
<tr>
<td><strong>3.0 - 10.0 μg/mL</strong></td>
<td><strong>3.5 - 50.0 μg/mL</strong></td>
</tr>
</tbody>
</table>

**AxSYM Gentamicin Controls (7A65-10)**

- **CONTROL L**: 0.00 (μg/mL) 0.00 (μmol/L)
- **CONTROL M**: 4.00 (μg/mL) 8.36 (μmol/L)
- **CONTROL H**: 8.00 (μg/mL) 16.72 (μmol/L)

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution A**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.
- **Solution B**: 2% Tetraethylammoniumhydroxide (TEAH). Preservative: Sodium Azide.
- **Solution C**: 0.1M Lactic Acid. Preservative: Sodium Azide.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution D**: 0.1M Phosphoric Acid. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution E**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution F**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution G**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution H**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution I**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution J**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution K**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution L**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution M**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution N**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution O**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution P**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution Q**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution R**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution S**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution T**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution U**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution V**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution W**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution X**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution Y**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution Z**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.

**AxSYM Probe Cleaning Solution (8A46-D1)**

- **Solution AA**: 0.1M Phosphate Buffer. Preservatives: Sodium Azide and 0.2% Tween 20.
The AxSYM Gentamicin Reagents are light sensitive. When the AxSYM Reagent Pack or Reagent Reagent is placed on the AxSYM analyzer, the pack must be stored protected from light.

**STORAGE INSTRUCTIONS**

- Gentamicin assay:
  - The AxSYM Gentamicin Reagent Pack, Calibrators and Controls must be stored at 2-8°C. The AxSYM Gentamicin 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 AxSYM Gentamicin Reagents.
  - The AxSYM Gentamicin Reagent Pack may be on-board the AxSYM System for a maximum of 224 cumulative hours; for example, 28 eight hour shifts. Recalibration may be required to obtain maximum on-board reagent stability. More frequent use of controls may be required to monitor reagent performance within the same lot. Refer to the AxSYM System Operations Manual, Sections 2 and 5, for further information on tracking on-board time.
  - Reagents are stable until the expiration date when stored and handled as directed.

**PARAMETERS**

- Gentamicin assay:
  - The AxSYM Probe Cleaning Solution and Solution 4 (Line Diluent) must be stored at 15-30°C.

**INSTRUMENT PROCEDURE**

**AxSYM File Installation**

The AxSYM Gentamicin Assay File must be installed on the AxSYM System from one of the following software disks, prior to performing the Gentamicin assay:

- 8A44-01, or higher (112 hours on-board Stability)
- 8A94-01, or higher (224 hours on-board Stability)

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

**AxSYM Gentamicin Assay Parameters**

The default values for the assay parameters used for the AxSYM Gentamicin assay are listed below. Assay parameters that can be edited contain a (>) symbol. These parameters can be displayed and edited on the specific Assay Parameter screen. Press PRINT to print the assay parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay Number</td>
<td>645</td>
</tr>
<tr>
<td>Assay Version</td>
<td>*</td>
</tr>
<tr>
<td>Assay Type</td>
<td>FPIA</td>
</tr>
<tr>
<td>Cal F Concentration</td>
<td>10.00</td>
</tr>
<tr>
<td>Cal E Concentration</td>
<td>6.00</td>
</tr>
<tr>
<td>Cal D Concentration</td>
<td>3.00</td>
</tr>
<tr>
<td>Cal C Concentration</td>
<td>1.50</td>
</tr>
<tr>
<td>Low Limit-Normal/Therapeutic Range lower limit</td>
<td>&gt; 0.00</td>
</tr>
<tr>
<td>High Limit-Normal/Therapeutic Range upper limit</td>
<td>&gt; 0.00</td>
</tr>
<tr>
<td>Low Extreme Value</td>
<td>&lt; 0.30</td>
</tr>
<tr>
<td>High Extreme Value</td>
<td>&gt; 100.00</td>
</tr>
</tbody>
</table>

**SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS**

- Serum or plasma (collected in heparin, citrate, EDTA, or isotonic collection tubes) may be used in the AxSYM Gentamicin assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.
- The AxSYM System does not provide the capability of verifying sample type, and it is the responsibility of the operator to verify the correct sample type(s) used in the Gentamicin assay.

