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

Key to symbols used

- **REF**: List Number
- **IVD**: In Vitro Diagnostic Medical Device
- **LOT**: Lot Number
- **$\text{\textdegree}C$**: Store at 2-8°C
- **i**: Consult instructions for use
- **EC REP**: Authorized Representative
- **Manufacturer**: Manufacturer
- **ASSAY CD-ROM**: Assay CD-ROM
- **T-UPTAKE UNITS**: T-Uptake Units
- **REACTION VESSELS**: Reaction Vessels
- **SAMPLE CUPS**: Sample Cups
- **REPLACEMENT CAPS**: Replacement Caps
- **REAGENT LOT**: Reagent Lot
- **CONTROL NO.**: Control Number
- **SN**: Serial Number
- **SEPTUM**: Septum

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT T-Uptake

INTENDED USE
The ARCHITECT T-Uptake assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of the total binding capacity of human serum or plasma for the thyroid hormone, Thyroxine (T4). The ARCHITECT T-Uptake assay should be used in conjunction with Total T4 to yield a calculated Free Thyroxine Index (FTI), as an aid in the assessment of thyroid function status.

SUMMARY AND EXPLANATION OF TEST
The classical in vitro thyroid hormone “Uptake” assays measure the unsaturated thyroxine binding sites of serum proteins. The ARCHITECT T-Uptake assay measures the total binding capacity present in a sample. The thyroid hormones, thyroxine (T4) and triiodothyronine (T3), are transported in serum bound to the thyroxine binding proteins, thyroxine binding globulin (TBG), thyroxine binding prealbumin (TBPA), and albumin. TBG, TBPA, and albumin bind approximately 75%, 15% and 10% of the total circulating T4, respectively, and bind 38%, 27% and 35% of T3, respectively.1 In a euthyroid patient, T3 occupies approximately one third of the binding sites.2 Free, or unbound fractions of the thyroid hormones are thought to be responsible for biologic activity.3-5 The FTI has been the most widely used method to estimate free T4. Uptake assays are of greatest value when used in conjunction with a serum Total T4 assay to provide the FTI.6

The Uptake assays are used to normalize the Total T4 levels for variations in serum thyroxine binding protein (TBP) concentrations. Performing an Uptake assay and subsequent calculation of the FTI is important since certain conditions such as pregnancy, estrogen therapy, infectious and chronic active hepatitis, biliary cirrhosis or congenital disorders alter the number of T4 binding sites.6-8 These variations can produce abnormal T4 values in an individual with no thyroid disease. Since the T4 values or the T-Uptake values alone can produce misleading information, an FTI can be calculated to provide a clinically useful and accurate estimate of circulating free thyroxine.9-11 To ensure maximum diagnostic accuracy of thyroid status, an FTI should be used in conjunction with clinical evaluation and other thyroid function tests such as human thyroid stimulating hormone (TSH).

Since the ARCHITECT T-Uptake assay is a direct measure of the total binding capacity in human serum or plasma, a linear relationship between signal and TBG activity is observed. This provides for both low and high end accuracy. By contrast, traditional %T3 T-Uptake assays are non-linear relative to TBP concentration.

ARCHITECT T-Uptake and %T3 Uptake both respond to variations in TBG concentration. The %T3 T-Uptake also responds to variations in T4 levels. Since T-Uptake and %T3 Uptake do not measure the same exact phenomenon, a direct conversion of units to % transformed is not possible and thus the % transformed value should be viewed as an approximation only.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT T-Uptake assay is a one-step immunoassay to measure the total binding capacity of human serum or plasma for T4 using CMIA technology with flexible assay protocols, referred to as Chemiflex.

Sample, assay diluent, anti-TBG coated paramagnetic microparticles and free anti-TBG are combined. TBG present in the sample binds to the anti-TBG coated microparticles and the free anti-TBG. After an incubation period, T4-acridinium conjugate is added to the reaction mixture and it binds to TBG, free or microparticle bound. After washing to remove free conjugate and conjugate bound to TBG-free anti-TBG complex, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of TBG in the sample and the RLUs detected by the ARCHITECT® System optics. A calibration curve is established using TBG calibrators of known T-Uptake Units plotted against their corresponding RLU signals.

