



Read Highlighted Changes: Revised April 2020.

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 Free T₃

INTENDED USE

The ARCHITECT Free T₃ (FT₃) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free triiodothyronine (Free 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 daltons¹ and a half-life in serum of 1.5 days.²

T₃ circulates in the blood as an equilibrium mixture of free and protein bound hormone.³

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.⁴

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 T₃.⁵

This free fraction represents the physiologically active thyroid hormone.³

Free T₃ is typically elevated to a greater degree than free thyroxine (T₄) in Graves' disease.^{6, 7}

Occasionally, free T₃ alone is elevated (T₃ thyrotoxicosis) in about 5% of the hyperthyroid population.⁸

In contrast, levels of free T₄ are elevated to a greater degree than free T₃ in toxic multinodular goiter and excessive T₄ therapy.⁹

Serum free T₃ is useful in distinguishing these forms of hyperthyroidism. Free T₃ may also be important in monitoring patients on anti-thyroid therapy where treatment is focused on reducing the T₃ production and the T₄ conversion to T₃. Serum free T₃ may also be useful in assessing the severity of the thyrotoxic state.

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

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Free T₃ assay is a two-step immunoassay to determine the presence of free (unbound) T₃ in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample and anti-T₃ coated paramagnetic microparticles are combined. Free T₃ (unbound) present in the sample binds to the anti-T₃ coated microparticles.
2. After washing, T₃ acridinium-labeled conjugate is added.
3. Pre-Trigger and Trigger Solutions are then 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 Free 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 Free T₃ 7K63

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

REF	7K63-27	7K63-37	7K63-32
	100	500	2000
MICROPARTICLES	1 x 6.6 mL	1 x 27.0 mL	4 x 27.0 mL
CONJUGATE	1 x 5.9 mL	1 x 26.3 mL	4 x 26.3 mL
MICROPARTICLES	anti-T ₃ (sheep) coated Microparticles in MES buffer with sheep IgG stabilizers. Minimum Concentration: 0.085% solids. Preservative: antimicrobial agent.		
CONJUGATE	T ₃ acridinium-labeled Conjugate in citrate buffer with NaCl and Triton X-100 stabilizers. Minimum concentration: 0.33 ng/mL. Preservative: antimicrobial agent.		

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

- **IVD**
- 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.¹⁰⁻¹³

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 8.

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.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/Opened*	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage.
On board	System temperature	28 days	Discard after 28 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. 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.** 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 Free T₃ assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM 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:

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

Default result unit	Conversion factor	Alternate result unit
pg/mL	1.536	pmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Validated specimen types to be used with this assay:

Specimen Types	Collection Tubes
Human serum	Serum Serum separator tubes
Human plasma	Sodium heparin Lithium heparin Potassium EDTA

- 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

Specimen Type	Storage Temperature	Maximum Storage Time
Serum/Plasma	2-8°C	≤ 6 days

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

7K63 ARCHITECT Free T₃ Reagent Kit

Materials Required but not Provided

- ARCHITECT Free T₃ Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 7K63-02 ARCHITECT Free T₃ Calibrators
- 7K63-12 ARCHITECT Free T₃ Controls
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- 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, discard the cap and 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 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: 72 µL
 - Sample volume for each additional test from same sample cup: 22 µL
 - ≤ 3 hours on board:
 - Sample volume for first test: 150 µL
 - Sample volume for each additional test from same sample cup: 22 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 Free T₃ Calibrators and Controls.
 - Mix calibrator(s) and controls by gentle inversion before use.
 - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
 - Recommended volumes:
 - for each calibrator: 4 drops
 - for each control: 4 drops
 - Load samples.
 - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
 - Press RUN.
 - 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 cannot be diluted for Free T₃ determinations. Specimens which read > 20.00 pg/mL should be reported as such.

Calibration

- Test Calibrators A to 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: 0.0 - 30.0 pg/mL.
- Once an ARCHITECT Free 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 Free T₃ 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.

Ensure that assay control values are within the concentration ranges specified in the control package insert.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

The ARCHITECT Free T₃ assay belongs to method group 2.

