Total T<sub>3</sub>

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

- **REF**: List Number
- **IVD**: In Vitro Diagnostic Medical Device
- **LOT**: Lot Number
- **Expiration Date**: Expiration Date
- **Store at 2-8°C**: Store at 2-8°C
- **Consult instructions for use**: Consult instructions for use
- **Manufacturer**: Manufacturer
- **REACTION VESSELS**: Reaction Vessels
- **SAMPLE CUPS**: Sample Cups
- **SEPTUM**: Septum
- **REPLACEMENT CAPS**: Replacement Caps
- **REAGENT LOT**: Reagent Lot
- **CONTROL NO.**: Control Number
- **SN**: Serial Number
- **WARNING; SENSITIZER**: Warning: May cause an allergic reaction

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT Total T3

INTENDED USE
The ARCHITECT Total T3 (TT3) assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of total triiodothyronine (Total T3) in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST
3,5,3' Triiodothyronine (T3) is a thyroid hormone with a molecular weight of 651 daltons and a half-life in serum of 1.5 days. T3 circulates in the blood as an equilibrium mixture of free and protein bound hormone. T3 is bound to thyroxine binding globulin (TBG), prealbumin, and albumin. The actual distribution of T3 among these binding proteins is controversial as estimates range from 38-80% for TBG, 9-27% for prealbumin, and 11-35% for albumin. The binding of these proteins is such that only 0.2-0.4% of the total T3 is present in solution as unbound or free T3. This free fraction represents the physiologically active thyroid hormone.

It has become apparent in recent years that T3 plays an important role in the maintenance of the euthyroid state. Serum T3 measurements can be a valuable component of a thyroid screening panel in diagnosing certain disorders of thyroid function as well as conditions caused by iodine deficiency. Clinically, measurements of serum T3 concentration are especially valuable in diagnosing hyperthyroidism and in following the course of therapy for this disorder. Under conditions of strong thyroid stimulation, the T3 measurement provides a good estimation of thyroid reserve. Recognition of a thyroid dysfunction called T3-thyrotoxicosis, associated with an increased serum T3 level but normal thyroxine (T4), free T4, and in vitro uptake results have further highlighted the importance of serum T3 measurements.

Dietary iodine deficiency results in inadequate production of thyroid hormones despite the presence of normal thyroid tissue. In these cases, the serum T4 concentration is often low while the thyroid stimulating hormone (TSH) concentration is elevated. Elevated TSH associated with low T4 is normally indicative of hypothyroidism. However, in iodine deficiency, these results together with normal or slightly elevated serum T3 are indicative of euthyroid status in most individuals. T3 levels are also affected by conditions which affect TBG concentration.

Slightly elevated T3 levels may occur in pregnancy or during estrogen therapy, while depressed levels may occur during severe illness, malnutrition, in renal failure and during therapy with anti-thyroid drugs, propranolol and propylthiouracil and salicylates. In patients with severe or chronic illnesses, many abnormalities of thyroid hormone balance occur. T4 production and the extent of serum thyroid hormone binding may be independently abnormal, resulting in a low, normal or high free T4 estimate. Serum T3 concentrations are often low; TSH levels may be normal or slightly elevated. Total T3 measurements may be valuable when hyperthyroidism is suspected and the free T4 estimate is normal.

The ARCHITECT Total T3 assay is to be used as an aid in the assessment of thyroid status.

BIOLICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT Total T3 assay is a two-step immunoassay to determine the presence of Total T3 in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiliffex. In the first step, sample and anti-T3 coated paramagnetic microparticles are combined. T3 present in the sample binds to the anti-T3 coated microparticles. After washing, T3 acridinium-labeled conjugate is added in the second step. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). An inverse relationship exists between the amount of Total T3 in the sample and the RLUs detected by the ARCHITECT i system.

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

REAGENTS
Reagent Kit, 100 Tests/500 Tests
NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT / Systems. Please contact your local distributor.

ARCHITECT Total T3 Reagent Kit (7K84)
• MICROPARTICLES 1 or 4 Bottle(s) (6.6 mL/27.0 mL) anti-T3 (sheep) coated microparticles in MES buffer with sheep IgG stabilizers. Preservative: antimicrobial agent.
• CONJUGATE 1 or 4 Bottle(s) (5.9 mL/26.3 mL) T3 acridinium-labeled conjugate in citrate buffer with NaCl and Triton X-100 stabilizers. Minimum concentration: 0.33 ng/mL. Preservative: antimicrobial agent.

