Free T3
Abbott AxSym

INTENDED USE

AxSYM Free T3 is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of free triiodothyronine (free T3) in human serum or plasma on the AxSYM System.

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 T3 among these binding proteins is controversial as estimates range from 38 - 80% for TBG, 9 - 27% for prealbumin, and 11 - 35% for albumin. The binding of these proteins is such that only 0.2 - 0.4% of the total T3 is present in solution as unbound or free T3 (FT3). This free fraction represents the physiologically active thyroid hormone.

FT3 is typically elevated to a greater degree than free T4 (FT4) in Graves’ disease and in toxic adenomas. Occasionally, FT3 alone is elevated (T3 thyrotoxicosis) in about 5% of the hyperthyroid population. In contrast, levels of FT4 are elevated to a greater degree than FT3 in toxic multinodular goiter and excessive T4 therapy. Serum FT3 is useful in distinguishing these forms of hyperthyroidism. FT3 may also be important in monitoring patients on antithyroid therapy where treatment is focused on reducing the T3 production and the T4 conversion to T3. Serum FT3 may also be useful in assessing the severity of the thyrotoxic state.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

AxSYM Free T3 is based on the Microparticle Enzyme Immunoassay (MEIA) technology.

The AxSYM Free T3 reagents and sample are pipetted in the following sequence:

SAMPLING CENTER

1. Sample and all AxSYM Free T3 reagents required for one test are pipetted by the Sampling Probe into various wells of a reaction vessel (RV).

2. The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe.
PROCESSING CENTER

1. Sample and Anti-T3 Coated Microparticles are combined in one RV well.

2. The free (unbound) T3 in the sample binds to the Anti-T3 Coated Microparticles forming an antibody-antigen complex.

3. An aliquot of the reaction mixture, containing the antibody-antigen complex bound to the microparticles, is transferred to the matrix cell. The microparticles bind irreversibly to the glass fiber matrix.

4. The T3:Alkaline Phosphatase Conjugate is dispensed onto the matrix cell and binds to the available sites on the Anti-T3 Coated Microparticles.

5. The matrix cell is washed to remove unbound materials.

6. The substrate, 4-Methylumbelliferyl Phosphate, is added to the matrix cell and the fluorescent product is measured by the MEIA optical assembly.

For further information regarding MEIA technology, refer to the AxSYM System Operations Manual, Section 3.

REAGENTS

REAGENT PACK, 100 TESTS

AxSYM FREE T3 REAGENT PACK (7A53-20)*

1. 1 Bottle (13.95 mL) LDS Wash Buffer containing surfactant. (Reagent Bottle 1)

2. 1 Bottle (13.55 mL) T3:Alkaline Phosphatase Conjugate in TRIS Buffer with protein (bovine) stabilizers. Minimum concentration: 0.4 ng/mL. Preservative: Sodium Azide. (Reagent Bottle 2)

3. 1 Bottle (10.16 mL) Anti-T3 (Sheep, Monoclonal) Coated Microparticles in TRIS Buffer with protein (bovine and ovine) stabilizers. Preservative: Sodium Azide. (Reagent Bottle 3)

4. 1 Bottle (50.20 mL) TRIS Buffer. Preservatives: Sodium Azide and Antimicrobial Agents. (Reagent Bottle 4) *7A53-66 includes an AxSYM Free T3 Reagent Pack (100 tests), reaction vessels (100 each), and matrix cells (100 each). 7A53-20 includes these items for international shipment.
CALIBRATORS

AxSYM FREE T3 CALIBRATORS (7A53-02)

6 Bottles (4 mL each) of Free T3 Calibrators containing T3 in processed human serum, nonreactive for HBsAg, HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2, to yield the following concentrations:

<table>
<thead>
<tr>
<th>Bottle</th>
<th>Free T3 Concentration (pg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0</td>
</tr>
<tr>
<td>B</td>
<td>140</td>
</tr>
<tr>
<td>C</td>
<td>350</td>
</tr>
<tr>
<td>D</td>
<td>700</td>
</tr>
<tr>
<td>E</td>
<td>1500</td>
</tr>
<tr>
<td>F</td>
<td>3000</td>
</tr>
</tbody>
</table>

Preservative: Sodium Azide

NOTE: The AxSYM will print out Free T3 results in pg/mL but Mysis will report Free T3 results in pg/dL. (pg/mL x 100 = pg/dL)

Unit in use is pg/dL

CONTROLS

BioRad Immunoassay Plus Control 1, 2 & 3

Each control is reconstituted with 5.0 mL of Type 1 deionized water. The reconstituted controls are stable for 7 days when stored at 2-8°C.

