Thyroglobulin ELISA

Enzyme immunoassay for the quantitative detection of thyroglobulin (hTg) in human serum.

REF  RE70971

Σ  96

i  2-8°C

EU: IVD  CE

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# Instruction Manual

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1 Intended Use

Thyroglobulin ELISA is an indirect solid phase enzyme immunoassay for the quantitative detection of thyroglobulin (Tg) in human serum. The assay employs selected specific monoclonal antibodies against human thyroglobulin (Tg).

The assay is a tool in the follow up and monitoring of thyroid carcinoma as well as for the differential diagnosis of thyroid diseases.

2 Clinical Application and Principle of the Assay

Thyroglobulin (Tg) is a glycoprotein of high molecular weight (660kDa) localized within the colloid of the thyroid follicle. It plays an essential role in the storage of iodine and acts as substratum for the synthesis of iodinated thyroid hormones thyroxine (T4) and 3,5,3'-triiodothyronine (T3).

Elevated thyroglobulin serum concentrations have been reported in various thyroid diseases, such as, hyperthyroidism, non-toxic goiter, thyroiditis and differentiated thyroid carcinoma.

The main indication of the Tg determination, however is the postoperative monitoring of differentiated thyroid carcinoma. Its clinical value is the early detection and exclusion of metastases or tumor relapses and the follow-up of radioiodine treatments. Serum Tg is non detectable in patients who underwent total thyroidectomy including ablation by radioiodine and are free of metastases and tumor. These patients in true complete remission will not display Tg levels, even by endogenous TSH stimulation.

Consequently detectable Tg values in these group of patients are an important indication for still existing or newly developed neoplasm. Particularly if these detectable Tg values are increasing under a TSH-suppressive thyroid hormone treatment (Tg profiles).

In contrast, thyroglobulin levels in patients with medullary carcinoma or undifferentiated tumors remain within the normal range. Since thyroglobulin levels could also be elevated in other benign thyroid diseases, this test is not a criteria for the diagnosis of malignant thyroid tumors.

Determination of thyroglobulin is of prognostic value in Graves` disease patients undergoing therapy.

Significantly elevated Tg levels at the end of a thyrostatic therapy are indication for a higher risk of relapse, whereas patients with continuous low thyroglobulin concentrations tend to continual recovery.

Principle of the test

Undiluted serum samples are incubated in the microplates coated with monoclonal antibodies against human thyroglobulin (Tg). Tg, if present in the specimen, bind to the antibodies. The unbound fraction is washed off in the following step. Afterwards monoclonal anti-Tg immunoglobulins conjugated to horseradish peroxidase (conjugate) are incubated and react with the antigen-antibody complex of the samples in the microplates. Unbound conjugate is washed off in the following step. Addition of TMB-substrate generates an enzymatic colorimetric (blue) reaction, which is stopped by diluted acid (color changes to yellow). The rate of color formation from the chromogen is a function of the amount of conjugate bound to the antigen-antibody complex and this is proportional to the initial concentration of Tg in the patient sample.
3 Kit Contents

