T3

Triiodothyronine

200 tests

<table>
<thead>
<tr>
<th>cobas e 601</th>
<th>cobas e 411</th>
<th>MODULAR ANALYTICS ¥TICS E170</th>
<th>Elecsys 2010</th>
<th>Elecsys 1010</th>
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- Indicates analyzers on which the kit can be used

English

Intended use

Immunoe assay for the in vitro quantitative determination of total triiodothyronine in human serum and plasma.

The electrochemiluminescence immunooassay "ECLA" is intended for use on Elecsys and cobas e immunoeassay analyzers.

Summary

Triiodothyronine (T3) is the hormone principally responsible for the development of the effects of the thyroid hormones on the various target organs.

T3 (3,5,3′-triiodothyronine) is mainly for med extrahepatically, particularly in the liver, by enzymatic 5′-deiodination of T4. Accordingly, the T3 concentration in serum is more a reflection of the functional state of the peripheral tissue than the secretory performance of the thyroid gland.

A reduction in the conversion of T4 to T3 results in a decrease in the T3 concentration. It occurs under the influence of medications such as propranolol, glucocorticoids or amiodarone and in severe non-thyroidal illness (NTI), and is referred to as "low T3 syndrome". As with T4, over 99 % of T3 is bound to transport proteins. However, the af finity of T3 to them is around 10^5-fold lower.

The determination of T3 is utilized in the diagnosis of T3 hyperthyroidism, the detection of early stages of hypothyroidism and for indicating a diagnosis of thyrotoxicosis factitia.

The Elecsys T3 assay employs a competitive test principle with polyclonal antibodies specifically directed against T3. Endogenous T3, released by the action of deiodination of T4, after the addition of the labeled antibody becomes free binding sites on the antibodies labeled with the ruthenium complex.

Test principle

Competition principle. Total duration of assay: 18 minutes.

- 1st incubation: 30 µL of sample and a T3-antibody labeled with a ruthenium complex; bound T3 is released from the binding proteins in the sample by ANS.

- 2nd incubation: After addition of streptavidin-coated microparticles and biotinylated T3, the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin.

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a volt age to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

- Results are deter mined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

Reagents - working solutions

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL; Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-T3-Ab-Ru(bpy) 6 (gray cap), 1 bottle, 16 mL; Polyclonal anti-T3-antibody (sheep) labeled with ruthenium complex 75 ng/mL; ANS 0.8 mg/mL; phosphate buffer 100 mmol/L, pH 7.4; preservative.

R2 T3-biotin (black cap), 1 bottle, 16 mL; Biotinylated T3 3 ng/mL; ANS 0.8 mg/mL; phosphate buffer 100 mmol/L, pH 7.4; preservative.

Specimen collection and pre processing

Only the specimens listed below were tested and found acceptable. Serum collected using standard sampling tubes or tubes containing separating gel.

- Li-, Na-, NH4-heparin, K3-EDTA , sodium citrate, and sodium fluoride/potassium oxalate plasma.

Criterion: Recover y within 90-110 % of serum value or slope 0.9-1.1 ± 2 x analytical sensitivity (DL) = coefficient of correlation > 0.95. Stable for 7 days at 2-8 °C, 1 month at -20 °C. Freeze only once.

The samples types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturer s were tested. Sample collection systems from various manufacturer s may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer. Centrifuge samples containing precipitates before processing the assay. Do not use heat-inactivated samples. Do not use samples and controls stabilized with azide.

Ensure the patients’ samples, calibrator s, and controls are at ambient temperature (20-25 °C) before measurement. Because of possible evaporation of efcs, samples, calibrator s, and controls on the analyzers should be measured within 2 hours.

Materials provided

See “Reagents - working solutions” section for reagents.

Materials required (but not provided)

- Cat. N o. 117315 48122, T3 CalSet, for 4 x 1 mL
- Cat. N o. 11731416122, PreciControl Univer sal, for 2 x 3 mL each of PreciControl Univer sal 1 and 2
- Cat. N o. 11731416190, PreciControl Univer sal, for 2 x 3 mL each of PreciControl Univer sal 1 and 2
- Cat. N o. 11731416160, PreciControl Univer sal, for 2 x 3 mL each of PreciControl Univer sal 1 and 2 (for USA)
- General laborator y equipment
- Elecsys 1010/2010, MODULAR ANALYTICS ¥TICS E170 or cobas e analyzer

Accessories for Elecsys 1010/2010 and cobas e 411 analyzers:
- Cat. N o. 11662988122, ProCell, 6 x 380 mL system buffer
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- Cat. No. 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- Cat. No. 11935342122, Elycsys SysWash, 1 x 500 mL washwater additive
- Cat. No. 11933159001, Adapter for SysClean
- Cat. No. 11708260011, Elycsys 1010 AssayCup, 12 x 32 reaction vessels
- Cat. No. 11706799001, Elycsys 2010 AssayTip, 30 x 120 pipette tips

Accessories for MODULAR ANALYTICS TICS E170 and cobas e 601 analyzers:
- Cat. No. 4880340190, ProCell M, 2 x 2 L system buffer
- Cat. No. 4880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- Cat. No. 1213527190, CleanCell M, 1 x 2 L measuring cell cleaning solution (for USA)
- Cat. No. 03023141001, PC/CC-Cups, 12 cups to prewash ProCell M and CleanCell M before use
- Cat. No. 0300571290, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- Cat. No. 0302137001, AssayTip-AssayCup Combination package, 46 magazines x 8 reaction vessels or pipette tips, waste bags
- Cat. No. 0302315001, WasteLiner, waste bags
- Cat. No. 03027651001, SysClean Adapter M

Accessories for all analyzers:
- Cat. No. 11298500316, Elycsys SysClean, 5 x 100 mL system cleaning solution

Only available in the USA:
- Cat. No. 11776690160, Elycsys T3 CalCheck, 3 concentration ranges

**Assay**

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically before use. Read in the test-specific parameter(s) via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

**MODULAR ANALYTICS TICS E170, Elycsys 2010 and cobas e analyzers:** Bring the cooled reagents to approx. 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid the formation of foam. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Elycsys 1010 analyzer: Bring the cooled reagents to approx. 20-25 °C and place on the sample/reagent disk of the analyzer (ambient temperature 20-25 °C). Avoid the formation of foam.

