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.

**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 THE 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 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 thyroid (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 and 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.

**BIOLOGICAL 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 Chemiluminescent Microparticle Immunoassay (CMIA). The ARCHITECT Total T3 assay provides the following benefits:

1. Sample and anti-T3 coated paramagnetic microparticles are combined. The T3 present in the sample binds to the anti-T3 coated microparticles.
2. After washing, T3 acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is an inverse relationship between the amount of Total T3 in the sample and the RLUs detected by the ARCHITECT iSystem optics.

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

**REAGENTS**

**Kit Contents**
ARCHITECT Total T3 7K64

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

**Summary of Kit Contents**

<table>
<thead>
<tr>
<th>Ref</th>
<th>7K64-27</th>
<th>7K64-37</th>
<th>7K64-32</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MICROPARTICLES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 x 6.6 mL</td>
<td>1 x 27.0 mL</td>
<td>4 x 27.0 mL</td>
<td></td>
</tr>
<tr>
<td><strong>CONJUGATE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 x 3.27 mL</td>
<td>1 x 13.27 mL</td>
<td>4 x 13.27 mL</td>
<td></td>
</tr>
<tr>
<td><strong>MICROPARTICLES</strong></td>
<td>Anti-T3 (sheep) coated microparticles in MES buffer with sheep IgG stabilizers. Minimum concentration: 0.05% solids. Preservative: ProClin 300.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CONJUGATE</strong></td>
<td>T3 acridinium-labeled conjugate in citrate buffer with NaCl and Triton X-100 stabilizers. Minimum concentration: 0.33 ng/mL. Preservative: ProClin 300.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other Reagents**

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

**TRIGGER SOLUTION** ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

**WASH BUFFER** ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

NOTE: Bottle and volume vary based on order.
Warnings and Precautions

- For In Vitro Diagnostic Use
- RX ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.

The following warnings and precautions apply to: MicroParticles / Conjugate

**WARNING:**

- Contains methylisothiazolones.

**H317** May cause an allergic skin reaction.

**Prevention**

- **P261** Avoid breathing mist / vapors / 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 water.
- **P333+P313** If skin irritation or rash occurs: Get medical advice / attention.
- **P362+P364** Take off contaminated clothing and wash it before reuse.

**Disposal**

- **P501** Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may 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 and 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.

### Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Maximum Storage Time</th>
<th>Additional Storage Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened/Opened*</td>
<td>2-8°C</td>
<td>Until expiration date</td>
</tr>
<tr>
<td>On board</td>
<td>System temperature</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discard after 30 days.</td>
</tr>
</tbody>
</table>

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

### 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 iSystem prior to performing the assay.

For detailed information on assay file installation and 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.

### Alternate Result Units

Edit assay parameter "Result concentration units" to select an alternate unit.

Conversion formula:

\[(\text{Concentration in Alternate result unit}) = (\text{Concentration in Default result unit}) \times (\text{Conversion factor})\]

<table>
<thead>
<tr>
<th>Default result unit</th>
<th>Conversion factor</th>
<th>Alternate result unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ng/mL</td>
<td>1.536</td>
<td>nmol/L</td>
</tr>
<tr>
<td>100.0</td>
<td></td>
<td>ng/dL</td>
</tr>
</tbody>
</table>

### SPECIMENT COLLECTION AND PREPARATION FOR ANALYSIS

**Specimen Types**

Validated specimen types to be used with this assay:

<table>
<thead>
<tr>
<th>Specimen Types</th>
<th>Collection Tubes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human serum</td>
<td>Serum</td>
</tr>
<tr>
<td>Human plasma</td>
<td>Sodium heparin</td>
</tr>
<tr>
<td></td>
<td>Lithium heparin</td>
</tr>
<tr>
<td></td>
<td>Potassium EDTA</td>
</tr>
</tbody>
</table>
• Other anticoagulants have not been validated for use with this assay.
• When serial specimens are being evaluated, the same type of specimen should be used throughout the study.
• Performance has not been established for the use of neonatal specimens.
• The instrument 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 assay.

Specimen Conditions
• Do not use specimens with the following conditions:
  - heat-inactivated
• 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.
• To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis
• Follow the tube manufacturer’s processing instructions for specimen collection tubes.
• 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.
• 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.

Specimen Storage
<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Storage Temperature</th>
<th>Maximum Storage Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum/Plasma</td>
<td>2-8°C</td>
<td>≤ 6 days</td>
</tr>
</tbody>
</table>

If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells. If testing will be delayed more than 6 days, specimens should be frozen at -10°C or colder. Specimens stored frozen at -10°C or colder for 6 days showed no performance difference. Avoid multiple freeze/thaw cycles.

Specimen Shipping
• Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
• Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided
7K64 ARCHITECT Total T3 Reagent Kit

Materials Required but not Provided
• ARCHITECT Total T3 Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
• 7K64-02 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) to deliver the volumes specified on the patient or control order screen.

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

Assay Procedure
• Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may 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 are still 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 about placing septums on bottles, refer to the Reagent Handling section of this package insert.
• Load the reagent kit on the ARCHITECT iSystem.
  • Verify that all necessary 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.
• Minimum sample cup volume is calculated by the system and printed on the Orderlist report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

Maximum number of replicates sampled from the same sample cup: 10
• Priority:
  • Sample volume for first test: 70 μL
  • Sample volume for each additional test from same sample cup: 20 μL
  • ≤ 3 hours on board:
    • Sample volume for first test: 150 μL
    • Sample volume for each additional test from same sample cup: 20 μL
  • > 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.
• Prepare ARCHITECT Total T3 Calibrators.
  • Mix calibrator(s) by gentle inversion before use.
  • Hold bottles vertically and dispense recommended volumes into each respective sample cup.
  • Recommended volumes:
    • for each calibrator: 4 drops
    • Follow the manufacturer’s instructions for preparation of commercially available control material.
• 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 System Operations Manual, Section 3.
• For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Specimen Dilution Procedures
Specimens with a Total T3 value exceeding 6.00 ng/mL are flagged with the code “> 6.00” and may be diluted using the Manual Dilution Procedure.