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

* i = immunoassay

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

ARCHITECT T-Uptake Reagent Kit (2K48)
- MICROPARTICLES 1 or 4 Bottle(s) (8.6 mL each) Anti-Thyroxine Binding Globulin (TBG) (mouse, monoclonal) coated microparticles and free Anti-TBG in phosphate buffer with protein (bovine and fish) stabilizers. Preservative: sodium azide.
- CONJUGATE 1 or 4 Bottle(s) (2.9 mL each) T4-acridinium conjugate in citrate buffer. Preservative: ProClin 300.
- ASSAY DILUENT 1 or 4 Bottle(s) (1.8 mL each) T-Uptake Assay Diluent in TRIS buffer. Preservative: sodium azide.

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

WARNINGS AND PRECAUTIONS
- IVD

Safety Precautions
- CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.12 Biosafety Level 213 or other appropriate biosafety practices14,15 should be used for materials that contain or are suspected of containing infectious agents.
- The ARCHITECT T-Uptake Conjugate contains methylisothiazolones, which are components of ProClin 300 and is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.
  - R43 May cause sensitization by skin contact.
  - S24 Avoid skin contact.
  - S35 This material and its container must be disposed of in a safe way.
  - S37 Wear suitable gloves.
  - S46 If swallowed, seek medical advice immediately and show this container or label.
- This product contains sodium azide; for a specific listing, refer to the REAGENTS section. Contact with acid liberates very toxic gas. This material and its container must be disposed of in a safe way.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- 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.
- Do not use reagent kits beyond the expiration date.
- Prior to loading the ARCHITECT T-Uptake Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.
To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.

Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.

Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.

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

Storage Instructions

The ARCHITECT T-Uptake Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.

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

The ARCHITECT T-Uptake Reagent Kit may be stored on board the ARCHITECT i System for a maximum of 28 days. After 28 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

Reagents may be stored on or off the ARCHITECT i System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. 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 must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The ARCHITECT T-Uptake assay file must be installed on the ARCHITECT i System from the ARCHITECT i Assay CD-ROM Addition B prior to performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

The default result unit for the ARCHITECT T-Uptake assay is T-Uptake Units. An alternate result unit, %Uptake, may be selected for reporting results. For transformation of result units, refer to the RESULTS, Transformation of T-Uptake Units to %Uptake section of this package insert.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The following specimen collection tubes may be used for the ARCHITECT T-Uptake assay.

<table>
<thead>
<tr>
<th>Glass</th>
<th>Plastic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>No Additives</td>
<td>Clot Activator</td>
</tr>
<tr>
<td>Serum Separator Tube with Clot Activators</td>
<td></td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
</tr>
<tr>
<td>Lithium Heparin</td>
<td>EDTA</td>
</tr>
<tr>
<td>Plasma Separator Tube - Lithium Heparin</td>
<td></td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>EDTA</td>
</tr>
</tbody>
</table>

Other specimen collection tubes have not been validated for use with the ARCHITECT T-Uptake assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.

- Inadequate centrifugation of the specimen may cause an erroneous result.
- When serial specimens are being evaluated, use the same specimen type throughout the evaluation.
- The ARCHITECT i System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen type is used in the ARCHITECT T-Uptake assay.
- Performance has not been established using body fluids other than human plasma or serum.

Specimen Conditions

- 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.
- Do not use samples with obvious microbial contamination.
- 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.
- Ensure specimens are free of fibrin, red blood cells, and other particulate matter.
- For serum specimens, ensure that complete clot formation has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting times. If the specimen is centrifuged before complete clot formation, the presence of fibrin may cause erroneous results.
- If a lipid layer forms on the specimen surface, avoid the lipid layer when withdrawing the specimen.

Preparation for Analysis

- 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.

Storage

- If testing will be delayed more than 24 hours, remove the plasma or serum from the cells, clot, or gel. Specimens removed from the cells, clot, or gel may be stored up to 14 days at 2-8°C. If testing will be delayed more than 14 days, specimens should be stored frozen (-10°C or colder) prior to being tested. Specimens frozen up to 30 days showed no performance differences from fresh samples.

Shipping

- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances. Prior to shipping, remove the plasma or serum specimen from the cells, clot, or gel. Ship specimens frozen on dry ice.

