This package insert must be read carefully before product 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

<table>
<thead>
<tr>
<th>Symbol</th>
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<td>Control Number</td>
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See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT/Vancomycin

INTENDED USE
The ARCHITECT/Vancomycin assay is an in vitro chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of vancomycin in human serum or plasma on the ARCHITECT System with STAT protocol capability. The ARCHITECT/ Vancomycin assay is used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to help ensure appropriate therapy.

SUMMARY AND EXPLANATION OF TEST
Vancomycin hydrochloride is a tricyclic glycopeptide derived from Amycolatopsis orientalis.1 It is commonly used in the treatment of methicillin-resistant Staphylococcus aureus infections.2 This glycopeptide inhibits the growth of the bacterium by intervening in the cell wall synthesis, thereby killing the bacterium. Extensive review articles have been published which fully examine vancomycin’s effectiveness and pharmacokinetics.1,3 Vancomycin is absorbed minimally from the gastrointestinal tract. In the first 24 hours after intravenous dosing, the usual route of administration, about 90% of the vancomycin is excreted unchanged by the kidneys. The average half-life in patients with normal renal function is about 6 hours. Vancomycin is approximately 55% bound to plasma proteins. Therapeutic serum levels vary depending on the microorganism involved and the patient’s tolerance to the drug.4,5 Vancomycin serum or plasma concentrations are monitored to guide therapy, since individual patient differences require dose changes that are difficult to predict. Monitoring serum or plasma levels of vancomycin decreases the frequency of serious toxic effects.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT/ Vancomycin assay is a one-step STAT immunoassay for the quantitative measurement of vancomycin in human serum or plasma using CMIA technology, with flexible assay protocols, referred to as Chemiflex. Sample, anti-vancomycin coated paramagnetic microparticles, and vancomycin acridinium-labeled conjugate are combined to create a reaction mixture. The anti-vancomycin coated microparticles bind to vancomycin present in the sample and to the vancomycin acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction mixture contains the vancomycin present in the sample and to the vancomycin acridinium-labeled conjugate. This product requires the handling of human specimens.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials are considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.6 Biosafety Level 27 or other appropriate biosafety practices8,9 should be used for materials that contain or are suspected of containing infectious agents.

WARRANTS AND PRECAUTIONS
For In Vitro Diagnostic Use.

Safety Precautions

• CAUTION: This product contains the following hazardous substances:
  - Irritant and sensitizing: Tris buffer.
  - Irritant and sensitizing: Sodium hydroxide.

Handling Precautions

• Do not use reagent kits beyond the expiration date.
• Do not pool reagents within a kit or between reagent kits.
• Before loading the ARCHITECT/Vancomycin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
• Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.
• To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
• Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
• Over time, residual liquids may dry on the septum surface. These are typically dried salts, which have no effect on assay efficacy.

Other Reagents

ARCHITECT/Pre-Trigger Solution
- **Pre-Trigger Solution** containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT/Trigger Solution
- **Trigger Solution** containing 0.35 N sodium hydroxide.

ARCHITECT/Wash Buffer
- **Wash Buffer** containing phosphate buffered saline solution. Preservative: antimicrobial agent.
Storage Instructions
- Store at 2–8°C in an upright position and may be used immediately after removal from 2–8°C storage.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT Vancomycin Reagent Kit may be stored on board the ARCHITECT i System with STAT protocol capability for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT i System. If reagents are removed from the system, store them at 2–8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.
- After reagents are removed from the system, initiate a scan to update the onboard stability timer.

Indications of Reagent Deterioration
When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE
- The ARCHITECT iVancomycin assay file must be installed on the ARCHITECT i System with STAT protocol capability from the ARCHITECT i Assay CD-ROM Addition E prior to performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT iVancomycin assay is μg/mL. Alternate result units, μmol/L or mg/L, may be selected for reporting results by editing assay parameter “Result concentration units” to μmol/L or mg/L. The conversion formulas used by the system are as follows:
  - Conversion Formula: (Concentration in μg/mL) x (0.69) = μmol/L
  - Conversion Formula: (Concentration in μg/mL) x (1.00) = mg/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS
Specimen Types
The specimen collection tubes listed below were verified to be used with the ARCHITECT i Vancomycin assay. Other specimen collection tubes, including gel separation tubes, have not been tested with this assay.
- Human serum
- Human plasma collected in:
  - lithium heparin
  - potassium EDTA
  - sodium citrate
- Plasma samples from different anticoagulant tube types should not be used interchangeably for monitoring vancomycin. Use of citrate should be performed only when the blood is collected in a full tube so as not to incur a dilution effect.
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The ARCHITECT i System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the ARCHITECT i Vancomycin assay.

