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

- **REF** List Number
- **IVD** In Vitro Diagnostic Medical Device
- **LOT** Lot Number
- **8°C** Store at 2-8°C
- **2°C**
- **i** Consult instructions for use
- **SN** Serial Number
- **Manufacturer**
- **REACTION VESSELS** Reaction Vessels
- **SAMPLE CUPS** Sample Cups
- **SEPTUM** Septum
- **REPLACEMENT CAPS** Replacement Caps
- **REAGENT LOT** Reagent Lot
- **ASSAY CD-ROM** Assay CD-ROM
- **CONTROL NO.** Control Number

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT i/Theophylline

INTENDED USE
The ARCHITECT i/Theophylline assay is an in vitro chemiluminescent microparticle immunoassay (CMA) for the quantitative measurement of theophylline in human serum or plasma on the ARCHITECT i System with STAT protocol capability. Theophylline is used in the treatment of bronchospasm associated with bronchial asthma, chronic bronchitis and pulmonary emphysema. The measurements obtained are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to help ensure appropriate therapy.

SUMMARY AND EXPLANATION OF TEST
Theophylline (1,3-dimethylxanthine) is a naturally occurring compound with bronchodilator effects that is used in the treatment of asthma.1,2 Because of the narrow therapeutic index3 and the wide interindividual variability in the rate of theophylline metabolism and clearance,4 virtually every patient receiving theophylline should have serum concentrations monitored.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT i/Theophylline assay is a one-step STAT immunoassay for the quantitative determination of theophylline in human serum or plasma using CMIA technology, with flexible assay protocols, referred to as Chemiflex. Sample, anti-theophylline coated paramagnetic microparticles, and theophylline acridinium-labeled conjugate are combined to create a reaction mixture. The anti-theophylline coated microparticles bind to theophylline present in the sample and to the theophylline acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of theophylline in the sample and the RLUs detected by the ARCHITECT i System optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS
Reagent Kit, 100 Tests
NOTE: Some kit sizes are not available in all countries; please contact your local distributor.
ARCHITECT i/Theophylline Reagent Kit (1P29)
- MICROPARTICLES 1 Bottle (6.6 mL) Anti-theophylline (mouse, monoclonal) coated goat anti-mouse (GAM) microparticles in TRIS buffer with protein (bovine) stabilizer. Preservative: ProClin 300.
- CONJUGATE 1 Bottle (5.9 mL) Theophylline acridinium-labeled conjugate in MES buffer with surfactant. Minimum concentration: 8 ng/mL. Preservative: ProClin 300.

Other Reagents
ARCHITECT i/Pre-Trigger Solution
- PRE-TRIGGER SOLUTION Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.
- TRIGGER SOLUTION Trigger Solution containing 0.35 N sodium hydroxide.
ARCHITECT i/Wash Buffer
- WASHER BUFFER Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agent.

WARNINGS AND PRECAUTIONS
For In Vitro Diagnostic Use.

Safety Precautions
- 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.5 Biosafety Level 26 or other appropriate biosafety practices7,8 should be used for materials that contain or are suspected of containing infectious agents.

- All components contain methylisothiazolones, which are components of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.
  - R43 May cause sensitization by skin contact.
  - S24 Avoid contact with skin.
  - S35 This material and its container must be disposed of in a safe way.
  - S37 Wear suitable gloves.
  - S46 If swallowed, seek medical advice immediately and show this container or label.

- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.

Handling Precautions
- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between reagent kits.
- Before loading the ARCHITECT i/Theophylline 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.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions
- 2-8°C The ARCHITECT i/Theophylline Reagent Kit must be stored 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 i/Theophylline 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 iTheophylline 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 i Theophylline 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 (5.55) = 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 Theophylline assay. Other specimen collection tubes, including gel separation tubes, have not been tested with this assay.
• Human serum
• Human plasma collected in:
  • lithium heparin
  • sodium fluoride/potassium oxalate
  • potassium EDTA
  • sodium heparin
  • sodium citrate
• 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 Theophylline 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 two 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 three months at -20°C or colder.9

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
• 1P29 ARCHITECT i Theophylline 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
• 1P29-01 ARCHITECT i Theophylline Calibrators
• 6E20-10 Abbott Immunoassay-MCC (Liquid) or other commercial controls
• ARCHITECT i PRE-TRIGGER SOLUTION
• ARCHITECT i TRIGGER SOLUTION
• ARCHITECT i WASH BUFFER
• ARCHITECT i REACTION VESSELS
• ARCHITECT i SAMPLE CUPS
• ARCHITECT i SEPTUM
• ARCHITECT i REPLACEMENT CAPS
• Pipettes or pipette tips (optional)

