Note Changes Highlighted

Key to symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REF</strong></td>
<td>List Number</td>
</tr>
<tr>
<td><strong>LOT</strong></td>
<td>Lot Number</td>
</tr>
<tr>
<td><strong>STD CAL</strong></td>
<td>Standard Calibrator (A-F)</td>
</tr>
<tr>
<td><strong>CTL</strong></td>
<td>Control Low, Medium, High (L, M, H)</td>
</tr>
<tr>
<td><strong>REP</strong></td>
<td>Authorized Representative</td>
</tr>
<tr>
<td><strong>EC REP</strong></td>
<td>Legal Manufacturer</td>
</tr>
</tbody>
</table>

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

Customer Service
United States: 1-877-4ABBOTT
International: Call your Abbott Representative

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.
NAME
Tobramycin

INTENDED USE
The AxSYM Tobramycin assay is a reagent system for the quantitative measurement of tobramycin, an antibiotic, in serum or plasma. The measurements obtained are used in the diagnostic and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

SUMMARY AND EXPLANATION OF TEST
The AxSYM Tobramycin assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology. Refer to the AxSYM System Operations Manual, Section 3, for a discussion of this technology.

Tobramycin is an aminoglycoside antibiotic whose in vivo activity is that of gentamicin against gram-negative bacteria. However, its activity against pseudomonas is definitely higher than gentamicin. Tobramycin exhibits a narrow therapeutic index which makes it use hazardous, especially in patients with impaired renal function. Therefore, accurate monitoring of the serum level is in such patients is mandatory. In addition, the dose serum level profile curve of tobramycin has found to be surprisingly unpredictable, both in terms of peak serum levels, and elimination half-life from plasma.

BIological PRINCIPLES OF THE PROCEDURE
The AxSYM Tobramycin assay is based on Fluorescence Polarization Immunoassay (FPIA) technology. The AxSYM Tobramycin Reagents and sample are pipetted in the following sequence:

SAMPLING CENTER
• Sample and all AxSYM Tobramycin Reagents required for one test are pipetted by the sampling probe into various wells of a Reaction Vessel (RV).

• Sample and Solution 4 (Line Diluent) are pipetted into one well of the RV.

• An aliquot of the predilution mixture, pretreatment solution and Sample 4 (Line Diluent) are transferred to the cuvette of the RV.

The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center with the processing probe.

PROCESSING CENTER
• A second aliquot of the predilution mixture is transferred to the cuvette along with the Tobramycin Antiserum (antibody) and the Tobramycin Fluorescein Tracer.

• Tobramycin from the sample and the Tobramycin Fluorescein Tracer competes for binding sites on the antibody molecule.

• The intensity of polarized fluorescent light is measured by the FPIA optical assembly.

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

REAGENTS
REAGENT PACK, 100 TESTS
AxSYM Tobramycin Reagent Pack (7A74-20)*

• 1 Bottle (14.5 mL) < 0.01% Tobramycin Fluorescein Tracer in TRIS buffer containing surfactant. Preservative: Sodium Azide. (Reagent Bottle 1)

• 1 Bottle (8.6 mL) Pretreatment Solution. Surfactant in TRIS buffer. Preservative: Sodium Azide. (Reagent Bottle 2)

• 1 Bottle (15.1 mL) < 0.01% Tobramycin Fluorescein Tracer in TRIS buffer containing surfactant. Preservative: Sodium Azide.

*7A74-99 includes an AxSYM Tobramycin Reagent Pack (100 Tests) and Reaction Vessels (100 each). 7A74-20 includes these items for international shipments.