Other Reagents
ARCHITECT / Pre-Trigger Solution
• PRE-TRIGGER SOLUTION Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.
ARCHITECT / Trigger Solution
• TRIGGER SOLUTION Trigger Solution containing 0.35 N sodium hydroxide.
ARCHITECT / Wash Buffer
NOTE: Bottle and volume vary based on order.
• WASH BUFFER Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

WARNINGS AND PRECAUTIONS
• IVD
• For In Vitro Diagnostic Use
• Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

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

The following warnings and precautions apply to these components:

- Microparticles
- Conjugate

WARNING: Contains methylisothiazolones. May cause an allergic skin reaction.

Prevention
- P261 Avoid breathing mist / vapours / spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves / protective clothing / eye protection.

Response
- P302+P352 IF ON SKIN: Wash with plenty of soap and water.
- P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
- P363 Wash contaminated clothing before use.

This material and its container must be disposed of in a safe way.

- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.
Handling Precautions

- Do not use reagent kits beyond the expiration date.
- Do not mix reagents from different reagent kits.
- Prior to loading the ARCHITECT Total T₃ 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.
- Septa MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septa are not used according to the instructions in this package insert.

Handling Precautions

- To avoid contamination, wear clean gloves when placing a septum on an open 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

- The ARCHITECT Total T₃ Reagent Kit must be stored at 2-8°C 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 Total T₃ Reagent Kit may be stored on board the ARCHITECT / System 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 off of the ARCHITECT / System. If reagents are removed from the system, store them at 2-8°C (with septa 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, you must 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 samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT Total T₃ assay file must be installed on the ARCHITECT / System from the ARCHITECT / System CD-ROM prior to performing the assay. For detailed instructions 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.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum (including serum collected in serum separator tubes) or plasma collected in sodium hepamin, lithium heparin, or potassium EDTA anticoagulant tubes may be used in the ARCHITECT Total T₃ assay. Other anticoagulants have not been validated for use with the ARCHITECT Total T₃ assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.
- When serial specimens are being evaluated, the same type of specimen should be used throughout the study.
- The ARCHITECT / System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT Total T₃ assay.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- Do not use heat-inactivated specimens.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- For optimal results, serum and plasma specimens should be free of fibrin, red blood cells or other particulate matter.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells. Specimens may be stored for up to 6 days at 2-8°C prior to being tested. If testing will be delayed more than 6 days, specimens should be frozen at -10°C or colder. Specimens stored frozen at -1°C or colder for 6 days showed no performance difference.
- Multiple freeze-thaw cycles of specimens should be avoided. Specimens must be mixed THOROUGHLY after thawing, by LOW speed vortexing or by gently inverting, and centrifuged prior to use to remove red blood cells or particulate matter to ensure consistency in the results.
- 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. Prior to shipment, it is recommended that specimens be removed from the clot, serum separator or red blood cells.

