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Tg Confirmatory Test

cobas®

Tg Confirmatory Test

REF	Σ	SYSTEM
05107555 190	50	Elecsys 2010 MODULAR ANALYTICS E170 **cobas e** 411 **cobas e** 601 **cobas e** 602

English

Intended use

Tg Confirmatory Test is intended for use in combination with the Elecsys Tg determination to assess potential interference effects and as an aid to confirm the respective Tg results.

Summary

Thyroglobulin (Tg) determinations can be affected by the presence of anti-thyroglobulin antibodies (anti-Tg) or by non-specific effects in patient samples.[1] Tg results should therefore either be verified with a Tg confirmatory test which is based on the principle of specific antibody neutralisation (e.g. Elecsys Tg Confimatory Test) or confirmed by the determination of anti-Tg autoantibodies (e.g. Elecsys Anti-Tg assay).

Test principle

Elecsys Tg Confirmatory Test:

The test principle is based on pretreatment of the samples with confirmatory reagent followed by the assay procedure using the Elecsys Tg assay. During this pretreatment antibodies in the patient sample are neutralized by the binding to the immunodominant epitopes of the Tg contained in the confirmatory reagent.

Elecsys Tg assay:

- 1st incubation: Tg from 20 µL of sample, a biotinylated monoclonal Tg-specific antibody, and a monoclonal Tg-specific antibody labeled with a ruthenium complex[a)] react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the 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/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

a) Tris(2,2'-bipyridyl) ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

Tg Confirmatory Test 1

Tg confirmatory reagent (black screw cap), 1 bottle for 3 mL:

Approximately 850 ng/mL Tg (human) in a lyophilized human serum matrix. See bottle label for lot-specific concentration.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

The initial thyroid glandular tissue extract containing the human thyroglobulin has shown to be free from HBsAg and antibodies to HCV and HIV.

The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[2,3]

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

Dissolve the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully. Store at 2-8 °C after use.

Storage and stability

Store at 2-8 °C.

Lyophilizate: up to the stated expiration date

Reconstituted reagent at 2-8 °C: 3 weeks

Specimen collection and preparation

The conditions regarding stability and specimen collection described for the Elecsys Tg assay also apply here.

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

- REF 05118921, Tg reagent kit for 100 tests
  (the materials required for performing the Elecsys Tg assay are listed in the Elecsys Tg Method Sheet)
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** analyzer

Assay

Sample pretreatment (Elecsys Tg Confirmatory Test)

Tg results should be confirmed by the following test:

- Pipette 200 µL undiluted sample + 50 µL confirmatory reagent into a sample cup. Mix well.

Perform an assay in addition to the determination of Tg in the sample without Tg confirmatory reagent.

Elecsys Tg assay:

The pretreated samples are placed in the sample zone and registered by entering the sample identification data.

The Elecsys Tg assay is performed in accordance with the instructions given in the Method Sheet of the reagent kit.

Note: The results of diluted samples cannot be confirmed by the recovery test.

Calibration

For calibration, calibration frequency, and calibration verification, see data given in the Method Sheet for the Elecsys Tg assay.

Quality control

For the Elecsys Tg assay the conditions given in the Method Sheet apply.

Calculation

The analyzer automatically calculates the analyte concentration of each sample (either in ng/mL or µg/L).

Tg results obtained from the untreated sample (Tg sample) as well as from the sample plus Tg confirmatory reagent (Tg sample + confirmatory reagent) are entered into the formula given below. The result obtained will give the percentage recovery of Tg contained in the Tg confirmatory reagent:

$$\frac{\text{Conc. Tg (sample + conf. reagent)} - 0.8 \times \text{conc. Tg (sample)}}{0.2 \times \text{conc. Tg conf. reagent (see bottle label)}} \times 100$$

Interpretation of the results (Tg confirmatory)

When interpreting the test results the possibility of anti-Tg antibodies in the sample should be taken into account. A finding of 70-130 % indicates correct recovery. If the recovery is not within these limits the results should be marked with an appropriate proviso.[4]

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Limitations - interference

For the Tg test the data given in the Method Sheet of the test reagents on "Limitations - interference" apply.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

References

1 Erali M, Bigelow RB, Meikle AW. ELISA for thyroglobulin in serum: recovery studies to evaluate autoantibody interference and reliability of thyroglobulin values. Clin Chem 1996;42(5):766-770.

2 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

3 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

4 Spencer C. International Thyroid Testing Guidelines. National Academy of Clinical Biochemistry, August 2001;Section 3E,11-14.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

CE

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