CALIBRATORS
AxSYM Tobramycin Standard Calibrators (7A74-01)

<table>
<thead>
<tr>
<th>Bottle</th>
<th>Concentration (µg/mL)</th>
<th>Range (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(µg/mL)</td>
<td>(µg/mL)</td>
</tr>
<tr>
<td>0.00</td>
<td>6.00</td>
<td>0.00 - 6.00</td>
</tr>
<tr>
<td>0.50</td>
<td>2.00</td>
<td>1.50 - 2.50</td>
</tr>
<tr>
<td>2.00</td>
<td>8.00</td>
<td>2.00 - 8.00</td>
</tr>
<tr>
<td>4.00</td>
<td>16.00</td>
<td>1.50 - 16.00</td>
</tr>
<tr>
<td>6.00</td>
<td>24.00</td>
<td>1.50 - 24.00</td>
</tr>
</tbody>
</table>

Preservative: Sodium Azide

Abbott manufactures internal reference standards for Tobramycin using Tobramycin Reference Standard (USP Grade). Tobramycin calibrators are manufactured gravimetrically and tested against these internal reference standards.

CONTROLS
AxSYM Tobramycin Controls (7A74-10)

3 Bottles (8 mL each) of AxSYM Tobramycin Controls contain tobramycin prepared in human serum, nonreactive for HBsAg, HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2, to yield the following concentration ranges:

<table>
<thead>
<tr>
<th>Bottle</th>
<th>Concentration (µg/mL)</th>
<th>Range (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(µg/mL)</td>
<td>(µg/mL)</td>
</tr>
<tr>
<td></td>
<td>(µg/mL)</td>
<td>(µg/mL)</td>
</tr>
<tr>
<td>0.00</td>
<td>6.00</td>
<td>0.00 - 6.00</td>
</tr>
<tr>
<td>0.50</td>
<td>2.00</td>
<td>1.50 - 2.50</td>
</tr>
<tr>
<td>2.00</td>
<td>8.00</td>
<td>2.00 - 8.00</td>
</tr>
<tr>
<td>4.00</td>
<td>16.00</td>
<td>1.50 - 16.00</td>
</tr>
<tr>
<td>6.00</td>
<td>24.00</td>
<td>1.50 - 24.00</td>
</tr>
</tbody>
</table>

Preservative: Sodium Azide

The AxSYM Tobramycin reporting unit is factory set to µg/mL. An alternate unit (µmol/L) may be selected for reporting results (Assay Parameter 45).

OTHER REAGENTS
AxSYM Probe Cleaning Solution (9A35-05)

PROBE CLEANING SOLUTION - A Bottles (200 mL each) AxSYM Probe Cleaning Solution containing 2% Tetraethylammoniumhydroxide (TEAH).

Solution 4 (Line Diluent) (8A46)

SALVATION BUFFER - B Bottles (10 L) Solution 4 (Line Diluent) containing 0.1M Phosphate Buffer. Preservatives: Sodium Azide and Antimicrobial Agents.

WARNINGS AND PRECAUTIONS
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 have been tested and found to be nonreactive for HBsAg, HIV-1 Ag, anti-HCV and anti-HIV-1/HIV-2. 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. Biohazard Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

SAFETY PRECAUTIONS
• 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 have been tested and found to be nonreactive for HBsAg, HIV-1 Ag, anti-HCV and anti-HIV-1/HIV-2. 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. Biohazard Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
• The AxSYM Probe Clearing Solution (2% TEA) 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. Antisera, Fluorescent Tracer, Standard Calibrators, Controls, and Solution 4 (Line Diluent) are classified per applicable European Community (EC) Directives as: Harmful (Xn). The following are the appropriate Risk (R) and Safety (S) phrases.

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.
S35 This material and its container must be disposed of in a safe way.
S46 If swallowed, seek medical advice immediately and show the container or label.

• The Pretreatment Solution contains Sodium Azide and is classified per applicable European Community (EC) Directives as: Harmful (Xn). The following are the appropriate Risk (R) and Safety (S) phrases.

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.
R35 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S35 This material and its container must be disposed of in a safe way.
S46 If swallowed, seek medical advice immediately and show the container or label.
S61 Avoid release to the environment. Refer to special instructions/safety data sheets.