Specimen Conditions
- Do not use specimens with the following conditions:
  - heat-inactivated specimens
  - grossly hemolyzed
  - obvious microbial contamination
  - cadaver specimens or body fluids other than human serum or plasma
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Preparation for Analysis
- Follow the tube manufacturer’s processing instructions for serum and plasma collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged before testing if
  - they contain fibrin, red blood cells, or other particulate matter, or
  - they were frozen and thawed.
- Transfer clarified specimen to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.

Storage
- Specimens may be stored on or off the clot or red blood cells for up to three days at room temperature. Specimens removed from the clot or red blood cells may be stored up to eight days at 2–8°C.
- Serum or plasma specimens can be stored up to one month at -20°C or colder.

Shipping
- Before shipping specimens, it is recommended that specimens be removed from the clot or red blood cells.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped at room temperature or on wet or dry ice. Do not exceed the storage limitations listed above.

PROCEDURE
Materials Provided
- 1P30 ARCHITECT i Vancomycin Reagent Kit

Materials Required but not Provided
- ARCHITECT i System with STAT protocol capability
- 1L66 ARCHITECT i ASSAY CD-ROM - WW (excluding US) - Addition E
- 1L65 ARCHITECT i ASSAY CD-ROM - US - Addition E
- 1P30-01 ARCHITECT i Vancomycin Calibrators
- 8E20-10 Abbott Immunoassay-MCC (Liquid) or other commercial controls
Assay Procedure

Before loading the ARCHITECT /Vancomycin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.

- Invert the microparticle bottle 30 times.
- Visually inspect the bottle to ensure microparticles are resuspended. If microparticles remain adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
- If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.
- Once the microparticles have been resuspended, place a septum on the bottle. For instructions on placing septums on bottles refer to the Handling Precautions section of this package insert.
- Load the ARCHITECT /Vancomycin Reagent Kit on the ARCHITECT System with STAT protocol capability.
- Verify that all necessary assay reagents are present.
- Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
- For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
- For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- The minimum sample volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be printed on the Orderlist report. No more than 10 replicates may be run on board.
- ≤3 hours on board: 150 μL for the first ARCHITECT /Vancomycin test plus 20 μL for each additional ARCHITECT /Vancomycin test from the same sample cup.
- ≤ 3 hours on board: 150 μL for the first ARCHITECT /Vancomycin test plus 20 μL for each additional ARCHITECT /Vancomycin test from the same sample cup.
- If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.

Prepare calibrators and controls.

- ARCHITECT /Vancomycin Calibrators and controls should be prepared according to their respective package inserts.
- To obtain the recommended volume requirements for the ARCHITECT /Vancomycin Calibrators, hold the bottles vertically and dispense 5 drops of each calibrator into each respective sample cup. Dispense 150 μL of each control into each respective sample cup.
- Load samples.
- For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.

Specimen Dilution Procedures

Specimens with vancomycin values exceeding 100.00 μg/mL are flagged with the code “>100.00” and may be diluted with the Manual Dilution Procedure.

- Manual dilutions should be performed as follows:
  - The suggested dilution for a vancomycin test is 1:2.
  - Add 100 μL of the patient specimen to 100 μL of ARCHITECT /Vancomycin Calibrator A or ARCHITECT /Multi-Assay Manual Diluent.
  - The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution. This will be the reported result. The dilution should be performed so that the diluted result (before the dilution factor is applied) reads greater than 2.0 μg/mL.
  - For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT /Vancomycin calibration, test calibrators A, B, C, D, E, and F in duplicate. A single sample of each vancomycin control level must be tested to evaluate the assay calibration. Ensure that assay control values are within established ranges. Calibrators should be priority loaded.
- Calibration Range: 0.0 - 100.0 μg/mL.
- Once an ARCHITECT /Vancomycin calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used.
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT /Vancomycin assay is that a single sample of each control level be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

Each laboratory should establish control ranges to monitor the acceptable performance of the assay. If a control is out of its specified range, the associated test results are invalid and must be retested. Recalibration may be indicated.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT /Vancomycin assay belongs to method group 1.

Use ARCHITECT /Vancomycin Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.

RESULTS Calculation

The ARCHITECT /Vancomycin assay uses a 4 Parameter Logistic Curve Fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

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 ARCHITECT System Operations Manual, Section 5.
Measurement Range (Reportable Range)
The measurement range of the ARCHITECT /Vancomycin assay is 0.24 μg/mL to 100.00 μg/mL.

