Thyroid Stimulating Hormone 3rd Generation Ultra Sensitive Assay
Introduction

Thyroid function tests (TFTs) is a collective term for blood tests used to check the function of the thyroid. TFTs may be requested if a patient is thought to suffer from hyperthyroidism (overactive thyroid) or hypothyroidism (underactive thyroid), or to monitor the effectiveness of either thyroid-suppression or hormone replacement therapy. It is also requested routinely in conditions linked to thyroid disease, such as atrial fibrillation, depression and anxiety disorder. Thyroid-stimulating hormone (TSH) test is the first line test of choice for evaluating thyroid function.
TSH

Thyroid-stimulating hormone (TSH) stimulates the thyroid gland to synthesize and secrete thyroid hormone. TSH serum measurements are used to detect primary hypothyroidism and hyperthyroidism. TSH is the most sensitive test for thyroid hormone function. TSH is produced in the pituitary gland. The production of TSH is controlled by Thyrotropin-releasing hormone (TRH), which is produced in the hypothalamus. TSH levels may be suppressed by excess free T4 thyroid hormone in the blood. The capability of a TSH assay to distinguish between normal and subnormal concentrations is essential for thyroid testing to ultimately yield information that is useful to clinicians treating patients with subnormal TSH/FT4 concentrations.

The performance goal of the vantix® TSH assay is quantification at a lower value of 0.02 mIU/L through an upper limit of 75 mIU/L. This is considered 3rd generation or ultrasensitive performance. Both of these terms relate to the evolution of the TSH test. Over time, increasingly sensitive and specific TSH tests have been developed and adopted. Most laboratories now use the 3rd generation/ultrasensitive TSH test as their "TSH test." Third generation assays have far superior sensitivity in the subnormal TSH range compared to the second-generation assay and about 100 times more sensitive than the first-generation TSH test.

Materials and Methods

Seventy five (75) sera samples were supplied by a large research hospital with known TSH values ranging from 0.02 mL/L through 120 mL/L. The samples included normal, elevated or suppressed individual results. TSH assays were performed simultaneously on the vantix® IBB II platform. Using the vantix® flow cell chip each sample was aspirated over the biosensors which had anti-TSH antibody bound to the surface. In the next conjugate step, dilutions of second TSH antibody conjugated to HRP, was run over the sensors for 80 seconds forming a sandwich immunoassay with TSH. The final step was to flow vantix® measuring solution over the sensors, which generates the mV electrical signal in the presence of HRP on the sensor. The quantified amount of analyte was determined by taking the mV electrical signal for each sample and comparing it to standard curve values derived from known calibrators using the biosensor/assay system. A log logistic curve fitting was employed.
**Results and Interpretation**

The vantix® TSH assay showed a 0.9851 $R^2$ correlation to the results achieved by a large research hospital’s testing of the same samples.

**Conclusion**

The vantix® system has demonstrated in clinical samples strong agreement with the reference lab method at a large research hospital. The 75 samples were across the dynamic range of a 3rd generation TSH assay comprised of both diseased and healthy patients.
Notes

1 The IBB II system is a semi-automated liquid aspirating reader and disposable chip that is the primary development platform for the vantix® point of care system.

How the vantix® System Will Work

- **Finger Stick Blood Sample**: Collect simple pin prick blood sample
- **Sample Transfer to Cartridge**: Place on a single use cartridge
- **Insert Single Use Cartridge into Reader**: Insert into a reader and...
- **Results Available on Reader and V-Lab™**: Produce results in under 10 minutes