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

HANDLING PRECAUTIONS
• 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.
• AxSYM Tobramycin Reagents are susceptible to bubbles/foaming and require inspection and removal of bubbles before loading. If bubbles are present, refer to the AxSYM System Operations Manual, Section 7, for instructions on removing bubbles from reagent packs.

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 Tobramycin Reagents are light sensitive. When the AxSYM Reagent Pack is not on the AxSYM analyzer, the pack must be stored protected from light.

\[ \text{ daylight } \]

The AxSYM Tobramycin Reagent Pack, Calibrators and Controls should be stored at 2-8°C. The AxSYM Tobramycin 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 Tobramycin Reagents.

The AxSYM Tobramycin Reagent Pack may be on-board the AxSYM System for a maximum of 112 cumulative hours; for example, 14 eight hour shifts. Refer to the AxSYM System Operations Manual, Sections 2 and 5, for further information on tracking on-board hours. Reagents are stable until the expiration date when stored and handled as directed.

\[ \text{ daylight } \]

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

INSTRUMENT PROCEDURE

Assay File Installation

The AxSYM Tobramycin Assay File must be installed on the AxSYM System from one of the following software disks, prior to performing the Tobramycin assay.
• 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 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. Complete mixing of each thawed sample 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 -8°C to -70°C. Failure to freeze samples containing additional antibiotics may result in falsely low tobramycin levels due to in vitro inactivation.

• To minimize the effect of sample evaporation, all samples (patients, controls and calibrators) should be tested within 1 hour of being placed on-board the AxSYM System. Refer to the AxSYM System Operations Manual, Section 5, for a detailed discussion on-board sample storage constraints.

• Inspect all samples for bubbles. Remove bubbles prior to analysis.

• When shipped, samples must be packaged and labeled in compliance with applicable federal and international regulations covering the transport of clinical samples and serologic agents. *Relative Centrifugal Force.

SAMPLE VOLUME
The sample volume required to perform a single undiluted tobramycin 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 tobramycin test performed (ROUTINE or STAT) from the same sample container, an additional 44 µL of sample is required.

The sample cup minimum volumes for both ROUTINE and STAT tests (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 dilute the additional sample volume needed for the retest will not be displayed on the Order screen at the time the test(s) it (are) ordered. Therefore the total sample volume should include the additional 44 µL of sample. For sample volume requirements in primary or aliquot tubes, and calibrator and control requirements for multiple reagent lots, refer to the AxSYM System Operations Manual, Section 5.

To obtain the recommended volume requirements for AxSYM Tobramycin Calibrators and Controls, hold the bottles vertically and dispense 4 drops of each calibrator or control into each respective sample cup.

AxSYM TOBRAMYCIN PROCEDURE
Materials Provided
• 7A74-09 AxSYM Tobramycin Reagent Kit, containing: AxSYM Tobramycin REAGENT PAK 100 REACTION VESSELS

Materials Required But Not Provided
• 7A74-01 AxSYM Tobramycin Standard Calibrators
• 7A74-10 AxSYM Tobramycin Controls
• 8A46 SOLUTION VIALS BLENDS
• 9A56-05 AxSYM PRIME CLEANER SOLUTION SAMPLE TUBES
• Pipettor and pipette tips

CAUTION:
For optimal performance it is important to follow the routine AxSYM System Operations Manual, Section 5, if your laboratory requires more frequent maintenance, follow those procedures.

QA QUALITY CONTROL PROCEDURES
CALIBRATION
The AxSYM Tobramycin assay must be calibrated using a Standard Calibration (6-point) procedure.

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

Once the AxSYM Tobramycin 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 the 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.

Operator Verification
An acceptable Tobramycin calibration curve should meet the following criteria:

a) Polarization Error (PERR) -3.50 to +3.50 for all calibrators.
b) Root Mean Squared Error (RMSE) less than or equal to 2.00.
c) L, M and H controls are all within the acceptable ranges.