OTHER REAGENTS

Solution 1 (MUP) (NO. 8A47-04)

4 Bottles (230 mL each) Solution 1 (MUP) containing 4-Methylumbelliferyl Phosphate, 1.2 mM, in AMP Buffer. Preservative: Sodium Azide.

Solution 3 (Matrix Cell Wash) (NO. 8A81-04)

4 Bottles (1000 mL each) Solution 3 (Matrix Cell Wash) containing 0.3 M Sodium Chloride in TRIS Buffer. Preservatives: Sodium Azide and Antimicrobial Agents.

Solution 4 (Line Diluent) (NO. 8A46)

1 Bottle (10 L) Solution 4 (Line Diluent) containing 0.1M Phosphate Buffer.
Preservatives: Sodium Azide and Antimicrobial Agents.

AxSYM Probe Cleaning Solution (NO. 9A35-05)
2 Bottles (220 mL each) AxSYM Probe Cleaning Solution containing 2% Tetraethylammonium Hydroxide (TEAH).

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

SAFETY PRECAUTIONS

1. The AxSYM Probe Cleaning Solution (2% TEAH) may cause mild eye irritation. If this solution comes into contact with eyes, rinse immediately with water. If irritation persists, seek medical attention.

2. Some components of this product contain Sodium Azide. For a specific listing, refer to the REAGENTS section of this package insert. The components containing Sodium Azide are classified per applicable European Community (EC) Directives as: Harmful (Xn).

The following are the appropriate Risk (R) and Safety (S) phrases.

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.
S35 This material and its container must be disposed of in a safe way.
S36 Wear suitable protective clothing.
$46 If swallowed, seek medical advice immediately and show this container or label.

HANDLING PRECAUTIONS

1. Do not use Solution 1 (MUP) beyond the expiration date or a maximum of 14 days on-board the AxSYM System. When loading new Solution 1 (MUP), it is important to immediately tighten the instrument cap for MUP to minimize exposure to air. Prolonged exposure of MUP to air may compromise performance.

2. Do not use Reagent Pack beyond the expiration date or a maximum of 112 cumulative hours on-board the AxSYM System.

3. Do not mix reagents from different reagent packs.

Refer to the AxSYM System Operations Manual, Sections 7 and 8, for a more detailed discussion of the safety and handling precautions during system operation.

STORAGE INSTRUCTIONS

The AxSYM Free T3 Reagent Pack must be stored at 2 to 8°C (do not freeze). The Free T3 Calibrators and Free T3 Controls must be stored at 2 to 8°C. The AxSYM
Free T3 Reagent Pack, Calibrators, and Controls may be used immediately after removing them from the refrigerator. Calibrators and Controls should be returned to 2 to 8°C storage immediately after use. Reagents are stable until the expiration date when stored and handled as directed.

The AxSYM Free T3 Reagent Pack may be on-board the AxSYM System for a maximum of 112 cumulative hours; for example, 14 eight hour shifts. After 112 hours, the reagent pack must be discarded. Refer to the AxSYM System Operations Manual, Sections 2, 5, and Appendix C, for further information on tracking on-board time.

**Solution 1 (MUP) must be stored at 2 to 8°C (do not freeze). It may be used immediately after removing it from the refrigerator. MUP may be on-board the AxSYM System for a maximum of 14 days. After 14 days, it must be discarded.**

The AxSYM Probe Cleaning Solution, Solution 3 (Matrix Cell Wash) and Solution 4 (Line Diluent) must be stored at 15 to 30°C.

**INSTRUMENT PROCEDURE**

**ASSAY FILE INSTALLATION**

The AxSYM Free T3 assay file must be installed on the AxSYM System from one of the following software disks, prior to performing Free T3 assays:

- 3D52-02
- 2G37-01, or higher

Refer to the AxSYM System Operations Manual, Section 2, for proper installation procedures.

**AXSYM FREE T3 ASSAY PARAMETERS**

The default values for the visible assay parameters used for the AxSYM Free T3 assay are listed below. Assay parameters that can be edited contain a (>) symbol. These parameters can be displayed and edited according to the procedure in the AxSYM System Operations Manual, Section 2. However, some parameters that contain a (>) symbol may not be editable if there are no additional options. In order to obtain values for the parameters with an asterisk (*), review the specific Assay Parameter screen. Press PRINT to print the assay parameters.