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Cap color</th>
<th>Solution color</th>
<th>Description / Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Buffer (5x)</td>
<td>1 x 20ml</td>
<td>White</td>
<td>Yellow</td>
<td>5 x concentrated Tris, sodium chloride (NaCl), bovine serum albumin (BSA), sodium azide &lt; 0.1% (preservative)</td>
</tr>
<tr>
<td>Wash Buffer (50x)</td>
<td>1 x 20ml</td>
<td>White</td>
<td>Green</td>
<td>50 x concentrated Tris, NaCl, Tween 20, sodium azide &lt; 0.1% (preservative)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Cap color</th>
<th>Solution color</th>
<th>Description / Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>1 x 1.5ml</td>
<td>Green</td>
<td>Colorless</td>
<td>Human serum (diluted), bovine serum albumin (BSA), sodium azide &lt; 0.1% (preservative)</td>
</tr>
<tr>
<td>10 ng Control</td>
<td>1 x 1.5ml</td>
<td>Red</td>
<td>Yellow</td>
<td>Human serum (diluted), bovine serum albumin (BSA), sodium azide &lt; 0.1% (preservative)</td>
</tr>
<tr>
<td>Tg Recovery</td>
<td>2 x 1.8ml</td>
<td>Blue</td>
<td>Yellow</td>
<td>Thyroglobulin, bovine serum albumin (BSA), sodium azide &lt; 0.1% (preservative)</td>
</tr>
<tr>
<td>Calibrators</td>
<td>5 x 1.5ml</td>
<td>White</td>
<td>Yellow</td>
<td>Concentration of each calibrator: 3.75, 7.5, 15, 30, 60 ng/ml. Thyroglobulin, bovine serum albumin (BSA), sodium azide &lt; 0.1% (preservative)</td>
</tr>
<tr>
<td>Conjugate, anti-Tg</td>
<td>1 x 15ml</td>
<td>White</td>
<td>Green</td>
<td>Monoclonal anti-Tg antibodies conjugated to horseradish peroxidase, bovine serum albumin (BSA)</td>
</tr>
<tr>
<td>TMB Substrate</td>
<td>1 x 15ml</td>
<td>Black</td>
<td>Colorless</td>
<td>Stabilized tetramethylbenzidine and hydrogen peroxide (TMB/H2O2)</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>1 x 15ml</td>
<td>White</td>
<td>Colorless</td>
<td>1M Hydrochloric Acid</td>
</tr>
<tr>
<td>Microtiter plate</td>
<td>12 x 8 well strips</td>
<td>N/A</td>
<td>N/A</td>
<td>With breakaway microwells. Refer to paragraph 1 for coating.</td>
</tr>
</tbody>
</table>

*M Color increasing with concentration

4 Storage and Shelf Life

Store all reagents and the microplate at 2-8°C/35-46°F, in their original containers. Once prepared, reconstituted solutions are stable at 2-8°C/35-46°F for 1 month. Reagents and the microplate shall be used within the expiry date indicated on each component, only. Avoid intense exposure of TMB solution to light. Store microplates in designated foil, including the desiccant, and seal tightly.
5 Precautions of Use

5.1 Health hazard data

**THIS PRODUCT IS FOR IN VITRO DIAGNOSTIC USE ONLY.** Thus, only staff trained and specially advised in methods of in vitro diagnostics may perform the kit. Although this product is not considered particularly toxic or dangerous in conditions of the intended use, refer to the following for maximum safety:

**Recommendations and precautions**

This kit contains potentially hazardous components. Though kit reagents are not classified being irritant to eyes and skin we recommend to avoid contact with eyes and skin and wear disposable gloves.

**WARNING !** Calibrators, Controls and Buffers contain sodium azide (NaN₃) as a preservative. NaN₃ may be toxic if ingested or adsorbed by skin or eyes. NaN₃ may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. Please refer to decontamination procedures as outlined by CDC or other local/national guidelines.

Do not smoke, eat or drink when manipulating the kit. Do not pipette by mouth.

All human source material used for some reagents of this kit (controls, standards e.g.) has been tested by approved methods and found negative for HbsAg, Hepatitis C and HIV 1. However, no test can guarantee the absence of viral agents in such material completely. Thus handle kit controls, standards and patient samples as if capable of transmitting infectious diseases and according to national requirements.

The kit contains material of animal origin as stated in the table of contents, handle according to national requirements.

5.2 General directions for use

Do not mix or substitute reagents or microplates from different lot numbers. This may lead to variations in the results.

Allow all components to reach room temperature (20-32°C/68-89.6°F) before use, mix well and follow the recommended incubation scheme for an optimum performance of the test.

**Incubation: We recommend test performance at 30°C/86°F for automated systems.**

Never expose components to higher temperature than 37°C/ 98.6 °F.

Always pipette substrate solution with brand new tips only. Protect this reagent from light. Never pipette conjugate with tips used with other reagents prior.

