### PRODUCT SPECIFICATIONS

**Name**  
Anti-h TSH 5404 SP-5

**Specificity**  
Antibody recognizes human thyrotropin and its free beta subunit

**Description**  
Monoclonal mouse antibody, cultured *in vitro* under conditions free from animal-derived components

**Product code**  
100026

**Product buffer solution**  
0.9 % NaCI, 0.095 % NaN\(_3\) as a preservative

**Shelf life and storage**  
36 months from manufacturing at 2–8 °C

**Analyte description**  
Thyroid-stimulating hormone (also known as TSH or thyrotropin) is a peptide hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland which regulates the endocrine function of the thyroid gland. TSH levels are tested in the blood of patients suspected of suffering from excess (hyperthyroidism), or deficiency (hypothyroidism) of thyroid hormone.

### PARAMETERS TESTED ON EACH LOT

**Product appearance**  
Liquid, may turn slightly opaque during storage

**Product concentration**  
5.0 mg/ml (+/- 10 %)

**Immunoreactivity**  
80–120 % compared to the reference sample in an FIA test

**IEF Profile**  
6.6 – 7.2

**Purity**  
≥ 95 %

### PARAMETERS DETERMINED DURING PRODUCT DEVELOPMENT

**Subclass**  
IgG\(_1\)

**Association rate constant**  
8.5 x 10\(^5\) 1/Ms

**Dissociation rate constant**  
3.9 x 10\(^{-5}\) 1/s

**Affinity constant**  
\(K_A = 2.2 \times 10^{10} \text{ 1/M}; K_D = 4.6 \times 10^{-11} \text{ M} (= 0.05 \text{ nM})\)

**Determination method**  
SPR analysis (ProteOn XPR36)

**Determination antigen**  
TSH, Scripps (T0114, Lot 2414402)
**Cross-reactivities**

- hCG: < 0.05 % (Boehringer, Cat 253065, Lot 10774821–25)
- LH: 1.0 % (Scripps Laboratories, Cat L0814, Lot 125711)
- FSH: 1.0 % (Boehringer, Cat 252999, Lot 1483403)

**Epitope**

Group 1

**Pair recommendations**

<table>
<thead>
<tr>
<th>CAPTURE ANTIBODY</th>
<th>DETECTION ANTIBODY</th>
</tr>
</thead>
<tbody>
<tr>
<td>S404</td>
<td>S403, S405, S407, S409</td>
</tr>
<tr>
<td>S403</td>
<td>S404</td>
</tr>
</tbody>
</table>

Please note that pair recommendations are based on results obtained by our laboratory. Equally good results may be obtained using other pairs and therefore these recommendations are only indicative.

**Product stability**

<table>
<thead>
<tr>
<th>TEMPERATURE, TIME</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>-70 °C, 21 days</td>
<td>Not Determined (N/D)</td>
</tr>
<tr>
<td>-20 °C, 21 days</td>
<td>N/D</td>
</tr>
<tr>
<td>+4 °C, 21 days</td>
<td>N/D</td>
</tr>
<tr>
<td>+25 °C, 21 days</td>
<td>N/D</td>
</tr>
<tr>
<td>+35 °C, 21 days</td>
<td>N/D</td>
</tr>
<tr>
<td>+45 °C, 7 days</td>
<td>N/D</td>
</tr>
</tbody>
</table>

Stability testing is performed in the product buffer to see whether different temperatures affect the antigen binding, charge or composition of the antibody. Please note that the shelf life given on the first page is based on real time stability testing at 2-8 °C in the product buffer.

**Miscellaneous**

von Lode et al. (2003) used clones S403 and S404 to develop a one-step TSH assay which had 0.2 mIU/L sensitivity in a 15-min assay and 1.5 mIU/L sensitivity in 2-min assay and hence their assay is applicable for point-of-care conditions.

Wu et al. (2002) developed a three antibody assay system which utilizes clones S403, S404 and S405. Clone S405 was used as a coated antibody and clones S403 and S405 were used as biotinylated label antibodies. They were able to achieve 0.002 mIU/L analytical and 0.017 mIU/L functional sensitivity. The test had negligible cross-reactivity with LH, FSH and hCG which were tested up to 200 mIU/L and 2500 IU/L, respectively.

**References**