<table>
<thead>
<tr>
<th>Assay Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Long Assay Name (English): FREE_T3</td>
</tr>
<tr>
<td>6 Abbrev Assay Name (English): FT3</td>
</tr>
<tr>
<td>11 Assay Number: 282</td>
</tr>
</tbody>
</table>
12 Assay Version: *
13 Calibration Version: *
14 Assay File Revision: *
15 Assay Enabled > ON
17 Assay Type: MEIA
18 Standard Cal Reps > 2
19 Master Cal Reps: 0
21 Cal A Concentration: 0.00
22 Cal B Concentration: 1.40
23 Cal C Concentration: 3.50
24 Cal D Concentration: 7.00
25 Cal E Concentration: 15.00
26 Cal F Concentration: 30.00
43 Default Dilution Protocol > UNDILUTED
44 Default Calibration Method > Standard Cal
45 Selected Result Concentration Units > pg/mL
46 Selected Result Decimal Places > 2
64 Max Intercept-Max MUP intercept: *
65 Min Intercept-Min MUP intercept: *
66 Upper limit for NRMSE for low rates: *
67 Upper limit for NRMSE for high rates: *
68 Max Rate-Max rate used to check Min MUP Intercept: *
69 Min Rate-Rate cutoff for NRMSE and Corr. Coef.: *
70 Min correlation coefficient for low rates: *
71 Min correlation coefficient for high rates: *
72 MUP T Delay-Time delay following MUP: *
73 Low Limit-Normal/Therapeutic Range lower limit > 0.00
74 High Limit-Normal/Therapeutic Range upper limit > 0.00
75 Low Extreme Value > 0.00
76 High Extreme Value > 0.00
91 Low Range Undiluted: *
92 High Range Undiluted: *

NOTE: Parameter 45 can be edited to the alternate result unit, pmol/L.


SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

1. Serum [including serum collected in serum separator tubes (SST)] or plasma (collected in lithium heparin, sodium heparin or dipotassium EDTA) may be used in the AxSYM Free T3 assay. Follow the manufacturer's processing instructions for serum or plasma collection tubes.

2. The AxSYM System does not provide the capability to verify sample type. It is the responsibility of the operator to verify the correct sample type(s) is(are) used in the AxSYM Free T3 assay.
3. Ensure that complete clot formation has taken place prior to centrifugation. Some samples, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the sample is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.

4. For optimal results, samples should be free of fibrin, red blood cells, or other particulate matter.

5. Patient samples should be mixed and centrifuged after any freeze-thaw cycle or to remove red blood cells or particulate matter.

6. Multiple freeze-thaw cycles should be avoided. Samples must be mixed **thoroughly** after thawing, by LOW speed vortexing or by gently inverting, then centrifuged prior to use to remove particulate matter, and to ensure consistency in the results.

7. If testing will be delayed more than 24 hours, serum or plasma should be separated from the clot or red blood cells. Samples may be stored for up to 48 hours at 2 to 8°C prior to being tested. If testing will be delayed more than 48 hours, samples should be stored frozen at -10°C or colder. Samples stored frozen at -10°C or colder for six months did not show performance differences.

8. To minimize the effects of evaporation, all samples (patient samples, controls and calibrators) should be tested within three hours of being placed on-board the AxSYM System. Refer to the AxSYM System Operations Manual, Section 5, for a more detailed discussion of on-board sample storage constraints.

9. Inspect all samples for bubbles. Remove bubbles prior to analysis.

10. When shipped, samples must be packaged and labeled in compliance with applicable federal and international regulations covering the transport of clinical samples and etiologic agents.

**SAMPLE VOLUME**

The sample volume required to perform a single Free T3 test on the AxSYM System varies depending on the type of sample container used. For sample cups, both ROUTINE and STAT tests require **180 µL**. For every additional Free T3 test performed (ROUTINE or STAT) from the same sample container, an additional 130 µL of sample is required.

The sample cup minimum volumes for both STAT and ROUTINE tests are calculated by the AxSYM System. They are displayed on the Order screen at the time the test(s) is(are) ordered and printed on the Orderlist Report. When using Host Order Query, the Order screen information and the Orderlist Report are not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query option.