LIMITATIONS OF THE PROCEDURE
- If the ARCHITECT /Vancomycin assay results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Plasma samples from different anticoagulant tube types should not be used interchangeably for monitoring vancomycin. Use of citrate should be performed only when the blood is collected in a full tube so as not to incur a dilution effect.
- 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 that employ mouse monoclonal antibodies.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. The presence of heterophilic antibodies in a patient specimen may cause anomalous values to be observed. Additional information may be required for diagnosis.

EXPECTED VALUES
Strong correlations have been shown between serum levels of vancomycin for both therapeutic and toxic effects. Therapeutic peak serum levels of 20 to 40 μg/mL and trough levels of 5 to 10 μg/mL have been reported to be effective for most strains of staphylococci and streptococci. However, therapeutic levels of vancomycin must be individually established based on patient differences and bacterial susceptibility. The risk of toxicity is appreciably increased by high concentration or prolonged therapy in patients with renal insufficiency. Toxic effects, such as ototoxicity and nephrotoxicity, have resulted when serum concentrations of vancomycin reach 80 to 100 μg/mL and are rarely seen when serum levels are maintained below 30 μg/mL. If an aminoglycoside is being used concurrently, the potential for toxicity is additive.

For diagnostic purposes, the test findings should always be assessed in conjunction with the patient’s medical history, clinical examinations, and other findings.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision
The ARCHITECT /Vancomycin assay is designed to have an assay precision of ≤10% total CV. A linearity study was performed by diluting five pooled serum samples with the ARCHITECT /Vancomycin Calibrator A and the ARCHITECT /Multi-Assay Diluent. The concentration of vancomycin was determined using the ARCHITECT /Vancomycin assay and the resulting percent recovery was calculated.

Recovery
The ARCHITECT /Vancomycin assay is designed to have a mean recovery of 100 ± 10%.

A study was performed on five pooled serum samples, where vancomycin was spiked into the samples to target concentrations of 0, 10, 20, 30, 40, and 50 μg/mL. The concentration of vancomycin was determined using the ARCHITECT /Vancomycin assay and the resulting percent recovery was calculated. The percent recovery of the ARCHITECT /Vancomycin assay ranged from 94.2 to 108.3 with a mean of 100.0%.

* Representative data; results in individual laboratories may vary from these data.

**Linearity**
The ARCHITECT /Vancomycin assay is designed to have a mean recovery of 100 ± 10% of the expected results for the diluted samples. A linearity study was performed by diluting five pooled serum samples with the ARCHITECT /Vancomycin Calibrator A and the ARCHITECT /Multi-Assay Diluent. The concentration of vancomycin was determined using the ARCHITECT /Vancomycin assay and the resulting percent recovery was calculated.

<table>
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<tr>
<th>Specimen</th>
<th>Dilution Factor</th>
<th>Mean Observed Concentration (μg/mL)</th>
<th>% Recovery</th>
<th>Mean Observed Concentration (μg/mL)</th>
<th>% Recovery</th>
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<td>27.6</td>
<td>108</td>
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</tbody>
</table>

* % Recovery = Mean Observed Diluted Concentration (μg/mL) x Dilution Factor Mean Observed Undiluted Concentration (μg/mL) x 100

* * Representative data; results in individual laboratories may vary from these data.

Sensitivity
Sensitivity is defined as the limit of detection (LoD). The ARCHITECT /Vancomycin assay is designed to have a LoD of ≤ 2.0 μg/mL. The limit of blank (LoB) and LoD of the ARCHITECT /Vancomycin assay were determined based on guidance from the CLSI Protocol EP17-A using proportions of false positives (α) less than 5% and false negatives (β) less than 5%. These determinations were performed using one blank (60 replicates) and four low level vancomycin samples (15 replicates each); LoB = 0.12 μg/mL and LoD = 0.24 μg/mL.

