



# ARCHITECT

## SYSTEM

# en

Total T<sub>3</sub>

**REF** 7K64

49-1222/R4

**B7K640**


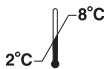


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Revised February, 2010

# Total T<sub>3</sub>

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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

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

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

## NAME

ARCHITECT Total T<sub>3</sub>

## INTENDED USE

The ARCHITECT Total T<sub>3</sub> (TT<sub>3</sub>) assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of total triiodothyronine (Total T<sub>3</sub>) in human serum and plasma.

## SUMMARY AND EXPLANATION OF TEST

3,5,3' Triiodothyronine (T<sub>3</sub>) is a thyroid hormone with a molecular weight of 651 daltons<sup>1</sup> and a half-life in serum of 1.5 days.<sup>2</sup> T<sub>3</sub> circulates in the blood as an equilibrium mixture of free and protein bound hormone.<sup>3</sup> T<sub>3</sub> is bound to thyroxine binding globulin (TBG), prealbumin, and albumin. The actual distribution of T<sub>3</sub> among these binding proteins is controversial as estimates range from 38-80% for TBG, 9-27% for prealbumin, and 11-35% for albumin.<sup>4</sup> The binding of these proteins is such that only 0.2-0.4% of the total T<sub>3</sub> is present in solution as unbound or free T<sub>3</sub>.<sup>5</sup> This free fraction represents the physiologically active thyroid hormone.<sup>3</sup>

It has become apparent in recent years that T<sub>3</sub> plays an important role in the maintenance of the euthyroid state. Serum T<sub>3</sub> 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 T<sub>3</sub> concentration are especially valuable in diagnosing hyperthyroidism and in following the course of therapy for this disorder.<sup>2,6,7</sup> Under conditions of strong thyroid stimulation, the T<sub>3</sub> measurement provides a good estimation of thyroid reserve.<sup>2</sup> Recognition of a thyroid dysfunction called T<sub>3</sub>-thyrotoxicosis, associated with an increased serum T<sub>3</sub> level but normal thyroxine (T<sub>4</sub>), free T<sub>4</sub>, and *in vitro* Uptake results have further highlighted the importance of serum T<sub>3</sub> measurements.<sup>2,8-11</sup> Dietary iodine deficiency results in inadequate production of thyroid hormones despite the presence of normal thyroid tissue. In these cases, the serum T<sub>4</sub> concentration is often low while the thyroid stimulating hormone (TSH) concentration is elevated. Elevated TSH associated with low T<sub>4</sub> is normally indicative of hypothyroidism. However, in iodine deficiency, these results together with normal or slightly elevated serum T<sub>3</sub> are indicative of euthyroid status in most individuals.<sup>12</sup>

T<sub>3</sub> levels are also affected by conditions which affect TBG concentration.<sup>13-15</sup> Slightly elevated T<sub>3</sub> 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.<sup>2,16,17</sup> In patients with severe or chronic illnesses, many abnormalities of thyroid hormone balance occur. T<sub>4</sub> production and the extent of serum thyroid hormone binding may be independently abnormal, resulting in a low, normal or high free T<sub>4</sub> estimate. Serum T<sub>3</sub> concentrations are often low; TSH levels may be normal or slightly elevated. Total T<sub>3</sub> measurements may be valuable when hyperthyroidism is suspected and the free T<sub>4</sub> estimate is normal.<sup>13</sup>

The ARCHITECT Total T<sub>3</sub> assay is to be used as an aid in the assessment of thyroid status.

## BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Total T<sub>3</sub> assay is a two-step immunoassay to determine the presence of Total T<sub>3</sub> in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-T<sub>3</sub> coated paramagnetic microparticles are combined. T<sub>3</sub> present in the sample binds to the anti-T<sub>3</sub> coated microparticles. After washing, T<sub>3</sub> 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 T<sub>3</sub> in the sample and the RLUs detected by the ARCHITECT *i* optical 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 *i* Systems. Please contact your local distributor.