PROCEDURE

Materials Provided
- 7K64 ARCHITECT Total T₃ Reagent Kit

Materials Required but not Provided
- ARCHITECT / System
- ARCHITECT / Assay CD-ROM
- 7K64-01 ARCHITECT Total T₃ Calibrators
- 7K64-50 ARCHITECT Total T₃ (MANUAL DILUENT)
- ARCHITECT / PRE-TRIGGER SOLUTION
- ARCHITECT / TRIGGER SOLUTION
- ARCHITECT / WASH BUFFER
- ARCHITECT / REACTION VESSELS
- ARCHITECT / SAMPLE CUPS
- ARCHITECT / SEPTUM
- ARCHITECT / REPLACEMENT CAPS
- Any commercially available controls
- 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 Total T₃ Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment:
  - Invert the microparticle bottle 30 times.
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - Once the microparticles have been resuspended, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Carefully snap the septum onto the top of the bottle.
  - If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.
• Order tests.
• Load the ARCHITECT Total T3 Reagent Kit on the ARCHITECT i System. Verify that all necessary reagents are present. Ensure that septa are present on all reagent bottles.
• The minimum sample cup 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: 75 μL for the first Total T3 test plus 25 μL for each additional Total T3 test from the same sample cup
  • ≤ 3 hours on board: 150 μL for the first Total T3 test plus 25 μL for each additional Total T3 test from the same sample cup
  • > 3 hours on board: additional sample volume is required. Refer to the ARCHITECT System Operations Manual, Section 5 for information on sample evaporation and volumes.
• If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
• ARCHITECT Total T3 Calibrators should be mixed by gentle inversion prior to use.
• To obtain the recommended volume requirements for the ARCHITECT Total T3 Calibrators, hold the bottles vertically and dispense 4 drops of each calibrator into each respective sample cup.
• Load samples.
• For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
• Press RUN. The ARCHITECT i System performs the following functions:
  • Moves the sample to the aspiration point
  • Loads a reaction vessel (RV) into the process path
  • Aspirates and transfers sample into the RV
  • Advances the RV one position and transfers microparticles into the RV
  • Mixes, incubates and washes the reaction mixture
  • Adds conjugate to the RV
  • Mixes, incubates and washes the reaction mixture
  • Adds Pre-Trigger and Trigger Solutions
  • Measures chemiluminescent emission to determine the quantity of Total T3 in the sample
  • Aspirates contents of RV to liquid waste and unloads RV to solid waste
  • Calculates the result
• For information on ordering patient specimens, calibrators and controls, and general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
• 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 Total T3 value exceeding 8.00 ng/mL are flagged with the code “>8.00” and may be diluted with the Manual Dilution Procedure.
• Manual Dilutions should be performed as follows:
  • The suggested dilution for Total T3 is 1:2. It is recommended dilutions not exceed 1:2.
  • For a 1:2 dilution, add a minimum of 75 μL of the patient specimen to 75 μL of ARCHITECT Total T3 Manual Diluent.
  • To avoid contamination of Manual Diluent, dispense several drops of Manual Diluent into a clean test tube prior to pipetting.
  • The operator must enter the dilution factor (2) 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 reported result reads greater than 1.0 ng/mL.
  • If the operator does not enter the dilution factor, the reported result will be that of the diluted sample. This result (before dilution factor is applied) should be greater than 0.5 ng/mL.
• For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration
• To perform an ARCHITECT Total T₃ calibration, test Calibrators 1 and 2 in duplicate. A single sample of all levels of controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the package insert. Calibrators should be priority loaded.
• Calibrator Range: 0.0 - 8.0 ng/mL
• Once an ARCHITECT Total T₃ 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 Total T₃ assay is a single sample of all control levels 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. Ensure that assay control values are within the concentration ranges specified in the package insert.

Verification of Assay Claims
For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix 8. The ARCHITECT Total T₃ assay belongs to method group 2.

RESULTS
The ARCHITECT Total T₃ utilizes a 4 Parameter Logistic Curve Fit data reduction method (4PLC, Y-weighted) to generate a calibration curve.

Alternate Result Units
• The default result unit for the ARCHITECT Total T₃ assay is ng/mL.
• Alternate result units available are as follows:
  • When the alternate result unit, nmol/L, is selected, the conversion factor used by the system is 1.536
    Conversion Formula: (Concentration in ng/mL) x (1.536) = Concentration in nmol/L
  • When the alternate result unit, ng/dL*, is selected, the conversion factor used by the system is 100.0
    Conversion Formula: (Concentration in ng/mL) x (100.0) = Concentration in ng/dL*
* / System Assay CD-ROM version 6.0 and higher will be required to install this alternate result unit (ng/dL).

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.

LIMITATIONS OF THE PROCEDURE
• For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other thyroid tests, clinical impressions, etc.
• If the Total T₃ results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
• Performance of this test has not been established with neonatal specimens.

EXPECTED VALUES
A normal range of 0.58 ng/mL to 1.59 ng/mL (central 95% interval) was obtained by testing serum specimens from 438 individuals determined as normal by AxSYM Ultrasensitive hTSH II and AxSYM Free T₄ assays. It is recommended that each laboratory establish its own normal range, which may be unique to the population it serves depending upon geographical, patient, dietary, or environmental factors.
SPECIFIC PERFORMANCE CHARACTERISTICS

Precision
The ARCHITECT Total T3 assay is designed to have a precision of ≤ 10% (total CV). A study based on guidance from Clinical Laboratory Standards Institute (CLSI, formerly NCCLS) document EP-A24 was performed for the ARCHITECT Total T3 assay. A three member processed human serum panel was assayed, using two lots of reagents, in replicates of two at two separate times per day for 20 testing days. Data from this study are summarized in the following table.*

<table>
<thead>
<tr>
<th>Panel Member</th>
<th>Reagent Lot</th>
<th>Instrument n</th>
<th>Mean Conc. Value (ng/mL)</th>
<th>Within Run SD</th>
<th>Total SD %CV</th>
<th>Total SD %CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>80.7</td>
<td>0.021</td>
<td>2.7</td>
<td>0.027</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>2</td>
<td>80.7</td>
<td>0.023</td>
<td>3.1</td>
<td>0.030</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>2</td>
<td>80.7</td>
<td>0.036</td>
<td>4.6</td>
<td>0.054</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>3</td>
<td>80.7</td>
<td>0.047</td>
<td>5.8</td>
<td>0.057</td>
</tr>
</tbody>
</table>