A definite clinical diagnosis should not be based on the results of the performed test only, but should be made by the physician after all clinical and laboratory findings have been evaluated.

The diagnosis is to be verified using different diagnostic methods.
6 Sample Collection, Handling and Storage

Use preferentially freshly collected serum samples. Blood withdrawal must follow national requirements. Do not use icteric, lipemic, hemolysed or bacterially contaminated samples. Sera with particles should be cleared by low speed centrifugation (<1000 x g). Blood samples should be collected in clean, dry and empty tubes.

After separation, the serum samples should be used during the first 8h, respectively stored tightly closed at 2-8°C/35-46°F up to 48h, or frozen at -20°C/-4°F for longer periods.

7 Assay Procedure

7.1 Preparations prior to starting

Dilute concentrated reagents:

Dilute the concentrated sample buffer 1:5 with distilled water (e.g. 20 ml plus 80 ml).
Dilute the concentrated wash buffer 1:50 with distilled water (e.g. 20 ml plus 980 ml).

To avoid mistakes we suggest to mark the cap of the different calibrators.

Washing:

Prepare 20 ml of diluted wash buffer (1x) per 8 wells or 200 ml for 96 wells
e.g. 4 ml concentrate plus 196 ml distilled water.

Automated washing:

Consider excess volumes required for setting up the instrument and dead volume of robot pipette.

Manual washing:

Discard liquid from wells by inverting the plate. Knock the microwell frame with wells downside vigorously on clean adsorbent paper. Pipette 300 µl of diluted wash buffer into each well, wait for 20 seconds. Repeat the whole procedure twice again.

Microplates:

Calculate the number of wells required for the test. Remove unused wells from the frame, replace and store in the provided plastic bag, together with desiccant, seal tightly (2-8°C/35-46°F).
7.2 Pipetting Scheme

We suggest pipetting calibrators, controls and samples as follows:

For QUANTITATIVE interpretation

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4...</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>CalA</td>
<td>CalE</td>
<td>P1 + SB</td>
<td>P1 + RC</td>
</tr>
<tr>
<td>B</td>
<td>CalA</td>
<td>CalE</td>
<td>P2 + SB</td>
<td>P2 + RC</td>
</tr>
<tr>
<td>C</td>
<td>CalB</td>
<td>10ng control + SB</td>
<td>P3 + SB</td>
<td>P3 + RC</td>
</tr>
<tr>
<td>D</td>
<td>CalB</td>
<td>10ng control + SB</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>E</td>
<td>CalC</td>
<td>NC + SB</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>F</td>
<td>CalC</td>
<td>NC + SB</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>G</td>
<td>CalD</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>H</td>
<td>CalD</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

CalA: calibrator 3, 75ng
CalB: calibrator 7, 5ng
CalC: calibrator 15ng
CON 10ng + SB: 50µl 10 ng control + 50µl sample buffer

CalD: calibrator 30ng
SB: sample buffer
P1: patient 1
CalE: calibrator 60ng
NC: negative control
P2: patient 2
Con 10ng: Control 10ng
RC: Recovery
P3: patient 3

7.3 Test Steps

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ensure preparations from step 7.1 above have been carried out prior to pipetting.</td>
</tr>
<tr>
<td>2.</td>
<td>Use the following steps in accordance with quantitative interpretation results desired:</td>
</tr>
<tr>
<td></td>
<td><strong>CONTROLS &amp; SAMPLES</strong></td>
</tr>
<tr>
<td>3.</td>
<td>Patient samples should be tested with and without TgRecovery reagent and therefore need to be run in duplicate.</td>
</tr>
<tr>
<td></td>
<td>a. Pipette 100µl of the each calibrator into its relevant well.</td>
</tr>
<tr>
<td></td>
<td>b. Pipette 50µl of the negative control, 10ng control and each patient sample into separate wells.</td>
</tr>
<tr>
<td></td>
<td>c. Pipette 50µl of sample buffer into the negative control, 10 ng control and each of the patient sample wells, without TgRecovery reagent.</td>
</tr>
<tr>
<td></td>
<td>• For patient results with TgRecovery, add 50µl of TgRecovery reagent to the patient samples.</td>
</tr>
<tr>
<td></td>
<td>Shake carefully.</td>
</tr>
<tr>
<td>4.</td>
<td>Incubate for 60 minutes at 20-32°C/68-89.6°F.</td>
</tr>
<tr>
<td>5.</td>
<td>Wash 3x with 300 µl washing buffer (diluted 1:50).</td>
</tr>
</tbody>
</table>
**CONJUGATE**