PROCEDURE

Materials Provided

- 2K48 ARCHITECT T-Uptake Reagent Kit

Materials Required but not Provided

- ARCHITECT i System
- 3K51 ARCHITECT i ASSAY CD-ROM -US- Addition B
- 3K53 ARCHITECT i ASSAY CD-ROM -WW (excluding US)- Addition B
- 2K48-01 ARCHITECT T-Uptake Calibrators
- 2K48-10 ARCHITECT T-Uptake Controls
- ARCHITECT i PRE-TRIGGER SOLUTION
- ARCHITECT i TRIGGER SOLUTION
- ARCHITECT i WASH BUFFER
- ARCHITECT i REACTION VESSELS
- ARCHITECT i SAMPLE CUPS
- ARCHITECT i SEPTUM
- ARCHITECT i REPLACEMENT CAPS
• For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.
• Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

Assay Procedure
• Before loading the ARCHITECT T-Uptake Reagent Kit on the ARCHITECT / System for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  • Invert the microparticle bottle 30 times.
  • Visually inspect the bottle to ensure that microparticles are resuspended. If microparticles are still adhered to the bottle, continue inverting the bottle until the microparticles have been completely resuspended.
  • If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott Laboratories representative.
• 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.
• 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, refer to the ARCHITECT System Operations Manual, Section 5.
  • Load the ARCHITECT T-Uptake Reagent Kit on the ARCHITECT / System.
  • Verify that all necessary assay reagents are present. Ensure that septums are present on all reagent bottles.
• The minimum sample volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be referred to the ARCHITECT System Operations Manual, Appendix B.
  • Priority: 70 μL for the first T-Uptake test plus 20 μL for each additional test from the same sample cup.
  • ≤ 3 hours on board: 150 μL for the first T-Uptake test plus 20 μL for each additional T-Uptake 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.
• Prepare calibrators and controls.
  • ARCHITECT T-Uptake Calibrators and Controls should be mixed according to their respective package inserts.
  • To obtain the recommended volume requirements for the ARCHITECT T-Uptake Calibrators and Controls, hold the bottles vertically and dispense 5 drops of each 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 / 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 assay diluent and microparticles into the RV.
  • Mixes and incubates 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 T-Uptake of the sample.
  • Aspirates contents of RV to liquid waste and unloads RV to solid waste.
  • Calculates the result.
• For information on principles of operation, 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
Samples cannot be diluted for T-Uptake determinations. Samples which read > 1.89 T-Uptake Units should be reported as such.

Calibration
• To perform an ARCHITECT T-Uptake calibration, test Calibrators A, B, C, D, E, and F in duplicate. A single sample of each T-Uptake control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the control package insert. Calibrators should be priority loaded.
  • Calibration Range: 0.0 - 1.9 T-Uptake Units.
  • Once an ARCHITECT T-Uptake 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 T-Uptake 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.

The ARCHITECT T-Uptake Control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and must be retested. Recalibration may be necessary.

Verification of Assay Claims
For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT T-Uptake assay belongs to method group 3. Use ARCHITECT T-Uptake Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.

RESULTS
Calculation
The ARCHITECT T-Uptake assay uses a 4 Parameter Logistic Curve Fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

Alternate Result Units
• The default result unit for the ARCHITECT T-Uptake assay is T-Uptake Units. When selecting the alternate result unit, %Uptake, follow the transformation procedure in the following section.

Transformation of T-Uptake Units to %Uptake
The ARCHITECT / System is programmed to provide the T-Uptake values in T-Uptake Units (dimensionless unit). Values are referenced to a T-Uptake value of 1.0, with 1.0 representing a normal binding capacity. T-Uptake Units are the suggested way to report the ARCHITECT T-Uptake values. This suggestion is based on the ability of the T-Uptake Unit to better compensate for extremes in thyroxine binding protein levels than classical %Uptake calculations.

NOTE: To ensure consistency, report all proficiency testing results in T-Uptake Units. Refer to the EXPECTED VALUES section of this package insert.
The ARCHITECT i System provides an option for transforming the T-Uptake Units to %Uptake equivalents. T-Uptake and %T₃ Uptake both respond to variations in TBG concentration. However, %T₃ Uptake also responds to variations in T₄ levels. Since T-Uptake and %T₃ Uptake do not measure the same exact phenomenon, a direct conversion of units to % transformed is not possible and thus the % transformed value should be viewed as an approximation only.

