

## PRODUCT SPECIFICATIONS

Date: 2011-12-07

|                               |   |   |
|-------------------------------|---|---|
| <b>PRODUCT NAME</b>           | : | Anti-h TSH 5403 SP-5  |
| <b>PRODUCT SPECIFICITY</b>    | : | Antibody recognizes human Thyrotropin   |
| <b>PRODUCT CODE</b>           | : | 100024  |
| <b>PRODUCT BUFFER</b>         | : | 0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative  |
| <b>SHELF LIFE AND STORAGE</b> | : | 36 months from manufacturing at +2-8 °C   |
| <b>ANALYTE DESCRIPTION</b>    | : | 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 FROM EACH LOT

|                              |   |  |
|------------------------------|---|--|
| <b>PRODUCT APPEARANCE</b>    | : | Clear liquid                                   |
| <b>PRODUCT CONCENTRATION</b> | : | 5.0 mg/ml (+/- 10 %)                           |
| <b>PRODUCT ACTIVITY</b>      | : | 80-120 % compared to reference in an IFMA-test |
| <b>IEF-RANGE</b>             | : | 7.1 - 8.1                                      |
| <b>PURITY</b>                | : | ≥ 95 %   |

## PARAMETERS DETERMINED ONLY DURING PRODUCT R&amp;D PHASE

|                              |   |  |
|------------------------------|---|--|
| <b>CLASS AND SUBCLASS</b>    | : | IgG <sub>1</sub>   |
| <b>ASSOCIATION CONSTANT</b>  | : | 2.5 x 10 <sup>5</sup>  |
| <b>DISSOCIATION CONSTANT</b> | : | 4.3 x 10 <sup>-5</sup>   |
| <b>AFFINITY CONSTANT</b>     | : | KA = 5.9 x 10 <sup>9</sup> 1/M; KD = 1.7 x 10 <sup>-10</sup> M (= 0.17 nM)   |
| <b>DETERMINATION METHOD</b>  | : | SPR analysis (ProteOn XPR36)   |
| <b>ANTIGEN</b>               | : | TSH, Scripps TO114, lot.2414402  |
| <b>CROSS-REACTIVITIES</b>    | : | hCG < 0.05 % (Boehringer Cat No 253065 Lot 10774821-25/Nov 87)<br>LH 1.0 % (Scripps Laboratories Cat No L0814 Lot 125711)<br>FSH 1.0 % (Boehringer Cat No 252999 Lot 1483403/Jan 85) |

**EPITOPE** : N/A

**EPITOPE GROUP** : Group 2

Two antibodies binding to the same, or closely located epitopes, belong to the same group and hence cannot be used as a pair in a sandwich assay. Epitope group numbering does not give any detailed information where the epitope is located.

| <b>PAIR RECOMMENDATIONS</b> | <b>SOLID</b> | <b>LABEL</b> |
|-----------------------------|--------------|--------------|
|                             | 5401         | 5403         |
|                             | 5405         | 5403         |
|                             | 5407         | 5403         |
|                             | 5403         | 5404         |
|                             | 5403         | 5407         |
|                             | 5403         | 5408         |

Please note that pair recommendations are based on results obtained in our laboratory. Equally good results may be obtained using other pairs and therefore these recommendations should be taken only as a directive.

| <b>PRODUCT STABILITY</b>  | <b>TEMPERATURE, DAYS</b> | <b>RESULT</b> |
|---|--------------------------|---------------|
| Please note that the shelf life given on page one is based on real time stability testing at +2-8 °C in the product buffer. | -70 °C, 21 days          | OK            |
|   | -20 °C, 21 days          | OK            |
|   | +4 °C, 21 days           | OK            |
|   | +25 °C, 21 days          | OK            |
|   | +35 °C, 21 days          | OK            |
|   | +45 °C, 7 days           | OK            |

Stability testing is performed in the product buffer to see whether different temperatures affect the antigen binding, charge or composition of the antibody. The maximum duration of the test is 21 days, except for the +45 °C only 7 days.

| <b>pH, 14 DAYS, +4 °C</b> | <b>RESULT</b> |
|---------------------------|---------------|
| 5.0                       | N/D           |
| 6.0                       | N/D           |
| 7.0                       | N/D           |
| 8.0                       | N/D           |

Stability testing is performed to see whether pH affects the antigen binding, charge or composition of the antibody during 14 days at +4 °C.

**MISCELLANEOUS** : von Lode et al. (2003) used clones 5403 and 5404 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 5403, 5404 and 5405. Clone 5405 was used as a coated antibody and clones 5403 and 5404 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** : von Lode, P., Hagrén, V., Palenius, T., and Lövgren, T., (2003) One-step quantitative thyrotropin assay for the detection of hypothyroidism in point-of-care conditions. Clin. Biochem., 36:121-128

Wu, F.-B., Han, S.-Q., and He, Y.-F. (2002) Time-resolved immunofluorometry of serum hTSH with enhanced sensitivity. J. Immunoassay & Immunochem., 23(2):191-210

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