6. **CONJ**

Pipette 100 µl conjugate into each well.

7. **WASHB**

Incubate for 60 minutes at 20-32°C/68-89.6°F.

8. **3x 300µl**

Wash 3x with 300 µl washing buffer (diluted 1:50).

**SUBSTRATE**

9. **SUB**

Pipette 100 µl TMB substrate into each well.

10. **60°**

Incubate for 60 minutes at 20-32°C/68-89.6°F, protected from intense light.

**STOP**

11. **STOP**

Pipette 100 µl stop solution into each well, using the same order as pipetting the substrate.

12. **5°**

Incubate 5 minutes minimum.

13. **OD<sub>450</sub>/OD<sub>620</sub>**

Agitate plate carefully for 5 sec.

14. **450/620 nm**

Read absorbance at 450 nm (recommended 450/620 nm) within 30 minutes.
8 Quantitative Interpretation

Establish the standard curve by plotting the optical density (OD) of each calibrator (y-axis) with respect to the corresponding concentration values in ng/ml (x-axis). For best results use linear regression with log-log coordinates for optical density and concentration (both logarithmic scale). From the OD of each sample, read the corresponding Tg concentrations expressed in ng/ml.

Example of a standard curve

We recommend pipetting calibrators in parallel for each run.

<table>
<thead>
<tr>
<th>Calibrators Tg</th>
<th>OD 450/620 nm</th>
<th>CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.75 ng/ml</td>
<td>0.232</td>
<td>2.7</td>
</tr>
<tr>
<td>7.5  ng/ml</td>
<td>0.440</td>
<td>3.9</td>
</tr>
<tr>
<td>15.0 ng/ml</td>
<td>0.805</td>
<td>2.6</td>
</tr>
<tr>
<td>30.0 ng/ml</td>
<td>1.436</td>
<td>0.68</td>
</tr>
<tr>
<td>60.0 ng/ml</td>
<td>2.444</td>
<td>3.2</td>
</tr>
</tbody>
</table>

Do not use this example for interpreting patients results!

Samples above the highest calibrator range should be reported as >Max. They should be diluted as appropriate and re-assayed. Samples below calibrator range should be reported as < Min.

For lot specific data, see enclosed quality control leaflet. Medical laboratories might perform an in-house quality control by using own controls and/or internal pooled sera, as foreseen by national regulations.

Each laboratory should establish its own normal range based upon its own techniques, controls, equipment and patient population according to their own established procedures.

In case that the values of the controls do not meet the criteria the test is invalid and has to be repeated.

The following technical issues should be verified: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, photometer, incubation conditions and washing methods.

If the items tested show aberrant values or any kind of deviation or that the validation criteria are not met without explicable cause please contact the manufacturer or the supplier of the test kit.

Recovery test

Anti-Tg antibodies or unspecific effects in a patient’s serum may interfere with serum thyroglobulin assays. Consequently, sera should be tested for such interferences by carrying out a recovery test as follows.

In parallel to the original patient sample add 50 µl of Tg Recovery to 50 µl of the serum of investigation.