* * Representative data; results in individual laboratories may vary from these data.
Specificity

Cross-reactivity was tested for compounds whose chemical structure or concurrent usage could cause potential interference with the ARCHITECT Vancomycin assay. A study has demonstrated that vancomycin crystalline degradation product 1 (CDP-1) at a concentration of 50 μg/mL has cross-reactivity less than 0.24 μg/mL in the absence of vancomycin. When CDP-1 is tested in the presence of vancomycin, at the same indicated concentration (50 μg/mL), the change in vancomycin measured is less than the designed LoD of the assay. CDP-1 may accumulate in patients with impaired renal function.\(^{17,18}\)

The following compounds were tested in the absence of vancomycin after adding 500 μg/mL of each compound (except Methotrexate and CDP-1) to human serum. Methotrexate was tested at 227 μg/mL. Cross-reactivity of each compound was less than 0.24 μg/mL.\(^a\)

<table>
<thead>
<tr>
<th>Compounds Tested</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Isoniazid</td>
</tr>
<tr>
<td>Amikacin</td>
<td>Kanamycin B</td>
</tr>
<tr>
<td>Amphotericin B</td>
<td>Methotrexate</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Methylprednisolone</td>
</tr>
<tr>
<td>Caffeine</td>
<td>Naproxen</td>
</tr>
<tr>
<td>CDP-1</td>
<td>Neomycin</td>
</tr>
<tr>
<td>Cephalaxin</td>
<td>Nitrofurantoin</td>
</tr>
<tr>
<td>Cephalexin</td>
<td>Nitrofurantoin</td>
</tr>
<tr>
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<td>Penicillin G</td>
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<td>Cephalothin</td>
<td>Penicillin V</td>
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<td>Hydrochlorothiazide</td>
<td>Trimethoprim</td>
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<tr>
<td>Ibuprofen</td>
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</tr>
</tbody>
</table>

\(^a\) Cross-reactivity = Observed Test Concentration (μg/mL) – Control Concentration (μg/mL)

Potential Interference

Potential interference in the ARCHITECT Vancomycin assay from the following compounds is designed to have a mean recovery of 100 ± 10% of the control results at the levels indicated. A study based on guidance from the CLSI Protocol EP7-A2\(^{19}\) was performed for the ARCHITECT Vancomycin assay. Serum specimens with vancomycin levels from 4.3 to 83.7 μg/mL were supplemented with the following potentially interfering compounds. The mean recovery observed during the study ranged from 98.9% to 106.6%.\(^*\)

<table>
<thead>
<tr>
<th>Potentially Interfering Compound</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triglycerides</td>
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</tr>
<tr>
<td>Hemoglobin</td>
<td>500 mg/dL</td>
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<tr>
<td>Bilirubin</td>
<td>20 mg/dL</td>
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<tr>
<td>Low Protein</td>
<td>3 g/dL</td>
</tr>
<tr>
<td>High Protein</td>
<td>10 g/dL</td>
</tr>
<tr>
<td>HAMA</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>Rheumatoid Factor</td>
<td>500 IU/mL</td>
</tr>
</tbody>
</table>

\(^*\) Representative data; results in individual laboratories may vary from these data.

Method Comparison

The ARCHITECT Vancomycin assay is designed to have a slope of 1.0 ± 0.15 and a correlation coefficient (r) of ≥ 0.93 for serum samples when compared to AxSYM Vancomycin II. Data from this study were analyzed using the Passing-Bablok regression method and are summarized in the following table.\(^*\)

<table>
<thead>
<tr>
<th>ARCHITECT Vancomycin vs. AxSYM Vancomycin II</th>
<th>Number of Observations</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>Correlation Coefficient (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>192</td>
<td>0.925 (0.912-0.938)</td>
<td>0.050 (-0.117-0.251)</td>
<td>0.996 (0.995-0.997)</td>
</tr>
</tbody>
</table>

Specimen Range (ARCHITECT) = 1.4 μg/mL to 83.5 μg/mL
Specimen Range (AxSYM) = 2.1 μg/mL to 94.3 μg/mL

\(a\) A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.\(^{20}\)

\(b\) Confidence Interval (CI)

\(^*\) Representative data; results in individual laboratories may vary from these data.

A bias analysis of ARCHITECT Vancomycin vs. AxSYM Vancomycin II was performed on the same 192 specimens in the range of 2.1 to 94.3 μg/mL. The following representative data are provided to aid in understanding the difference between the two assays. The average bias exhibited by ARCHITECT vs. AxSYM in this study was -7.29%. The 95% confidence interval of that average bias is -23.40 to 8.82%. Within the typical therapeutic range of vancomycin therapy (5 to 40 μg/mL, as read in the AxSYM), the average bias was -4.41% with a 95% confidence interval of -19.51 to 10.70%. Results of the study are summarized below.\(^*\) The vertical lines depict the typical therapeutic range of vancomycin therapy.
**ARCHITECT / Vancomycin % Bias to AxSYM**

Vancomycin II

* Representative data; results in individual laboratories may vary from these data.

**BIBLIOGRAPHY**


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