

ThyroScreen™ Clinical data

Clinical Study 1 - FDA

Intended use:

The cassette based rapid TSH test is a whole blood, qualitative assay for the detection of an increased level of TSH (Thyroid Stimulating Hormone). An increase level of TSH can be an indication of primary hypothyroidism. For professional use only.

Summary of Technology:

Purified Polyclonal anti-TSH antibodies are passively absorbed on the absorbent membrane. Anti-TSH monoclonal antibodies are absorbed on colloidal gold and then mixed in a protein matrix to obtain the final dye conjugate.

Once applied to the specimen well, blood sample undergoes vertical capillary filtration through the porous filtration system. The blood cells are retained in the top layers while the liquid phase (plasma) reaches the bottom membrane layer. The buffer, when applied to the: specimen well, flows along the bottom membrane layer, mixes with plasma and migrates horizontally along the test membrane. If TSH is present in the sample in concentrations at or above the detection level, labelled antibody-dye conjugates binds to it, forming an antigen-antibody-dye complex. The complex is then captured by antibody immobilised in the Test Zone ("T") of the membrane, producing a visible pink-rose colour band on the membrane. A similarly coloured conjugate is captured by a parallel immunochemical reaction in the Control Zone ("C") of the membrane. A distinctive control band is the marker of proper test performance.

Performance data:

A three centre clinical trial was done to compare the performance of the rapid TSH test to an approved FDA TSH method, the Abbott AxSYM. The following is a *summary* of the data

Generated.	
Total Participants	289
Total Rapid TSH Positives	33
True Positives (TP)	26
False Positives (FP)	7
Total Negatives	256
True Negatives	250
False Negatives	6

Performance Characteristics:

	AxSYM Positive	AxSYM Negative	Total
Rapid Test Positive	26	7	33
Rapid Test Negative	6	250	256
Total	32	257	289

Positive Agreement	81.25%
Negative Agreement	97.28%
Correlation	95.50%

Statement of safety and efficacy

The Rapid Test when compared to an FDA cleared laboratory TSH method demonstrated a correlation when compared to another FDA cleared method of 96% with a positive agreement of 81 % and a negative agreement of 97%.

These data clearly demonstrate the safety and efficacy of this rapid TSH test and further confirm the accuracy, sensitivity and specificity of this product when compared to a substantially equivalent device currently being sold for professional use. A trained Laboratory Technician performed testing in a CLIA registered laboratory.

Clinical Study 2 – University of Oklahoma

A second study was conducted at the University of Oklahoma Health Sciences Centre to evaluate the effectiveness and overall performance of the Rapid TSH test for screening for primary hypothyroidism. Accuracy and sensitivity of the device was evaluated against a reference method, which is considered an appropriate test for the determination of elevated TSH levels.

For the purpose of the study, all results were correlated with test results of a FDA approved method; the Siemens Centaur4. Approximately, 80 patient samples were be used for the study. One laboratory technician conducted the tests. A whole blood sample from an EDTA (anti-coagulant) tube was used to perform the rapid test and results were compared to plasma results generated using the Siemens Centaur. All results were documented. The detection level cut-off for the device is 5mIU/mL.

Study design

- All plasma samples were frozen (as needed) and maintained until completion of the study.

The clinical trial was conducted at one clinical site utilizing approximately 80 study samples. The study was designed to include:

- Fifty to sixty (50-60) tests with TSH levels within the range of 3.0 mIU/mL to 7.0 mIU/mL.
- Twenty to thirty (20-30) tests with a mixture of results that are below 3.0 mIU/mL or above 7.0 mIU/mL.
- And two (2) or more tests with results extremely high (above 20 mIU/mL) to test for the presence of high-dose hook effect.

All sample collection, handling and processing were performed under Good Laboratory Practice. Data was evaluated and the following criteria calculated.

- Sensitivity
- Specificity
- Accuracy

Results

Sensitivity is calculated by dividing the number of test kit positive results by the number of reference method positive results. 1.00 (or 100%) is perfect. Specificity is calculated by dividing the number of test kit negative results by the number of reference method negative results. Accuracy is the proportion of right answers (positives and negatives).

Sensitivity: 89%

Specificity: 100%

Accuracy: 94%

The Rapid TSH test gave seven false positive results and no false negative results. Significantly, the false positive results were for patient samples that had Centaur results of 3.1 to 4.4mIU/mL. All of these results were within 2.9mIU/mL of the target cut off value of 5mIU/mL. Because the results are so close to the target level, many doctors would begin to monitor these patients on a regular basis.