Refer to the AxSYM System Operations Manual, Section 5, for sample volume requirements in primary or aliquot tubes and calibrator/control requirements for multiple reagent lots.
**AxSYM Free T3 PROCEDURE**

**MATERIALS PROVIDED**

No. 7A53-66 AxSYM Free T3 Reagent Kit, containing:

1. AxSYM Free T3 Reagent Pack
2. 100 reaction vessels
3. 100 matrix cells

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. NO. 7A53-02 AxSYM Free T3 Calibrators
2. NO. 8A47-04 Solution 1 (MUP)
3. NO. 8A81-04 Solution 3 (Matrix Cell Wash)
4. NO. 8A46 Solution 4 (Line Diluent)
5. NO. 9A35-05 AxSYM Probe Cleaning Solution
6. NO. 8A76-01 Sample Cups
7. Pipettes or pipette tips (optional) to deliver the volumes specified on the Order screen

**CAUTION:**

1. When manually dispensing sample into sample cups, verify that dispensing equipment does not introduce cross contamination and delivers the specified sample volume. Use a separate pipette tip for each sample. Use accurately calibrated equipment.
2. For optimal performance, it is important to follow the routine maintenance procedures defined in the AxSYM System Operations Manual, Section 9.

**ASSAY PROCEDURE**

Sections 5 and 6 of the AxSYM System Operations Manual contain detailed steps for performing assay calibration and sample testing procedures.

Prior to ordering tests, confirm that the System inventory of matrix cells, bulk solutions, and waste levels are acceptable.

The Orderlist Report contains sample placement information and sample cup volume
requirements for all ordered tests. It is recommended that this report be referenced when loading samples into sample segments. When using Host Order Query, the Orderlist Report is not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query Option.

**CAUTION:** When operating the AxSYM System, always observe the following:

1. The System status must be WARMING, PAUSED, READY, or STOPPED before adding or removing sample segments, reagent packs or reaction vessels (RV’s).

2. Do not open the Interior Waste Door or the AxSYM Processing Center Cover while any test is in process. If opened, all processing will stop. Tests in process will be terminated and must be repeated.

3. When testing is completed, it is recommended that samples and the AxSYM Free T3 Reagent Pack are removed from the Sampling Center to maximize the on-board reagent pack use. Store at 2 to 8°C.

**SAMPLE DILUTION PROCEDURES**

Samples **cannot** be diluted for Free T3 determinations.

**QUALITY CONTROL PROCEDURES**

**CALIBRATION**

The AxSYM Free T3 assay must be calibrated using a Standard Calibration (6-point) procedure.

**STANDARD CALIBRATION**

To perform an AxSYM Free T3 Standard Calibration, test the Calibrators A, B, C, D, E, and F in duplicate. A single sample of all levels of free T3 controls must be tested as a means of evaluating the assay calibration.

Once the AxSYM Free T3 calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

1. A reagent pack with a new lot number is used.
2. Controls are out of range.

Refer to the AxSYM System Operations Manual, Section 6, for:

1. Setting up an assay calibration
2. When recalibration may be necessary
3. Calibration verification
The AxSYM System verifies that the results of an assay calibration meet the specifications assigned to selected validity parameters. An error message occurs when the calibration fails to meet a specification. Refer to the AxSYM System Operations Manual, Section 10, for an explanation of the corrective actions for the error code. Refer to the AxSYM System Operations Manual, Appendix E, for an explanation of the calibration validity parameters that may be used by the AxSYM System.

QUALITY CONTROL

The recommended control requirement for the AxSYM Free T3 assay is a single sample of all free T3 control levels tested once every 24 hours each day of use. Controls may be placed in any position in the Sample Carousel.

To achieve maximum on-board stability, more frequent use of controls may be required to monitor reagent performance within the same lot.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

When a free T3 control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and require retesting. Assay recalibration may be indicated.

Refer to the AxSYM System Operations Manual, Section 10, for further troubleshooting information.

FLUORESCENCE BACKGROUND ACCEPTANCE CRITERIA

Quality Control with regards to the MUP substrate blank is automatically determined by the instrument and checked under Assay Parameter 64, Max Intercept-Max MUP intercept, each time a test result is calculated. If the MUP intercept value is greater than the maximum allowable value, the result is invalid. The test request will be moved to the Exceptions List where it will appear with the message “1064 Invalid test result, intercept too high” and the calculated intercept value. Refer to the AxSYM System Operations Manual, Section 10, when this error message is obtained.

Refer to the AxSYM System Operations Manual, Section 2, for further information on this parameter.