- The alternate result unit, %Uptake, may be selected for reporting results by configuring “Result units” to %Uptake in the Configure Result units window. In addition to configuring result units, you must edit the general assay parameters “Low Normal Uptake” and “High Normal Uptake” values in the Configure Assay parameters - general view window.
  - Low Normal Uptake is the lower limit value of your reference radioimmunoassay %T₃ Uptake normal range.
  - High Normal Uptake is the upper limit value of your reference radioimmunoassay %T₃ Uptake normal range.

**WARNING:** If the result unit is changed, all previous control information will be lost. Also be aware that this assay is used in a calculated assay formula, and the formula may become invalid if units do not match.

- For information on configuring assay settings, refer to the ARCHITECT System Operations Manual, Section 2.
- The Low Normal Uptake and High Normal Uptake values are used to obtain a mean normal that is factored into the transformed equation. This transformation, which is based on the following equation, is automatically performed by the ARCHITECT i System when the alternate unit, %Uptake, is selected and the Low and High Normal Uptake values are configured accordingly.

\[
\text{Transformed } \%\text{Uptake} = \frac{\text{MEAN NORMAL RANGE}}{0.8(\text{T-Uptake Units})^2 + 0.2}
\]

\[
\text{MEAN NORMAL RANGE} = \frac{\text{LOW NORMAL} + \text{HIGH NORMAL}}{2}
\]

- The ARCHITECT i System will not transform %Uptake results to T-Uptake Units upon completion of a run. Thus, if required, %Uptake can be transformed to T-Uptake Units manually with the following equation.

\[
\text{T-Uptake Units} = \sqrt{\frac{\text{MEAN NORMAL RANGE} / \%\text{Uptake})^2 - 0.2}{0.8}}
\]

\[
\text{MEAN NORMAL RANGE} = \frac{\text{LOW NORMAL} + \text{HIGH NORMAL}}{2}
\]

**NOTE:** If you are reporting results in T-Uptake Units, the Low Normal Uptake and High Normal Uptake values will not need to be edited. They should remain at their default values of “0.00”.

The transformed %Uptake values may differ from measured %T₃ Uptake values on a given specimen for a number of reasons:

- The two assays measure different parameters of thyroxine binding proteins:
  - T-Uptake – Total binding capacity of TBG.
  - %T₃ Uptake – Unsaturated binding capacity of binding proteins.
  - T-Uptake levels for Hypothyroid and Hyperthyroid subjects are generally within the normal range.
  - %T₃ Uptake is sensitive to both binding protein concentration and T₄ levels.

**Calculation of FTI**

- The FTI value can be calculated when both ARCHITECT T-Uptake and ARCHITECT Total T₄ results are obtained for the same sample.
- The ARCHITECT i System (ARCHITECT software version 2.00 or higher) can automatically calculate the FTI value. For information on configuring a calculated assay, refer to the ARCHITECT System Operations Manual, Section 2.

- The ARCHITECT T-Uptake assay better compensates for extreme thyroxine binding protein levels than the transformed %T₃ Uptake value. Therefore, the T-Uptake Unit derived FTI calculation may have better clinical utility in situations of abnormally low or high thyroxine binding protein levels than FTI values derived using transformed %Uptake values.

- The ARCHITECT T-Uptake assay better compensates for extreme thyroxine binding protein levels than the transformed %T₃ Uptake value. Therefore, the T-Uptake Unit derived FTI calculation may have better clinical utility in situations of abnormally low or high thyroxine binding protein levels than FTI values derived using transformed %Uptake values.

**LIMITATIONS OF THE PROCEDURE**

- For diagnostic purposes, the ARCHITECT T-Uptake values should be used in conjunction with a Total T₄ determination to yield the FTI.
- Performance of this assay has not been established with neonatal specimens.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits that employ mouse monoclonal antibodies. Additional clinical or diagnostic information may be required to determine patient status.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. The presence of heterophilic antibodies in a patient specimen may cause anomalous values to be observed. Additional information may be required for diagnosis.