QUALITY CONTROL
The recommended control requirement for an AxSYM Tobramycin assay is a single sample of all at least two different tobramycin control levels, which span the medical decision range, tested once every 24 hours, each day of use. Controls may be placed in any 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 this package insert. Refer to the REAGENTS, CONTROLS section of this package insert for AxSYM Tobramycin Control ranges.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

When a 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, for further data. At the discretion of the laboratory, selected quality control rules may be applied to the quality control data.

RESULTS

AxSYM Tobramycin assay utilizes a Four Parameter Logistic Curve Fit method (4PLC, Y weighted) to generate a calibration curve. The curve is stored in memory and concentrations of drug in controls and unknown samples are calculated from this curve using polarization values generated.

To convert µg/mL to µmol/L, multiply the value obtained by the conversion factor of 2.14.

Flags

Some results may contain information in the Flags field. Samples flagged as low extreme values (LG), Assay Parameter #75, must be reviewed prior to reporting assay results. Results at or near the assay sensitivity should be verified prior to reporting drug concentrations. For a description of the flags that may appear in this field, refer to the AxSYM System Operations Manual, Section 2.

LIMITATIONS OF THE PROCEDURE

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

Patient samples which contain kanamycin A, kanamycin B, 3’,4’-dideoxykanamycin B or amikacin will yield falsely elevated values for tobramycin. However, these drugs are not usually coadministered with tobramycin. High concentrations of penicillin or cephalosporins have been shown to inactivate aminoglycosides on this. The degree of inactivation is dependent on the particular aminoglycoside being measured, the type and concentration of the penicillin or cephalosporin that is also present and the storage conditions of the sample.

Samples from patients receiving additional antibiotics of these types should be assayed immediately.

SAMPLE DILUTION PROCEDURES

Automated Dilution Protocol

Patient samples with tobramycin 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 5, for additional information on ordering sample dilutions.

Manual Dilution Protocol

Patient samples with tobramycin concentrations reported as greater than 40.00 µg/mL by the Automated Dilution Protocol may be diluted using a manual dilution of 1:1.0. Add one part of the patient sample to nine parts of the AxSYM Tobramycin Calibrator A. Repeat the test using this manually diluted sample. The concentration reported by the AxSYM System must be multiplied by the manual dilution factor to obtain the final sample concentration.

Final Sample Concentration = Reported Concentration x Manual Dilution Factor

Manual Dilution Factor = Volume of Sample / Volume of Dilution Reagent

EXPECTED VALUES

Strong correlations have been shown between serum levels of tobramycin and both therapeutic effect and toxicity in specific patient types. Peak serum levels of tobramycin in the range of 5 to 10 µg/mL are suggested for optimal therapeutic effectiveness. Persistent elevated peak concentrations (10 µg/mL) have been shown to cause renal and eighth cranial nerve toxicity. Nephrotoxicity 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. Tough levels offer a more discrete calculation of impending toxicity since they more closely correspond to tissue levels and are less affected by sampling errors. Slowly rising trough levels have been shown to correspond to tissue accumulation of the drug, and levels greater than 2 µg/mL have been associated with renal failure in some patients. Refer to the drug manufacturer’s package insert or the Physicians’ Desk Reference® or the literature for proper drug dosages and for tobramycin measurement sampling times.

SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION

Precision was determined as described in National Committee for Clinical Laboratory Standards (NCCLS) protocol EP-T2. Using human serum with 1.0, 4.0, and 8.0 µg/mL of tobramycin added. Results from these studies typically yielded CVs of less than 9%.

Representative data are shown in the following table.