Recovery (in %) in the serum sample is calculated as stated below:
ng Tg/ml (PR1) – ng Tg/ml (P1)  
\[ \text{\% Recovery} = \left( \frac{\text{ng Tg/ml (P1)}}{\text{ng Tg/ml (C)}} \right) \times 100 \]  
P1: Patient result without Tg recovery  
PR1: Patient result with Tg recovery  
C: 10 ng Control  

Given unimpaired recovery (100%), (e.g. no factors are present in the patient’s serum that interfere with Tg determination), the result shall be approximately 10 ng/ml above the Tg level of the corresponding original sample. Taking into consideration pipetting inaccuracies, recoveries between 70% and 130% are considered valid. Levels of < 70% or > 130% are due to interference and the Tg level of the relevant original sample has to be considered invalid.  
The concentration for Tg Recovery is included in the enclosed quality control leaflet and is approximately 10 ng Tg/ml.  

**Do not use QC data for calculation.**  

### Interpretation  
Positive results should be verified concerning the entire clinical status of the patient. Also every decision for therapy should be taken individually. It is recommended that each laboratory establishes its own normal and pathological ranges of serum Tg.  

### Technical Data  
<table>
<thead>
<tr>
<th>Sample material:</th>
<th>serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample volume:</td>
<td>100 µl of sample, undiluted</td>
</tr>
<tr>
<td>Total incubation time:</td>
<td>180 minutes at room temperature (20-32°C/68-89.6°F)</td>
</tr>
<tr>
<td>Calibration range:</td>
<td>3.75 - 60 ng/ml</td>
</tr>
<tr>
<td>Analytical sensitivity:</td>
<td>3.75 ng/ml</td>
</tr>
<tr>
<td>Storage:</td>
<td>at 2-8°C/35-46°F use original vials, only</td>
</tr>
<tr>
<td>Number of determinations:</td>
<td>96 tests</td>
</tr>
</tbody>
</table>

### Performance Data  

#### 10.1 Functional assay sensitivity  
The functional sensitivity of this kit has been found at 3.75 ng/ml.  

#### 10.2 Specificity  
The microplate is coated with monoclonal antibodies highly specific for Tg. No crossreactivities to other antigens have been found.
10.3 Linearity

Chosen sera have been tested with this kit and found to dilute linearly. However, due to the heterogeneous nature of human autoantibodies there might be samples that do not follow this rule.

10.4 Calibration

Thyroglobulin ELISA is calibrated against the Certified Reference Material CRM 457 from BCR, Brussels for human Thyroglobulin. The results are expressed in ng/ml.

10.5 "High dose hook" effect

Concentrations of up to 100,000 ng Tg/ml did not result in a "high dose hook" effect.

10.6 Interference with autoantibodies

Chosen seras with various levels of anti-Tg have been spiked with Tg. No effect on results has been observed. However, this does not mean that all patient seras follow this results. Thus recovery test should be performed always.

11 Literature


**Symbols / Symbole / Symbôles / Símbolos / Σύμβολα**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.° Cat.: / N.–Cat.: / Αριθμός-Κατ.:</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.°: / Lotto n.: / Αριθμός-Παραγωγή:</td>
</tr>
<tr>
<td></td>
<td>Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρήσιμοποιείται από:</td>
</tr>
<tr>
<td>CONC</td>
<td>Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα</td>
</tr>
<tr>
<td>LYO</td>
<td>Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.</td>
</tr>
<tr>
<td></td>
<td>Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit de evaluación. / Kit Αξιολόγησης.</td>
</tr>
<tr>
<td></td>
<td>Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Leggere le istruzioni prima dell’uso. / Αναγνώστε τις οδηγίες πριν την χρήση.</td>
</tr>
<tr>
<td></td>
<td>Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l’abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου.</td>
</tr>
<tr>
<td></td>
<td>Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:</td>
</tr>
<tr>
<td></td>
<td>Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabricante: / Παραγωγός:</td>
</tr>
<tr>
<td></td>
<td>Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!</td>
</tr>
</tbody>
</table>

Symbols of the kit components see MATERIALS SUPPLIED.

Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.

Voir MATERIEL FOURNI pour les symbôles des composants du kit.

Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.

Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.

Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.

Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER’S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

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