Open bottle caps manually before use and close manually after use. Store at 2-8 °C after use.

**Calibration**

**Traceability:** This method has been standardized against reference standards for measuring T3 into analyte-free human serum matrix. Ever y Elycsys T3 reagent set has a barcoded weighing T3 into analyte set. The assay is unaffected by icterus (bilirubin < 599 µmol/L or < 35 mg/dL), hemolysis (Hb < 1.2 mmol/L or < 2.0 g/dL), lipemia (intralipid < 1800 mg/dL), and biotin < 40.9 mmol/L or < 10 ng/mL.

**Criterion:** Recover y within ± 10 % of initial value.

In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration.

N o inter ference was observed from rheumatoid factor s up to a concentration of 1500 IU/mL and samples from dialysis patients. N o inter ference with the assay was found.

Therapy with amiodarone can lead to depressed T3 values. Phenylthioethylbutylazene, and salicylates cause release of T3 from the binding proteins, thus leading to a reduction in the total T3 hormone level at normal T3 levels.

Autoantibodies to thyroid hormones can interfere with the assay. Binding protein anomalies seen with FH (familial dysautoimmunenic hyperthyroxinemia), for example, may cause values which, while characteristic of the condition, deviate from the expected results. Pathological concentrations of binding proteins (TBG, albumin) can lead to total T3 values outside the normal range being found despite a euthyroid metabolic state (e.g. in N T1 -patients, pregnancy, use of oral contraceptives). In such cases a T3 or FT4 determination is indicated.

In rare cases, interference due to extremely high titer s of antibodies to analyze-specific antibodies, streptavidin or ruthenium can occur. These ef fects are minimized by suitable test design.

**Measuring range**

0.300-10.00 nmol/L or 0.195-6.51 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as < 0.300 nmol/L or < 0.195 ng/mL. Values above the measuring range are reported as > 10.00 nmol/L or > 6.51 ng/mL.

**Dilution**

N o necessary due to the broad measuring range.

**Expected values**

1.3-3.1 nmol/L or 0.8-2.0 ng/mL - guthyroid

The values correspond to the 2.5th and 97.5th percentiles of findings from a total of 514 healthy test subjects.

**Status:** MCE Elycsys 2010, status 1996, verified 1st quarter 1998

For specific information about reference inter vals in children, adolescents and pregnant women, refer to the brochure “Reference Intervals for Children and Adults”. Cat. N o. English: 0 46 40290, German: 0 46 25889.

This booklet also contains results of a detailed study about influencing factor s on thyroid parameter s in a well characterized reference group of adults. Different inclusion and exclusion criteria were applied (e.g. sonographic results (thyroid volume and density) as well as criteria according to the guidelines of the National Academy of Clinical Biochemistry - NACB).

Each laborator y should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.
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**Specific performance data**

Representative performancer data on the analyzers are given below. Results obtained in individual laboratories may differ.

**Precision**

Reproducibility was determined using Elecsys reagents, pooled human sera, and controls in a modified protocol (EPS-A) of the N CCLS (National Committee for Clinical Laboratory Standards): 6 times daily for 10 days (n = 60); within-run precision on MODULAR ANALYTICS E170 analyzer, n = 21. The following results were obtained:

<table>
<thead>
<tr>
<th>Method</th>
<th>Total precision</th>
<th>Within-run precision</th>
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<tbody>
<tr>
<td></td>
<td>CV %</td>
<td>SD nmol/L</td>
</tr>
<tr>
<td>Elecsys 1010/2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.4</td>
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<td>MODULAR ANALYTICS E170</td>
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<td></td>
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Analytical sensitivity (lower detection limit)

0.300 nmol/L or 0.195 ng/mL

The lower detection limit represents the lowest analyte level that can be distinguished from zero.

**Method comparison**

A comparison of the Elecsys T3 assay (y) with the Enzymun-Test T3 method (x) using clinical samples gave the following correlations (nmol/L): Number of samples measured: 300

<table>
<thead>
<tr>
<th>Linear regression</th>
<th>Passing/Bablok</th>
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<tbody>
<tr>
<td>y = 1.18x - 0.35</td>
<td>y = 1.26x - 0.56</td>
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<tr>
<td>r = 0.957</td>
<td>r = 0.754</td>
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The sample concentrations were between approx. 0.5 and 9 nmol/L (0.3 and 5.9 ng/mL).

**Analytical specificity**

For the antibody derivative used, the following cross-reactivities were found: D-T3 = 100 %; L-T4 < 0.16 %; D-T4 = 0.16 %; L-T3 < 0.04 %; L-T2 < 1.0 %; 3,3',5,5'-tetraiodothyroacetic acid 106 %; 3,3',5,5'-tetraiodothyroacetic acid < 0.01 %.

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**References**


For further information, please refer to the appropriate operator’s manual for the analyzer concerned, the respective application sheets, the product information, and the packaging inserts of all necessary components.

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