RESULTS

Calculation

The ARCHITECT Free 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 pg/mL which meets the limits of acceptable performance for both imprecision and linearity. The measuring interval for the ARCHITECT Free T₃ assay is 1.5 (Limit of Quantitation - LoQ) to 20 pg/mL.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other thyroid tests, clinical impressions, etc.
- If the Free T₃ results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

EXPECTED VALUES

A normal range of 1.58-3.91 pg/mL (Central 95% interval) was obtained by testing serum specimens from 311 individuals determined as normal by ARCHITECT TSH and FT₄ assays. The minimum concentration obtained was 1.16 pg/mL and the maximum 4.60 pg/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.

Free T₃ is a secondary indicator of thyroid status. Although the majority of patients with hyperthyroidism will have free T₃ values greater than the upper limit of the euthyroid range, some may have free T₃ values which fall within the normal range.^{14, 15} Specimens from patients described as "sick euthyroids" generally yield values in the low to normal range.^{16, 17}

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Free 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-A¹⁸ was performed for the ARCHITECT Free 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.*

Panel Member	Reagent		n	Mean Conc. Value (pg/mL)	Within Run		Total	
	Lot	Instrument			SD	%CV	SD	%CV
1	1	1	80	3.22	0.096	3.0	0.115	3.6
1	1	2	80	3.16	0.133	4.2	0.143	4.5
1	2	1	80	3.60	0.108	3.0	0.141	3.9
1	2	2	80	3.35	0.113	3.4	0.131	3.9
2	1	1	80	6.00	0.099	1.7	0.168	2.8
2	1	2	80	5.88	0.166	2.8	0.184	3.1
2	2	1	80	6.28	0.154	2.5	0.176	2.8
2	2	2	80	6.06	0.194	3.2	0.225	3.7
3	1	1	80	10.50	0.252	2.4	0.481	4.6
3	1	2	80	10.01	0.289	2.9	0.496	5.0
3	2	1	80	10.50	0.145	1.4	0.237	2.3
3	2	2	80	10.12	0.217	2.1	0.265	2.6

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

Sensitivity

The ARCHITECT Free T₃ assay is designed to have a Limit of Quantitation (LoQ) of ≤ 1.5 pg/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-A2²⁰ with four zero-level samples and 8 samples with T₃ target concentrations ranging from 1.0 to 3.2 pg/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 0.94 pg/mL, Limit of Detection (LoD) was 1.07 pg/mL and LoQ was 1.25 pg/mL.*

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

Analytical Specificity

The ARCHITECT Free T₃ assay is designed to have a mean analytical specificity of ≤ 0.001% cross reactivity with thyroxine (T₄) at a concentration of 1,000,000 pg/mL.

Interference

The ARCHITECT Free 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 Free T₃ 6 point assay is designed to have a slope of 1.00 +/- 0.15 and a correlation coefficient (r) of ≥ 0.90 when compared to the ARCHITECT Free T₃ 2 point assay. A study was performed where specimens were tested using the ARCHITECT Free T₃ 6 point assay and ARCHITECT Free T₃ 2 point assay. Data from this study were analyzed using least squares and Passing Bablok¹⁹ regression methods and are summarized in the following table.*

Abbott ARCHITECT Free T₃ 6 point assay vs. Abbott ARCHITECT Free T₃ 2 point assay

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares Linear Regression	144	-0.32	1.04	0.99
Passing-Bablok Linear Regression**	144	-0.09	0.97	0.99

In this evaluation, serum specimens tested ranged from 1.50 pg/mL to 17.81 pg/mL with the ARCHITECT Free T₃ 6 point assay and from 1.55 pg/mL to 17.66 pg/mL with the ARCHITECT Free 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.¹⁹

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Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols

CONJUGATE	Conjugate
CONTROL NO.	Control Number
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
MICROPARTICLES	Microparticles
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF IRELAND	Product of Ireland
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REPLACEMENT CAPS	Replacement Caps
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
TRIGGER SOLUTION	Trigger Solution
WARNING: SENSITIZER	Warning: May cause an allergic reaction.
WASH BUFFER	Wash Buffer

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