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.

Avoid the formation of foam with all reagents and sample types (specimens, calibrator s, and controls).

Reagent handling

The reagents in the kit have been assembled into a ready-for-use unit that cannot be separated. All information required for correct operation is read in via the respective reagent barcodes.

Storage and stability

Store at 2-8 °C.

Store the Elecsys TSH reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use. Stability:

<table>
<thead>
<tr>
<th>up to the stated expiration date</th>
<th>unopened at 2-8 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 weeks</td>
<td>after opening at 2-8 °C</td>
</tr>
<tr>
<td>6 weeks</td>
<td>on MODULAR ANALYSIS E170, cobas e 601 and cobas e 602</td>
</tr>
<tr>
<td>8 weeks</td>
<td>on Elecsys 2010 and cobas e 411</td>
</tr>
</tbody>
</table>

Specimen collection and preparation

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

Li+, Na+, K+, 4-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 + intercept within ± 2 x analytical sensitivity (LLD) + coefficient of correlation > 0.95. Stable for 7 days at 2-8 °C, 1 month at -20 °C. Freeze only once.

The sample 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 manufacturers were tested. Sample collection systems from various manufacturers may contain different 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 precipitants before performing the assay. Do not use heat-inactivated samples. Do not use specimens collected into tubes containing azide.

Ensure the patients’ samples, calibrator s, and controls are at ambient temperature (20-25 °C) before measurement.

Because of possible evaporation of tests, 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)

- REF 4738551190, TSH CalSet, 4 x 1.3 mL
- REF 117 76 479122, PreciControl TSH, 4 x 2 mL
- REF 11731416122, PreciControl Univer sal, for 2 x 3 mL each of PreciControl Univer sal 1 and 2 or REF 11731416190, PreciControl Univer sal, for 2 x 3 mL each of PreciControl Univer sal 1 and 2
- REF 03609987190, Diluent MultiAssay, 2 x 16 mL sample diluent
- General laboratory equipment
- Elecsys 2010, MODULAR ANALYSIS E170 or cobas e analyzer

Accessories for Elecsys 2010 and cobas e 411 analyzers:

- REF 11662988122, ProCell, 6 x 380 mL system buffer
- REF 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- REF 11930346122, Elecsys SysWash, 1 x 500 mL washer additive
- REF 11933159001, Adapter for SysClean
- REF 1170680201, Elecsys 2010 AssayCup, 60 x 60 reaction vessels
- REF 11706799001, Elecsys 2010 AssayTip, 30 x 120 pipette tips

Accessories for MODULAR ANALYSIS E170, cobas e 601 and cobas e 602 analyzers:

- REF 4880340190, ProCett M, 2 x 2 L system buffer
Comparison of precision with the 2nd IRP WHO Reference Standard 80/558.

- 80/558 TSH (human serum 2)
- 80/558 TSH (human serum 1)

Calculation

The assay automatically calculates the analyte concentration of each sample either in µIU/mL or mIU/L (selectable).

Limitations - inter ference

The assay is unaffected by icterus (bilirubin < 701 µmol/L or < 41 mg/dL), hemolysis (Hb < 0.621 mmol/L or < 1 g/dL), lipemia (Intralipid < 1500 mg/dL), and biotin < 102 nmol/L or < 25 ng/mL.

N o interfer e nce was observed from rheumatoid factor s up to a concentration of 3250 IU/mL and samples from dialysis pa t ients.

N o interfer e nce was observed from rheumatoid factor s up to a concentration of 3250 IU/mL and samples from dialysis pa t ients.

Intermediate pr ecision

<table>
<thead>
<tr>
<th>Sample</th>
<th>CV %</th>
<th>SD µIU/mL</th>
<th>R epeatability %</th>
<th>Mean µIU/mL</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.7</td>
<td>0.003</td>
<td>8.5</td>
<td>0.003</td>
<td>0.024</td>
<td>Human serum 1</td>
</tr>
<tr>
<td>3.3</td>
<td>0.021</td>
<td>2.1</td>
<td>0.02</td>
<td>0.91</td>
<td>Human serum 2</td>
</tr>
<tr>
<td>3.6</td>
<td>0.14</td>
<td>1.8</td>
<td>0.07</td>
<td>3.96</td>
<td>Human serum 3</td>
</tr>
<tr>
<td>2.2</td>
<td>0.05</td>
<td>1.9</td>
<td>0.05</td>
<td>2.45</td>
<td>PreciControl Univer sal 1</td>
</tr>
<tr>
<td>1.8</td>
<td>0.19</td>
<td>1.5</td>
<td>0.16</td>
<td>10.67</td>
<td>PreciControl Univer sal 2</td>
</tr>
<tr>
<td>5.4</td>
<td>0.005</td>
<td>-</td>
<td>0.008</td>
<td>-</td>
<td>PreciControl TSH</td>
</tr>
</tbody>
</table>

(a) Repeatability = within run precision
Thyrotropin

**MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers**

<table>
<thead>
<tr>
<th>Intermediate precision</th>
<th>Repeatability</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV %</td>
<td>Mean µIU/mL</td>
</tr>
<tr>
<td>7.2</td>
<td>0.003</td>
</tr>
<tr>
<td>3.2</td>
<td>0.005</td>
</tr>
<tr>
<td>3.3</td>
<td>0.120</td>
</tr>
<tr>
<td>3.5</td>
<td>0.031</td>
</tr>
<tr>
<td>4.2</td>
<td>0.316</td>
</tr>
</tbody>
</table>

**Method comparison**

A comparison of the Elecsys TSH assay (y) with the Enzymun-Test TSH method (x) using clinical samples gave the following correlations: Number of samples measured: 109

\[
y = 0.98x + 0.04 \\
y = 0.91x + 0.04 \\
r = 0.993 \\
\tau = 0.944
\]

The sample concentrations were between approx. 0 and 19 µIU/mL.

**Analytical specificity**

For the monoclonal antibodies used, the following cross-reactivities were found: LH 0.038 %, FSH 0.008 %, hGH and hCG no cross-reactivity.

**Functional sensitivity**

0.014 µIU/mL

The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of 20 %.

**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 package inserts of all necessary components.

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