RESULTS

The AxSYM Free T3 assay utilizes a Four-Parameter Logistic Curve Fit method (4PLC, Y weighted) to generate a calibration curve. Refer to the AxSYM System Operations Manual, Appendix F, for further information.
Samples cannot be diluted for free T3 determinations. Test results reading greater than 2500 pg/dL should be reported as >2500 pg/dL.

ALTERNATE RESULT UNIT

The default result unit for AxSYM Free T3 is pg/mL. When selecting the alternate result unit, pmol/L, the conversion factor used by the AxSYM System is 1.536. To convert from pg/mL to pg/dL, multiply by 100.

NOTE: Misys will automatically convert the pg/mL reported out by the AxSYM into pg/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 AxSYM System Operations Manual, Sections 1 and 2.

LIMITATIONS OF THE PROCEDURE

1. For diagnostic purposes, the AxSYM Free T3 results should be used in conjunction with other data; e.g., symptoms, results of other thyroid tests, clinical impressions, etc.

2. Performance of this assay has not been established with neonatal specimens.

Refer to the SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert for additional information.

EXPECTED VALUES

Specimens from 1,275 apparently healthy individuals and from 104 patients described as "sick euthyroids" were evaluated using the AxSYM Free T3 assay. The normal range was calculated from the 1,275 specimens and was found to be 145 to 348 pg/dL.

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.\(^\text{14,15}\)

Elevated thyroxine binding globulin (TBG) in pregnancy is a condition in which low to normal free T3 levels are observed.

Specimens from patients described as the “sick euthyroids” generally yield values in the low to normal range.\(^\text{16,17}\)
REPORTING RESULTS

1. Report values less than 110 pg/dL as <110 pg/dL.

2. Report values greater than 2000 pg/dL as >2000 pg/dL.

SPECIFIC PERFORMANCE CHARACTERISTICS

PRECISION

Precision was determined as described in National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-T218 (including an estimate of between run and between day precision). A three member processed human serum based panel was assayed, in replicates of two, at two separate times per day, for twenty days, using a single lot of reagents and a single calibration per instrument. Data from this study are summarized in the following table.

**PANEL MEMBER 1**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>n</th>
<th>Mean Conc. Value (pg/dL)</th>
<th>Within Run</th>
<th>Between Run</th>
<th>Between Day</th>
<th>Total Run</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD</td>
<td>CV (%)</td>
<td>SD</td>
<td>CV (%)</td>
</tr>
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<tr>
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<td>80</td>
<td>273</td>
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<td>3.12</td>
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<tr>
<td>5</td>
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<td>310</td>
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**PANEL MEMBER 2**

<table>
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<tr>
<th>Instrument</th>
<th>n</th>
<th>Mean Conc. Value (pg/dL)</th>
<th>Within Run</th>
<th>Between Run</th>
<th>Between Day</th>
<th>Total Run</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD</td>
<td>CV (%)</td>
<td>SD</td>
<td>CV (%)</td>
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**PANEL MEMBER 3**

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<tr>
<th>Instrument</th>
<th>n</th>
<th>Mean Conc. Value (pg/dL)</th>
<th>Within Run</th>
<th>Between Run</th>
<th>Between Day</th>
<th>Total Run</th>
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<td></td>
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<td>30.3</td>
<td>2.84</td>
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</tr>
</tbody>
</table>
SENSITIVITY

The sensitivity of the AxSYM Free T3 assay was calculated to be better than 110 pg/dL at the 95% confidence interval (n = 24 runs in replicates of 10). This sensitivity is defined as the concentration at two standard deviations from the Free T3 Calibrator A (0 pg/dL) and represents the lowest measurable concentration of free T3 that can be distinguished from zero.

SPECIFICITY

The specificity of the AxSYM Free T3 assay was determined by studying the cross reactivity of the antibody used in the AxSYM Free T3 assay. Human serum specimens were supplemented with 24,000,000 pg/dL of L-T4 and assayed for free T3 activity. Crossreactivity of L-T4 has been shown to be <0.001%.

CARRYOVER

Carryover from a sample reading greater than 3000 pg/dL (estimated to be 5000 pg free T3/dL) to an adjacent 0.0 pg free T3/dL sample was determined to be <1%.

INTERFERENCE

Specimens with triglycerides (up to 2000 mg/dL), hemoglobin (up to 1000 mg/dL) and bilirubin (up to 20 mg/dL) interfered less than 10% with the determination of Free T3 using the AxSYM Free T3 assay.

REFERENCE


19. ABBOTT Free T3 package insert, January 2003