Manual Dilution Procedure
Suggested dilution: 1:2
It is recommended that dilutions not exceed 1:2.
1. 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.
2. 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
• Test Calibrators A - F in duplicate. The calibrators should be priority loaded.
   A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
• Calibration Range: 0.2 - 6.0 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 or
  • 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 B.
The ARCHITECT Total T3 assay belongs to method group 2.

RESULTS

Calculation
The ARCHITECT Total T3 assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted) to generate a calibration curve.
For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

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.

Measuring Interval
Measuring interval is defined as the range of values in ng/mL which meets the limits of acceptable performance for both imprecision and linearity.
The measuring interval for the ARCHITECT Total T3 assay is 0.40 (Limit of Quantitation - LoQ) to 6.00 ng/mL.

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.

EXPECTED VALUES
A normal range of 0.35 - 1.93 ng/mL (Central 99% interval) was obtained by testing serum specimens from 379 individuals determined as normal by ARCHITECT TSH and FT4 assays. The minimum concentration obtained was 0.00 ng/mL and the maximum concentration obtained was 2.02 ng/mL. 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 and Laboratory Standards Institute (CLSI, formerly NCCLS) document EP5-A2<sup>2</sup> was performed for the ARCHITECT Total T3 assay. A three member processed human serum based 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</th>
<th>Reagent Lot</th>
<th>Instrument</th>
<th>n</th>
<th>Mean Conc. (ng/mL)</th>
<th>Within Run %CV</th>
<th>Total %CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>80</td>
<td>0.75</td>
<td>0.021</td>
<td>2.7</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>2</td>
<td>80</td>
<td>0.73</td>
<td>0.023</td>
<td>3.1</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>1</td>
<td>80</td>
<td>0.79</td>
<td>0.036</td>
<td>4.6</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>2</td>
<td>80</td>
<td>0.81</td>
<td>0.047</td>
<td>5.8</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>1</td>
<td>80</td>
<td>1.50</td>
<td>0.029</td>
<td>1.9</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>2</td>
<td>80</td>
<td>1.49</td>
<td>0.040</td>
<td>2.7</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>1</td>
<td>80</td>
<td>1.53</td>
<td>0.031</td>
<td>2.0</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>80</td>
<td>1.54</td>
<td>0.040</td>
<td>2.6</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>1</td>
<td>80</td>
<td>3.27</td>
<td>0.062</td>
<td>1.9</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>2</td>
<td>80</td>
<td>3.29</td>
<td>0.107</td>
<td>3.3</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>1</td>
<td>80</td>
<td>3.55</td>
<td>0.054</td>
<td>1.5</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>2</td>
<td>80</td>
<td>3.54</td>
<td>0.066</td>
<td>1.9</td>
</tr>
</tbody>
</table>

* 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 added to nine normal human serum samples. The concentration of 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>
**Sensitivity**

The ARCHITECT Total T₃ assay is designed to have a Limit of Quantitation (LoQ) of ≤ 0.4 ng/mL. The LoQ is defined as the lowest concentration at which analyte in a sample can be accurately quantified with precision of ≤ 20% CV. A study was performed based on guidance from the CLSI document EP17-A2²⁴ with four zero-level samples and 8 samples with T₃ target concentrations ranging from 0.10 ng/mL to 0.40 ng/mL. The samples were tested over a minimum of 3 days using 2 reagent lots and 6 instruments. In this study, the Limit of Blank (LoB) was 0.0 ng/mL, Limit of Detection (LoD) was 0.09 ng/mL and LoQ was 0.3 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**

A representative study between ARCHITECT Total T₃ 6 point assay and the ARCHITECT Total T₃ 2 point assay demonstrated a slope of 1.00 +/- 0.22 with a correlation coefficient (r) of ≥ 0.90 when compared to the ARCHITECT Total T₃ 2 point assay.

The study was performed where specimens were tested using the ARCHITECT Total T₃ 6 point assay and ARCHITECT Total T₃ 2 point assay. Data from this study was analyzed using Passing Bablok²³ regression method and is summarized in the following table.

- **Abbott ARCHITECT Total T₃ 6 point assay vs. Abbott ARCHITECT Total T₃ 2 point assay**

<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>Passing Bablok Linear</td>
<td>126</td>
<td>-0.12</td>
<td>1.22</td>
<td>0.99</td>
</tr>
</tbody>
</table>

In this evaluation, specimens were tested ranging from 0.45 ng/mL to 4.60 ng/mL with the ARCHITECT Total T₃ 6 point assay and from 0.43 ng/mL to 3.53 ng/mL with the ARCHITECT Total T₃ 2 point assay.

* Representative data; variables such as differences in sampling size and sample population may impact the 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.²³

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**BIBLIOGRAPHY**

Key to Symbols

ISO 15223 Symbols

- Consult instructions for use
- Manufacturer
- Sufficient for
- Temperature limitation
- Use by/Expiration date
- In Vitro Diagnostic Medical Device
- Lot Number
- List Number
- Serial number

Other Symbols

- Conjugate
- Control Number
- Distributed in the USA by
- Information needed for United States of America only
- Microparticles
- Pre-Trigger Solution
- Product of Ireland
- Reaction Vessels
- Reagent Lot
- Replacement Caps
- Rx Only
- Sample Cups
- Septum
- Trigger Solution
- Warning: May cause an allergic reaction.
- Wash Buffer

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