**STORAGE INSTRUCTIONS**

- Ensure that complete clot formation has taken place prior to centrifugation. Some samples, especially those from patients receiving antiobacterial or thrombolytic therapy, may exhibit increased clotting time. If the sample is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- Specimens containing particulate matter or red blood cells may give inconsistent results and should be centrifuged before testing (recommended 8,000-10,000 RCF* x 10 minutes).
- Samples should be refrigerated upon collection and stored frozen if not analyzed within 24 hours. Complex mixing of thawed plasma is required before analysis.
- Samples containing additional antibiotics should be stored frozen if a delay in analysis of more than 8 hours is anticipated. The samples should be frozen at -4°C to -7°C. Failure to freeze samples containing additional antibiotics may result in falsely low gentamicin levels due to reactivation.
- Refer to the AxSYM System Operations Manual, Section 5, for a detailed discussion on on-board sample storage constraints.
- Inspect samples for signs of in vitro infection before analysis.
- When shipped, samples must be packaged and labeled in compliance with applicable federal and international regulations covering the transport of clinical samples and xenobiotic agents.

**SAMPLE VOLUME**

The sample volume required to perform a single undiluted gentamicin 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 94 μL. For every additional gentamicin test performed (undiluted or diluted) are calculated by the AxSYM System. They are displayed on the Order screen at the time the test(s) is (are) ordered. If the assay is configured for auto retest/auto dilution the additional sample volume is required before analysis.

**Materials Provided**

- AxSYM Gentamicin Reagent Pack, containing:
  - 7AES-99 AxSYM Gentamicin Reagent Kit, containing:
  - 8A46 AxSYM Gentamicin Controls

**Materials Required But Not Provided**

- Pipettor and pipette tips

**INSTRUMENT PROCEDURE**

**AxSYM Gentamicin Procedure**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay Name (English): Gentamicin</td>
<td>Gent</td>
</tr>
<tr>
<td>Abbrev Assay Name (English): Gent</td>
<td>Gent</td>
</tr>
<tr>
<td>Assay Version</td>
<td>*</td>
</tr>
<tr>
<td>Calibration Version</td>
<td>*</td>
</tr>
<tr>
<td>Assay File Revision</td>
<td>*</td>
</tr>
<tr>
<td>Assay Enabled</td>
<td>ON</td>
</tr>
<tr>
<td>Assay Type</td>
<td>FPIA</td>
</tr>
<tr>
<td>Cal F Concentration</td>
<td>10.00</td>
</tr>
<tr>
<td>Cal E Concentration</td>
<td>6.00</td>
</tr>
<tr>
<td>Cal D Concentration</td>
<td>3.00</td>
</tr>
<tr>
<td>Cal C Concentration</td>
<td>1.50</td>
</tr>
<tr>
<td>Low Limit-Normal/Therapeutic Range lower limit</td>
<td>&gt; 0.00</td>
</tr>
<tr>
<td>High Limit-Normal/Therapeutic Range upper limit</td>
<td>&gt; 0.00</td>
</tr>
<tr>
<td>Low Extreme Value</td>
<td>&lt; 0.30</td>
</tr>
<tr>
<td>High Extreme Value</td>
<td>&gt; 100.00</td>
</tr>
<tr>
<td>Low Range</td>
<td>1.00</td>
</tr>
<tr>
<td>High Range</td>
<td>100.00</td>
</tr>
</tbody>
</table>

**INSTRUMENT PROCEDURE**

**AxSYM Gentamicin Procedure**

<table>
<thead>
<tr>
<th>Material Provided</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AxSYM Gentamicin Reagent Pack</td>
<td>8A46</td>
</tr>
<tr>
<td>AxSYM Gentamicin Controls</td>
<td>8A46</td>
</tr>
<tr>
<td>AxSYM Probe Cleaning Solution</td>
<td>8A76-01</td>
</tr>
</tbody>
</table>

**INSTRUMENT PROCEDURE**

**AxSYM Gentamicin Procedure**

- Pipettor and pipette tips

Note: Parameter 45 can be edited to the alternate result unit μg/mL or μg/L.