Average Recovery: 98.6%

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

Recovery
The ARCHITECT Total T3 assay is designed to have a mean recovery of 100 ± 10% when analyzing samples spiked with known amounts of T3. T3 was determined using the ARCHITECT Total T3 assay and the resulting percent recovery was calculated.*

<table>
<thead>
<tr>
<th>Sample</th>
<th>Endogenous T3 Concentration (ng/mL)</th>
<th>T3 Added (ng/mL)</th>
<th>Observed Total T3 Concentration (ng/mL)</th>
<th>% Recovery**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.01</td>
<td>0.77</td>
<td>2.74</td>
<td>94.8</td>
</tr>
<tr>
<td>2</td>
<td>0.97</td>
<td>0.78</td>
<td>1.64</td>
<td>85.9</td>
</tr>
<tr>
<td>3</td>
<td>1.13</td>
<td>0.79</td>
<td>1.95</td>
<td>103.8</td>
</tr>
<tr>
<td>4</td>
<td>0.99</td>
<td>1.54</td>
<td>2.43</td>
<td>93.5</td>
</tr>
<tr>
<td>5</td>
<td>0.88</td>
<td>1.53</td>
<td>2.41</td>
<td>100.0</td>
</tr>
<tr>
<td>6</td>
<td>0.90</td>
<td>1.54</td>
<td>2.54</td>
<td>106.5</td>
</tr>
<tr>
<td>7</td>
<td>1.07</td>
<td>3.03</td>
<td>4.28</td>
<td>105.9</td>
</tr>
<tr>
<td>8</td>
<td>1.23</td>
<td>3.04</td>
<td>4.21</td>
<td>98.0</td>
</tr>
<tr>
<td>9</td>
<td>0.90</td>
<td>3.03</td>
<td>3.89</td>
<td>98.7</td>
</tr>
</tbody>
</table>

Average Recovery: 98.6%

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

** % Recovery = \( \frac{\text{Observed Total T3 Conc. (ng/mL)} - \text{Endogenous Total T3 Conc. (ng/mL)}}{\text{T3 Added (ng/mL)}} \times 100 \)

Analytical Sensitivity
The ARCHITECT Total T3 assay is designed to have an analytical sensitivity of ≤ 0.25 ng/mL. Analytical sensitivity is defined as the concentration calculated as the mean plus two standard deviations of replicates of the ARCHITECT Total T3 MasterCheck Level 0 (0.0 ng/mL). The analytical sensitivity (low-linearity) is defined in the ARCHITECT Total T3 assay parameters as 0.25 ng/mL.

Analytical Specificity
The ARCHITECT Total T3 assay is designed to have a mean analytical specificity of ≤ 0.1% cross reactivity with thyroxine (T4) at a concentration of 1,100 ng/mL.

Interference
The ARCHITECT Total T3 assay is designed to have a mean potential interference from hemoglobin, bilirubin, triglycerides, and protein of ≤ 10% at the levels indicated below.

- Hemoglobin: ≤ 500 mg/dL
- Bilirubin: ≤ 20 mg/dL
- Triglycerides: ≤ 2000 mg/dL
- Protein: ≤ 12 g/dL

Accuracy by Correlation
The ARCHITECT Total T3 assay is designed to have a slope of 1.00 ± 0.20 and a correlation coefficient (r) of ≥ 0.90 when compared to the AxSYM Total T3 assay.

A study was performed where specimens were tested using the ARCHITECT Total T3 assay and AxSYM Total T3 assay. Data from this study were analyzed using Least Squares and Passing-Bablok** regression methods and are summarized in the following table.*

<table>
<thead>
<tr>
<th>Method</th>
<th>Number of Specimens</th>
<th>Intercept</th>
<th>Slope</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least Squares</td>
<td>1440</td>
<td>0.02</td>
<td>1.04</td>
<td>0.964</td>
</tr>
<tr>
<td>Passing-Bablok</td>
<td>1440</td>
<td>-0.08</td>
<td>1.13</td>
<td>0.964</td>
</tr>
</tbody>
</table>

In this evaluation, serum specimens tested ranged from 0.25 ng/mL to 5.83 ng/mL with the ARCHITECT Total T3 assay and from 0.34 ng/mL to 5.19 ng/mL with the AxSYM Total T3 assay.

* Representative data; variables such as differences in sampling size and sample population may impact correlation of the assay; therefore, results in individual laboratories may vary from these data.

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

BIBLIOGRAPHY


AxSYM, ARCHITECT, Chemiflex and MasterCheck are trademarks of Abbott Laboratories in various jurisdictions.

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