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure
• Before loading the ARCHITECT i Theophylline 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 i Theophylline Reagent Kit on the ARCHITECT i 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 sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
  • Priority: 70 μL for the first ARCHITECT /Theophylline test plus 20 μL for each additional ARCHITECT /Theophylline test from the same sample cup.
  • ≤ 3 hours on board: 150 μL for the first ARCHITECT /Theophylline test plus 20 μL for each additional ARCHITECT /Theophylline 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 /Theophylline Calibrators and controls should be prepared according to their respective package inserts.
  • To obtain the recommended volume requirements for the ARCHITECT /Theophylline 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.
  • Press RUN.
  • For additional information on principles of operation, refer to the ARCHITECT Operations Manual, Section 3.
  • For optimal performance, it is important to follow the routine maintenance procedures defined in the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.
 Specimen Dilution Procedures
Specimens with a theophylline value exceeding 40.0 μg/mL are flagged with the code ">40.0." and may be diluted with the Manual Dilution Procedure.
  • Manual dilutions should be performed as follows:
    • The suggested dilution for a theophylline test is 1:2.
    • Add 100 μL of the patient specimen to 100 μL of ARCHITECT /Theophylline Calibrator A.
    • 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.
  • For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.
Calibration
  • To perform an ARCHITECT /Theophylline calibration, test Calibrators A, B, C, D, E, and F in duplicate. A single sample of each theophylline 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 - 40.0 μg/mL.
  • Once an ARCHITECT /Theophylline 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 /Theophylline 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 /Theophylline assay belongs to method group 1.
Use ARCHITECT /Theophylline Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.

RESULTS
Calculation
The ARCHITECT /Theophylline 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 for the ARCHITECT /Theophylline assay is 0.05 μg/mL to 40 μg/mL.

LIMITATIONS OF THE PROCEDURE
  • If the ARCHITECT /Theophylline 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.
  • 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. Some immunoassays may cross-react with metabolites, which can lead to a positive bias in patient results. Refer to the following Specificity section for estimates of cross-reactivity of ARCHITECT /Theophylline to some metabolites of theophylline.
  • 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 theophylline serum levels for both therapeutic and toxic effects. In most patients, theophylline serum concentrations of 10 to 20 μg/mL effectively suppress chronic asthmatic and other bronchospastic symptoms. Serum concentrations of 5 to 10 μg/mL theophylline reportedly control apneic spells in neonates without causing apparent side effects. Peak concentrations above 20 μg/mL are often associated with toxicity. Adverse effects associated with serum concentrations above 20 μg/mL include nausea, headache, diarrhea, and at higher levels, vomiting, gastrointestinal bleeding, seizures and cardiac arrhythmias. Refer to the drug manufacturer’s package insert or the Physicians’ Desk Reference (PDR) for proper drug dosage and for theophylline measurement sampling time.
For effective treatment, some patients may require theophylline levels outside these ranges. Therefore, this information is provided only as a guide, and individual patient results should be interpreted in light of other clinical signs and symptoms.

SPECIFIC PERFORMANCE CHARACTERISTICS
Precision
The ARCHITECT /Theophylline assay is designed to have an assay precision of ≤ 10% total CV. A study was performed with guidance from the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol EPS-A2. Theophylline assay results are consistent with expected values in a variety of patient populations. Theophylline assay results are comparable to results obtained using immunoassays. Theophylline assay results are consistent with expected values in a variety of patient populations.
The ARCHITECT Theophylline assay is designed to have a mean recovery of 100 ± 10%. A study was performed on five pooled serum samples, where theophylline was spiked into the samples to target concentrations of 0, 5, 10, 20, and 30 μg/mL. The concentration of theophylline was determined using the ARCHITECT Theophylline assay and the resulting percent recovery was calculated. The percent recovery of the ARCHITECT Theophylline assay ranged from 94.3% to 104.6% with a mean of 99.4%.*

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

### Recovery
The ARCHITECT Theophylline assay was determined by spiking each compound into human serum specimens. Cross-reactivity with the compounds listed in the following table.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (μg/mL)</th>
<th>Cross-reactivity Concentration (μg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeine</td>
<td>10</td>
<td>0.1</td>
</tr>
<tr>
<td>8-Chlorotheophylline</td>
<td>10</td>
<td>0.1</td>
</tr>
<tr>
<td>1,3-Dimethyl uric acid</td>
<td>100</td>
<td>0.6</td>
</tr>
<tr>
<td>Dyphylline</td>
<td>100</td>
<td>0.5</td>
</tr>
<tr>
<td>1-Methyl uric acid</td>
<td>100</td>
<td>0.0</td>
</tr>
<tr>
<td>1-Methylxanthine</td>
<td>40</td>
<td>1.2b</td>
</tr>
<tr>
<td>Theobromine</td>
<td>100</td>
<td>0.1</td>
</tr>
<tr>
<td>Paraxanthine</td>
<td>50</td>
<td>0.1</td>
</tr>
<tr>
<td>3-Methylxanthine</td>
<td>8</td>
<td>1.3b</td>
</tr>
</tbody>
</table>