<table>
<thead>
<tr>
<th>Target value (n=80)</th>
<th>Mean</th>
<th>SD Within Run</th>
<th>SD Between Day</th>
<th>CV Total</th>
<th>CV Between Day (%)</th>
<th>CV Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>0.86</td>
<td>0.02</td>
<td>0.11</td>
<td>10.00</td>
<td>5.0</td>
<td>10.00</td>
</tr>
<tr>
<td>4.0</td>
<td>3.0</td>
<td>0.03</td>
<td>0.28</td>
<td>18.6</td>
<td>5.0</td>
<td>18.6</td>
</tr>
<tr>
<td>8.0</td>
<td>5.0</td>
<td>0.04</td>
<td>0.31</td>
<td>13.8</td>
<td>5.0</td>
<td>13.8</td>
</tr>
</tbody>
</table>

ACCURACY BY RECOVERY

Recovery was determined by adding tobramycin to human serum and to buffer at concentrations of 0.75, 1.25, 2.5, 4.0, 5.0, 7.0 and 8.0 µg/mL. The concentration of tobramycin was determined using the AxSYM Tobramycin assay, and the resulting % recovery was calculated according to the following equation:

% Recovery = (sample concentration / added concentration) x 100

Representative data are shown in the following table.

<table>
<thead>
<tr>
<th>Added Concentration (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>0.75</td>
<td>0.84</td>
<td>0.84</td>
<td>100.0</td>
</tr>
<tr>
<td>1.25</td>
<td>1.34</td>
<td>1.13</td>
<td>118.6</td>
</tr>
<tr>
<td>2.5</td>
<td>2.33</td>
<td>2.32</td>
<td>100.0</td>
</tr>
<tr>
<td>4.0</td>
<td>3.85</td>
<td>3.79</td>
<td>101.6</td>
</tr>
<tr>
<td>5.0</td>
<td>4.73</td>
<td>4.92</td>
<td>96.1</td>
</tr>
<tr>
<td>7.0</td>
<td>6.75</td>
<td>6.40</td>
<td>105.5</td>
</tr>
<tr>
<td>8.0</td>
<td>8.35</td>
<td>8.19</td>
<td>102.0</td>
</tr>
</tbody>
</table>

Average Recovery: 105.3 +/− 2%

Sensitivity

The sensitivity of the AxSYM Tobramycin assay was calculated to be 0.18 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 concern over potential interference with the Tobramycin assay.

The aminoglycosides, kanamycin, dibekacin, and amikacin cross-react with the Tobramycin assay due to their structural similarity. Therefore, the results of this assay cannot be used to accurately quantify tobramycin serum or plasma levels in patients using these antibiotics separately or in combination with tobramycin. Other antibiotics, netilmicin, gentamicin, and vancomycin were tested in the Tobramycin assay at levels beyond their respective therapeutic ranges; none of these compounds registered values above the sensitivity of the Tobramycin assay.
The compounds listed below, added to human serum, resulted in less than 10% error in detecting added drug when assayed with the AxSYM Tobramycin assay.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration tested</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL</td>
<td>&lt;10% Error</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1.0 g/dL</td>
<td>&lt;10% Error</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>1100 mg/dL</td>
<td>&lt;10% Error</td>
</tr>
<tr>
<td>Total Protein</td>
<td>2.0 - 10.0 g/dL</td>
<td>&lt;10% Error</td>
</tr>
</tbody>
</table>

ACCURACY BY CORRELATION

The Abbott AxSYM Tobramycin assay was compared to a Fluorescence Polarization Immunoassay. The results of the specimen testing follow.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Number of Observations</th>
<th>Intercept</th>
<th>Slope</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott AxSYM</td>
<td>104</td>
<td>0.04</td>
<td>0.94</td>
<td>0.992</td>
</tr>
<tr>
<td>vs. TDx®/TDxFLx</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sample Range (AxSYM): 0.18 - 13.67 µg/mL.

AxSYM and TDx/TDxFLx are registered trademarks of Abbott Laboratories, Abbott Park, IL 60064 USA.

BIBLIOGRAPHY


RELATED READING


Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064 USA

May, 2003