Values associated with the Low and High Extremes, Assay Parameters 75 and 76, are assay specific and should not be edited. We recommend that you set General Configuration Parameter, Release Mode, to the “Manual” or “Hold” release mode to ensure that all flagged results are reviewed prior to reporting assay results. Refer to the AxSYM System Operations Manual, Section 2, for a detailed description of Instrument Procedures. If General Configuration Parameter, Release Mode, is configured to the “Automatic” release mode, ensure that all flagged results are reviewed prior to reporting assay results.
To achieve maximum on-board reagent stability, more frequent use of controls to verify test results, follow those procedures.

Prior to ordering tests, confirm that the system inventory of both solutions and waste levels are acceptable.

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

**CAUTION:** When operating the AxSYM System, always observe the following:

- The System status must be WARMING, PRINSED, READY or STOPPED before adding or removing sample segments, reagent packs or Reaction Vessels (RVs).
- When only performing FPIA assays, the instrument homes all motors and may not automatically enter the sample and reagent deck cell detector, two door, processing center*. Select OK to proceed with testing the FPIA assay.
- 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.
- When testing is completed, it is recommended that samples and the AxSYM Gentamicin Reagent Pack are removed from the Sampling Center to maximize the on-board reagent pack use. Store Reagent Packs protected from light at 2-8°C.

**QUALITY CONTROL PROCEDURES**

**CALIBRATION:**

The AxSYM Gentamicin assay must be calibrated using a Standard Calibration (S-print) procedure. Standard Calibration

To perform a Standard Calibration, test the AxSYM Gentamicin Standard Calibrator A, B, C, D, E, and F in duplicate. A single sample of all levels of gentamicin controls must be tested as a means of evaluating the assay calibration.

Once the AxSYM Gentamicin 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

- Error messages occur when the calibration fails to meet a specification.

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

**Operator Verification**

An acceptable Gentamicin calibration curve should meet the following criteria:

- A Linear correlation coefficient (R²) of 0.99 or greater
- A Root Mean Squared Error (RMSE) less than or equal to 3.00
- A Centrifugal assay variation (CV%) less than or equal to 7.00
- A Linearity greater than or equal to 95% for each concentration
- A Centrifugal assay between 0.00 ng/mL and 1800 ng/mL
- A Manual assay between 0.00 mg/L and 7000 mg/L

**EXPECTED VALUES**

Stable concentrations have been shown between serum levels and both therapeutic effect and toxicity in specific patient types. Peak serum levels of gentamicin in the range of 5 to 10 μg/mL are suggested for optimal therapeutic effectiveness. Persistently elevated peak concentrations (15 μg/mL) have been shown to cause renal and eighth cranial nerve toxicity. Hypersensitivity takes the form of damage to the proximal renal tubules, and is associated with impaired renal function. Central nervous system toxicity is most often manifested as damage to the vestibular and auditory branches of the eighth cranial nerve. \(^{5,10}\) Trough levels offer a more concise indication of impending toxicity since they more closely correspond to tissue levels and are less affected by sampling errors. \(^{10}\) Slowly rising trough levels have been shown to correspond to tissue accumulation of the drug, and trough levels greater than 5 μg/mL have been associated with renal failure in some patients. \(^ {4,12,13}\)

**LIMITATIONS OF THE PROCEDURE**

As with all analyte determinations, the gentamicin value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Patient samples which contain the drugs sagamicin, sisomycin and netilmicin will yield falsely elevated values for gentamicin. \(\text{See SPECIFICITY section for further explanation.}\) However, these drugs are not usually coadministered with gentamicin. High concentration of penicillins or cephalosporins have been shown to inactivate gentamicin in vitro. The degree of inactivation is dependent on the particular amnoglycoside being measured, the type and concentration of the penicillin or cephalosporin that is also present and the storage conditions of the sample. \(^ {11}\) Samples from patients receiving additional antibiotics of these types should be assayed immediately or stored frozen.

**SAMPLE DILUTION PROCEDURES**

**Automated Dilution Protocol**

Patient samples with gentamicin concentrations reported as greater than 10.00 μg/mL may be diluted using an automated dilution protocol. The AxSYM System automatically calculates the concentration of the diluted sample and reports the result. Refer to the AxSYM System Operations Manual, Section 6, for additional information on ordering sample dilutions.

**Manual Dilution Protocol**

Patient samples with gentamicin concentrations reported as greater than 40.00 μg/mL, by the Automated Dilution Protocol may be diluted using a manual dilution of 1:10. Add one part of the patient sample to nine parts of Dilution Reagent. Mix well and test the diluted sample.