### ARCHITECT Total T<sub>3</sub> Reagent Kit (7K64)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL/27.0 mL) anti-T<sub>3</sub> (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) T<sub>3</sub> 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 *i* Pre-Trigger Solution

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

#### ARCHITECT *i* Trigger Solution

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

#### ARCHITECT *i* 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<sup>18</sup>. Biosafety Level 2<sup>19</sup> or other appropriate biosafety practices<sup>20,21</sup> 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:**  
H317 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 T<sub>3</sub> 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.**
- 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

-  The ARCHITECT Total T<sub>3</sub> 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 T<sub>3</sub> Reagent Kit may be stored on board the ARCHITECT *i* 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 on or off the ARCHITECT *i* 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 T<sub>3</sub> assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay 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 heparin, lithium heparin, or potassium EDTA anticoagulant tubes may be used in the ARCHITECT Total T<sub>3</sub> assay. Other anticoagulants have not been validated for use with the ARCHITECT Total T<sub>3</sub> 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 *i* 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 T<sub>3</sub> 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 -10°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 T<sub>3</sub> Reagent Kit

#### Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* Assay CD-ROM
- 7K64-01 ARCHITECT Total T<sub>3</sub> Calibrators
- 7K64-50 ARCHITECT Total T<sub>3</sub> **MANUAL DILUENT**
- 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**
- 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> test plus 25 µL for each additional Total T<sub>3</sub> test from the same sample cup
  - ≤ 3 hours on board: 150 µL for the first Total T<sub>3</sub> test plus 25 µL for each additional Total T<sub>3</sub> 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 T<sub>3</sub> Calibrators should be mixed by gentle inversion prior to use.
- To obtain the recommended volume requirements for the ARCHITECT Total T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> assay belongs to method group 2.

#### RESULTS

The ARCHITECT Total T<sub>3</sub> 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 T<sub>3</sub> 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\*

\* *i* 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 T<sub>3</sub> 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 T<sub>4</sub> 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 T<sub>3</sub> 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-A<sup>22</sup> was performed for the ARCHITECT Total T<sub>3</sub> 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.\*

Panel Member	Reagent Lot	Instrument	n	Mean Conc. Value (ng/mL)	Within Run SD	%CV	Total SD	%CV
1	1	1	80	0.75	0.021	2.7	0.027	3.6
1	1	2	80	0.73	0.023	3.1	0.030	4.1
1	2	1	80	0.79	0.036	4.6	0.043	5.4
1	2	2	80	0.81	0.047	5.8	0.057	7.0
2	1	1	80	1.50	0.029	1.9	0.110	7.3
2	1	2	80	1.49	0.040	2.7	0.053	3.6
2	2	1	80	1.53	0.031	2.0	0.035	2.3
2	2	2	80	1.54	0.040	2.6	0.049	3.2
3	1	1	80	3.27	0.062	1.9	0.128	3.9
3	1	2	80	3.29	0.107	3.3	0.140	4.2
3	2	1	80	3.55	0.054	1.5	0.071	2.0
3	2	2	80	3.54	0.066	1.9	0.077	2.2

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

### Recovery

The ARCHITECT Total T<sub>3</sub> assay is designed to have a mean recovery of 100 ± 10% when analyzing samples spiked with known amounts of T<sub>3</sub>. T<sub>3</sub> was added to nine normal human serum samples. The concentration of T<sub>3</sub> was determined using the ARCHITECT Total T<sub>3</sub> assay and the resulting percent recovery was calculated.\*

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

Average Recovery: 98.6%

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

$$** \% \text{ Recovery} = \frac{\text{Observed Total T}_3 \text{ Conc. (ng/mL)} - \text{Endogenous Total T}_3 \text{ Conc. (ng/mL)}}{\text{T}_3 \text{ Added (ng/mL)}} \times 100$$

### Analytical Sensitivity

The ARCHITECT Total T<sub>3</sub> 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 T<sub>3</sub> MasterCheck Level 0 (0.0 ng/mL). The analytical sensitivity (low-linearity) is defined in the ARCHITECT Total T<sub>3</sub> assay parameters as 0.25 ng/mL.

### Analytical Specificity

The ARCHITECT Total T<sub>3</sub> assay is designed to have a mean analytical specificity of ≤ 0.1% cross reactivity with thyroxine (T<sub>4</sub>) at a concentration of 1,100 ng/mL.

### Interference

The ARCHITECT Total T<sub>3</sub> 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 T<sub>3</sub> 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 T<sub>3</sub> assay.