**EXPECTED VALUES**

ARCHITECT T-Uptake values are expressed as dimensionless units with a value of 1.0 representing a normal binding capacity. A reference range study was conducted based on guidance from the National Committee for Clinical Laboratory Standards (NCCLS) Protocol C28-A2. The suggested range for ARCHITECT T-Uptake is 0.69 – 1.41 T-Uptake Units. The suggested FTI range is 5.06 - 9.42 μg/dL. These ranges (central 95%) represent the T-Uptake values obtained by testing 150 specimens classified as normal by the ARCHITECT TSH and ARCHITECT Free T₄ assays. Due to differences in calculation methods, normal ranges may vary for different methodologies. Normal ranges may also vary across populations. It is recommended that each laboratory establish its own normal ranges. Women who are pregnant or taking oral contraceptives can be expected to have elevated T-Uptake values. Individuals with low serum TBG levels will tend to have a lower T-Uptake value than normal.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Precision**

The ARCHITECT T-Uptake assay precision is ≤ 7% total CV for samples ≥ 0.49 T-Uptake Units. A study was performed with the ARCHITECT T-Uptake assay based on guidance from the NCCLS Protocol EP5-A. Samples were assayed in replicates of two at two separate times per day for 20 days. Data from this study are summarized in the following table.

**NOTE:** When configuring a calculated assay, the created formula must use units that are consistent with the result units currently selected for the ARCHITECT T-Uptake assay.

**NOTE:** PROFICIENCY TESTING RESULTS

To ensure consistency, all proficiency testing results should be reported in T-Uptake Units. Do not report transformed %Uptake values because reference ranges differ between laboratories and will not accurately reflect inter-laboratory variation.
Within Run Total

Potentially Interfering yield samples with values of 0.57 and 1.80 T-Uptake Units. These samples

Triglycerides 2000 mg/dL
Total Protein (High) 10 g/dL
Bilirubin 20 mg/dL

Interference from elevated levels of bilirubin, hemoglobin, Interference due to T4 autoantibodies is not expected. Such antibodies form soluble complexes that would be removed during the wash step of the assay.

Potential interference from elevated levels of bilirubin, hemoglobin, triglycerides, and total protein in the ARCHITECT T-Uptake assay is ≤ 10%. Ten specimens positive for HAMA and ten specimens positive for RF were evaluated for % Interference. Known amounts of TBG were added to the specimens, yielding samples with values between 1.34 and 1.64 T-Uptake Units. Results are summarized in the following table.*

<table>
<thead>
<tr>
<th>Lot</th>
<th>2</th>
<th>1</th>
<th>49</th>
<th>36</th>
<th>3.51</th>
<th>0.018</th>
<th>1.31</th>
<th>0.062</th>
<th>2.97</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>1</td>
<td>80</td>
<td>1.30</td>
<td>0.013</td>
<td>0.97</td>
<td>0.032</td>
<td>2.44</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Panel 2 1 2 1 80 0.32 | 0.010 | 0.78 | 0.018 | 1.35 |

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

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

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

Evaluation of Potentially Interfering Clinical Conditions

The ARCHITECT T-Uptake assay was evaluated using specimens with HAMA and Rheumatoid Factor (RF) to further assess the clinical specificity. Interference from these specimen types in the ARCHITECT T-Uptake assay is ≥ 10%. Ten specimens positive for HAMA and ten specimens positive for RF were evaluated for % Interference. Known amounts of TBG were added to the specimens, yielding samples with values between 1.34 and 1.64 T-Uptake Units. Results are summarized in the following table.*

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>Number of Specimens</th>
<th>% Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAMA</td>
<td>10</td>
<td>-2.0</td>
</tr>
<tr>
<td>RF</td>
<td>10</td>
<td>-9.2</td>
</tr>
</tbody>
</table>

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

High Dose Hook

High dose hook is a phenomenon whereby very high level specimens may read within the dynamic range (0.2 - 1.9 T-Uptake Units) of the assay. For the ARCHITECT T-Uptake assay, no high dose hook effect was observed when a high sample (12 mg/dL TBG > 1.89 T-Uptake Units) was assayed.

Accuracy by Correlation

The ARCHITECT T-Uptake assay was compared to the Abbott AxSYM T-Uptake assay. The method comparison correlation coefficient (r) is ≥ 0.95 and the method comparison slope is 1.0 ± 0.20. Data from the study were analyzed using the Passing-Bablok regression method. Results are summarized in the following table.*

<table>
<thead>
<tr>
<th>Regression Method</th>
<th>n</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>Correlation Coefficient (r)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passing-Bablok**</td>
<td>338</td>
<td>1.019</td>
<td>0.027</td>
<td>0.956</td>
</tr>
<tr>
<td></td>
<td>(1.000 -1.059)</td>
<td>(-0.004 - 0.050)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

BIBLIOGRAPHY


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