**REAGENTS**

AxSYM Gentamicin and AxSYM Gentamicin Reagent Packs are removed from the Sampling Center to maximize the on-board reagent pack use. Store Reagent Packs protected from light at 2-8°C.

**EXPECTED VALUES**

Stable concentrations have been shown between serum levels and both therapeutic effect and toxicity in specific patient types. Peak serum levels of gentamicin in the range of 5 to 10 μg/mL are suggested for optimal therapeutic effectiveness. Persistently elevated peak concentrations (15 μg/mL) have been shown to cause renal and eighth cranial nerve toxicity.\(^ {5,10}\) Hypersensitivity takes the form of damage to the proximal renal tubules, and is associated with impaired renal function. Central nervous system toxicity is most often manifested as damage to the vestibular and auditory branches of the eighth cranial nerve.\(^ {5,10}\) Trough levels offer a more concise indication of impending toxicity since they more closely correspond to tissue levels and are less affected by sampling errors.\(^ {10}\) Slowly rising trough levels have been shown to correspond to tissue accumulation of the drug, and trough levels greater than 5 μg/mL have been associated with renal failure in some patients.\(^ {4,12,13}\)

Refer to the drug manufacturer's package insert or the Physicians' Desk Reference® (PDR) for proper drug dosage and for gentamicin measurement sampling times. **REAGENTS**

AxSYM Gentamicin and AxSYM Gentamicin Reagent Packs are removed from the Sampling Center to maximize the on-board reagent pack use. Store Reagent Packs protected from light at 2-8°C.
SPECIFIC PERFORMANCE CHARACTERISTICS

**PRECISION**

Precision was determined as described in National Committee for Clinical Laboratory Standards (NCCLS) protocol EPS-T2R using human serum with 1.0, 2.0, 3.0, 4.0, and 8.0 μg/mL of gentamicin added. Results from these studies typically yielded CV’s of less than 7%.

<table>
<thead>
<tr>
<th>Target value (μg/mL)</th>
<th>Concentration in serum (μg/mL)</th>
<th>Concentration in Buffer (μg/mL)</th>
<th>Percent Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>0.99</td>
<td>0.95</td>
<td>104.2</td>
</tr>
<tr>
<td>2.0</td>
<td>2.08</td>
<td>2.08</td>
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<tr>
<td>3.0</td>
<td>3.13</td>
<td>2.88</td>
<td>108.7</td>
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<tr>
<td>4.0</td>
<td>3.80</td>
<td>3.74</td>
<td>101.6</td>
</tr>
<tr>
<td>8.0</td>
<td>7.61</td>
<td>8.01</td>
<td>95.0</td>
</tr>
</tbody>
</table>

Average Recovery: 101.8 ± 5.1%

**SENSITIVITY**

The sensitivity of the AxSYM Gentamicin assay was calculated to be 0.30 μg/mL. This sensitivity is defined as the lowest measurable concentration that can be distinguished from zero with 95% confidence.

**SPECIFICITY**

Cross-reactivity was tested for compounds whose chemical structure or concurrent usage could cause potential interference with the AxSYM Gentamicin assay. The aminoglycosides netilmicin and sisomicin cross-react with the Gentamicin assay.

**INTERFERENCE**

The compounds listed below, added to human serum, resulted in less than 10% error in detecting drug added when assayed with the AxSYM Gentamicin assay.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration Tested (μg/mL)</th>
<th>% Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>15 mg/dL</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1.0 g/dL</td>
<td>&lt;10%</td>
</tr>
<tr>
<td>Tryglicerides</td>
<td>890 mg/dL</td>
<td>&lt;10%</td>
</tr>
<tr>
<td>Total Protein</td>
<td>3.2-12.8 g/dL</td>
<td>&lt;10%</td>
</tr>
</tbody>
</table>

**ACCURACY BY RECOVERY**

The formula used for determining % recovery was calculated according to the following equation:

\[
\text{% Recovery} = \left( \frac{\text{serum concentration}}{\text{buffer concentration}} \right) \times 100
\]

Representative data are shown below.

**BIBLIOGRAPHY**


Related Reading

2. AxSYM, TDx and TDxFLx are trademarks of Abbott Laboratories, Abbott Park IL Manufactured for Abbott Laboratories, Abbott Park IL by Abbott Diagnostics International, L.D.T. Barcelona, Puerto Rico

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