A study was performed where specimens were tested using the ARCHITECT Total T<sub>3</sub> assay and AxSYM Total T<sub>3</sub> assay. Data from this study were analyzed using Least Squares and Passing-Bablok<sup>23</sup> regression methods and are summarized in the following table.\*

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares				
Linear Regression	1440	0.02	1.04	0.964
Passing-Bablok				
Linear Regression**	1440	-0.08	1.13	0.964

In this evaluation, serum specimens tested ranged from 0.25 ng/mL to 5.83 ng/mL with the ARCHITECT Total T<sub>3</sub> assay and from 0.34 ng/mL to 5.19 ng/mL with the AxSYM Total T<sub>3</sub> 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.<sup>23</sup>

### BIBLIOGRAPHY

1. Budavari S, editor. *Merck Index* (11<sup>th</sup> Ed.). Rahway, NJ: Merck and Co., Inc., 1989:868.
2. Larsen PR. Triiodothyronine: Review of Recent Studies of Its Physiology and Pathophysiology in Man. *Metabolism* 1972;21:1073-1092.
3. Ekins RP, editor. *Methods for the Measurement of Free Thyroid Hormones*. Amsterdam: Excerpta Medica Foundation. 1979;72-92.
4. Robbins J, Rall JE. The Iodine-containing Hormones. In: *Hormones in Blood* (3<sup>rd</sup> Ed.). London: Academic Press, 1979:1:632-667.
5. DeGroot LJ, Larsen PR, Refetoff S, Stanbury JB. Transport of Thyroid Hormone and Cell Uptake. In: *The Thyroid and Its Diseases*. New York: Wiley and Sons, 1984;62-66.
6. Wahner HW, Gorman CA. Interpretation of Serum Tri-Iodothyronine Levels Measured by the Sterling Technic. *N Engl J Med* 1971;282:225-230.
7. Marsden P, McKerron CG. Serum Triiodothyronine Concentration in the Diagnosis of Hyperthyroidism. *Clin Endocrinol* 1975;4:183-189.
8. Ivy HK, Washner HW, Gorman CA. Triiodothyronine (T<sub>3</sub>) Toxicosis: Its Role in Graves' Disease. *Arch Intern Med* 1971;128:529-534.
9. Hollander CS, Mitsuma T, Nihei N, Shenkman L, Burday SZ, Blum M. Clinical and Laboratory Observations in Cases of Triiodothyronine Toxicosis Confirmed by Radioimmunoassay. *Lancet* 1972;1:609-611.
10. Sterling K, Refetoff S, Selenkow HA. T<sub>3</sub> Thyrotoxicosis: Thyrotoxicosis Due to Elevated Serum Triiodothyronine Levels. *JAMA* 1970;213:571-575.
11. Hollander CS, Mitsuma T, Shenkman L, Stevenson C, Pineda G, Silva E. T<sub>3</sub> Toxicosis in an Iodine-Deficient Area. *Lancet* 1972;2:1276-1278.
12. Ermans AM. Disorders of Iodine Deficiency. In: Ingbar SH, Braverman LE, editors. *The Thyroid* (5<sup>th</sup> Ed.). Philadelphia: JB Lippincott Co., 1986:705-721.
13. Kaplan MM, Larsen PR, Crantz FR, Deau VJ, Rossing TH. Prevalence of Abnormal Thyroid Function Test Results in Patients with Acute Medical Illnesses. *Am J Med* 1982;72:9-16.
14. Bermudez F, Surks MI, Oppenheimer JH. High Incidence of Decreased Serum Triiodothyronine Concentration in Patients with Nonthyroid Disease. *J Clin Endocrinol Metab* 1975;41:27-40.



15. Oppenheimer JH. Thyroid Function Tests in Nonthyroidal Disease. *J Chronic Dis* 1982;35:697-701.
16. Abuid J, Larsen PR. Triiodothyronine and Thyroxine in Hyperthyroidism: Comparison of the Acute Changes During Therapy with Antithyroid Agents. *J Clin Invest* 1974;54:201-208.
17. Felig P, Baxter JD, Broadus AE, Frohman LA, editors. *Endocrinology and Metabolism* (2<sup>nd</sup> Ed.). New York: McGraw-Hill Book Co., 1987:408-416.
18. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
19. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; January 2007.
20. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
21. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline – Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.
22. National Committee for Clinical Laboratory Standards, Evaluation of Precision Performance of Clinical Chemistry Devices - Approved Guideline. NCCLS Document EP5-A. Wayne, PA: NCCLS, 1999.
23. Passing H, Bablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods. *J Clin Chem. Clin Biochem*. 1983;21:709-20.

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