**Elecsys® Anti-TSHR**

**Electro-chemiluminescence immunoassay (ECLIA) for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum**

**Indication**
Anti-TSH is used for differential diagnosis of hyperthyroidism. Hyperthyroidism in Graves’ disease (autoimmune hyperthyroidism) is caused by autoantibodies to the TSH receptor (TSHR), and measurement of these TSHR antibodies (TRAb) can be useful in disease diagnosis and treatment management. Another application is TRAb measurement during the last trimester of pregnancy, because TRAb are IgG-class antibodies crossing the placenta and causing neonatal thyroid disease.

**Test principle: inverted modified two-step competitive assay**

1st incubation (2 x 9 minutes)
50 µL of sample, solubilized porcine TSH receptor (pTSHR), and biotinylated anti-porcine TSH receptor mouse monoclonal antibody are incubated. pTSHR and biotinylated antibody form an immune-complex, which further binds anti-TSHR autoantibodies from the patient’s sample. Depending on the titer of autoantibodies in the patient’s sample, more or less of the initial, biotinylated immune-complex is saturated.

2nd incubation (9 minutes)
Streptavidin-coated microparticles and ruthenylated human monoclonal anti-TSHR autoantibodies are added and occupying the remaining epitopes of the biotinylated immune-complex, that are not yet blocked by endogeneous anti-hTSHR. Microparticles bind to all biotinylated sites in the reaction mixture.

**Measurement**
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. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
Elecsys technology
ECL (ElectroChemiluminescence) is Roche’s technology for immunoassay detection. Based on this technology and combined with well-designed, specific and sensitive immunoassays, Elecsys delivers reliable results. The development of ECL immunoassays is based on the use of a ruthenium-complex and tripropylamine (TPA). The chemiluminescence reaction for the detection of the reaction complex is initiated by applying a voltage to the sample solution resulting in a precisely controlled reaction. ECL technology can accommodate many immunoassay principles while providing superior performance.

Elecsys® Anti-TSHR test characteristics

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<td>27 min</td>
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<td>Test principle</td>
<td>Inverted modified two-step competitive assay</td>
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<td>Calibration</td>
<td>2 point</td>
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<td>Sample material</td>
<td>Serum</td>
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<tr>
<td>Sample volume</td>
<td>50 µL</td>
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<tr>
<td>Detection limit</td>
<td>0.3 IU/L</td>
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<tr>
<td>Functional sensitivity</td>
<td>0.9 IU/L</td>
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<tr>
<td>Measuring range</td>
<td>0.3 - 40 IU/L</td>
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<td>Traceability</td>
<td>NIBSC 90/672</td>
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<td>Total imprecision (NCCLS)</td>
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Expected values

- **Anti-TSHR negative:** ≤ 1.75 IU/L
- **Anti-TSHR positive:** > 1.75 IU/L

**Typical Anti-TSHR findings**

- **Not detectable or low (≤ 1.75 IU/L)**
  - Hashimoto’s thyroiditis

- **Detectable (>1.75 IU/L)**
  - Graves’ disease

**Order information**

- **Elecsys® Anti-TSHR**
  - 100 tests
  - Order code: 04388780

- **PreciControl ThyroAB**
  - 2 x 2 mL each
  - Order code: 05042666