* Additional testing was performed with 1-Methylxanthine and 3-Methylxanthine. In this study, samples containing theophylline (7 and 28 μg/mL) were spiked with 40 μg/mL of 1-Methylxanthine or 8 μg/mL 3-Methylxanthine and tested with the ARCHITECT Theophylline assay. Results showed a mean recovery of 114.4% and 109.8%, respectively.

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

### Interference
Potential interference in the ARCHITECT Theophylline assay from the following compounds is designed to have a mean recovery of 100 ± 10% of the control results at the levels indicated.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (μg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triglycerides</td>
<td>2000 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>500 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL</td>
</tr>
<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>

* Additional testing was performed with 1-Methylxanthine and 3-Methylxanthine. In this study, samples containing theophylline (7 and 28 μg/mL) were spiked with 40 μg/mL of 1-Methylxanthine or 8 μg/mL 3-Methylxanthine and tested with the ARCHITECT Theophylline assay. Serum specimens with theophylline levels from 2.7 to 34.4 μg/mL were supplemented with the following potentially interfering compounds. The mean recovery observed during the study ranged from 94.2% to 102.4%.*

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

### Linearity
The ARCHITECT Theophylline assay was determined by spiking each compound into human serum specimens. Cross-reactivity data are summarized in the following table.*

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Dilution Factor</th>
<th>Observed Concentration (μg/mL)</th>
<th>% Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Undiluted</td>
<td>11.3</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>1:1.25</td>
<td>9.5</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td>1:2.00</td>
<td>5.8</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>1:3.33</td>
<td>3.4</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>Undiluted</td>
<td>16.2</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>1:1.25</td>
<td>12.4</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>1:2.00</td>
<td>8.0</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:3.33</td>
<td>4.9</td>
<td>101</td>
</tr>
<tr>
<td>3</td>
<td>Undiluted</td>
<td>18.5</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>1:1.25</td>
<td>15.6</td>
<td>105</td>
</tr>
<tr>
<td></td>
<td>1:2.00</td>
<td>9.5</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>1:3.33</td>
<td>5.8</td>
<td>104</td>
</tr>
<tr>
<td>4</td>
<td>Undiluted</td>
<td>31.2</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>1:1.25</td>
<td>25.5</td>
<td>102</td>
</tr>
<tr>
<td></td>
<td>1:2.00</td>
<td>15.4</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:3.33</td>
<td>9.6</td>
<td>102</td>
</tr>
<tr>
<td>5</td>
<td>Undiluted</td>
<td>34.5</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>1:1.25</td>
<td>29.9</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>1:2.00</td>
<td>17.5</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>1:3.33</td>
<td>10.9</td>
<td>105</td>
</tr>
</tbody>
</table>

* % Recovery = \( \frac{\text{Observed Diluted Concentration (μg/mL)} \times \text{Dilution Factor}}{\text{Observed Undiluted Concentration (μg/mL)}} \) x 100

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

The ARCHITECT® Theophylline assay is designed to have a slope of 1.0 ± 0.1 and a correlation coefficient (r) of ≥ 0.93 for serum samples when compared to AxSYM Theophylline II. Data from this study were analyzed using the Passing-Bablok method and are summarized in the following table and graph.*

**ARCHITECT® Theophylline vs AxSYM Theophylline II**

<table>
<thead>
<tr>
<th>Number of Observations</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>198</td>
<td>0.992</td>
<td>0.084</td>
<td>0.994</td>
</tr>
<tr>
<td></td>
<td>(0.975-1.009)</td>
<td>(-0.114-0.220)</td>
<td>(0.992-0.995)</td>
</tr>
</tbody>
</table>

Specimen Range (ARCHITECT®) = 1.4 μg/mL to 37.6 μg/mL
Specimen Range (AxSYM) = 1.4 μg/mL to 39.5 μg/mL

* A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.20

* Confidence Interval (CI)

A bias analysis of ARCHITECT® Theophylline vs AxSYM Theophylline II was performed on the same 198 Method Comparison specimens. The average percent bias exhibited by ARCHITECT vs AxSYM in this study was 1.05%. The 95% confidence interval of the average percent bias is −13.32% to 15.43%. Results of the study are summarized below.*

**ARCHITECT® Theophylline % Bias to AxSYM Theophylline**

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

**BIBLIOGRAPHY**
