Monobind Inc.
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AccuLite
CLIA Microwells

# Thyrotropin (TSH) Test System

***Product Code: 375-300***

## 1.0 INTRODUCTION

**Intended Use: The Quantitative Determination of Thyrotropin Concentration in Human Serum by a Microplate Enzyme Immunoassay, Chemiluminescence.**

## 2.0 SUMMARY AND EXPLANATION OF THE TEST

Measurement of the serum concentration of thyrotropin (TSH), a glycoprotein with a molecular weight of 28,000 Daltons and secreted from the anterior pituitary, is generally regarded as the most sensitive indicator available for the diagnosis of primary and secondary (pituitary) hypothyroidism.[1,2] The structure of human TSH is similar to that of the pituitary and placental gonadotropins, consisting of an 89-amino acid α-subunit which is similar or identical between these hormones and a 115-amino acid β-subunit, which apparently confers hormonal specificity. The production of the 2 subunits is separately regulated with apparent excess production of the α-subunit. The TSH molecule has a linear structure consisting of the protein core with carbohydrate side chains; the latter accounts for 16% of the molecular weight.

Increase in serum concentrations of TSH, which is primarily responsible for the synthesis and release of thyroid hormones, is an early and sensitive indicator of decrease thyroid reserve and in conjunction with decreased thyroxine (T4) concentrations is diagnostic of primary hypothyroidism. The expected increase in TSH concentrations demonstrates the classical negative feedback system between the pituitary and thyroid glands. That is, primary thyroid gland failure reduces secretion of the thyroid hormones, which in turn stimulates the release of TSH from the pituitary.

Additionally, TSH measurements are equally useful in differentiating secondary and tertiary (hypothalamic) hypothyroidism from the primary thyroid disease. TSH release from the pituitary is regulated by thyrotropin releasing factor (TRH), which is secreted by the hypothalamus, and by direct action of T4 and triiodothyronine (T3), the thyroid hormones, at the pituitary. Increase levels of T3 and T4 reduces the response of the pituitary to the stimulatory effects of TRH. In secondary and tertiary hypothyroidism, concentrations of T4 are usually low and TSH levels are generally low or normal. Either pituitary TSH deficiency (secondary hypothyroidism) or insufficiency of stimulation of the pituitary by TRH (tertiary hypothyroidism) causes this. The TRH stimulation test differentiates these conditions. In secondary hypothyroidism, TSH response to TRH is blunted while a normal or delayed response is obtained in tertiary hypothyroidism.

Further, the advent of immunoenzymometric assays has provided the laboratory with sufficient sensitivity to enable the differentiating of hyperthyroidism from euthyroid population and extending the usefulness of TSH measurements. This method is a second-generation assay, which provides the means for discrimination in the hyperthyroid-euthyroid range.
In this method, TSH calibrator, patient specimen or control is first added to a streptavidin coated well. Biotinylated monoclonal and enzyme labeled antibodies (Abs) are added and the reactants mixed. Reaction between the various TSH antibodies and native TSH forms a sandwich complex that binds with the streptavidin coated to the well.

After the completion of the required incubation period, the antibody bound enzyme-thyrotropin conjugate is separated from the unbound enzyme-thyrotropin conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable signal to produce light.

The employment of several serum reference calibrators of known thyrotropin levels permits construction of a dose response curve of activity and concentration. From comparison to the dose response curve, an unknown specimen's activity can be correlated with thyrotropin concentration.

## 3.0 PRINCIPLE

**Immunoenzymometric assay (Type 3)**
The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (enzyme conjugated and immobilized), with different and distinct epitope recognition, **in excess,** and native antigen. In this procedure, the immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal anti-TSH antibody.

Upon mixing monoclonal biotinylated antibody, the enzyme-labeled antibody and a serum containing the native antigen, reaction results between the native antigen and the antibodies, without competition or stearic hindrance, to form a soluble sandwich complex. The interaction is illustrated by the following equation:

$$^{Enz}Ab_{(p)} + Ag_{TSH} + {}^{Btn}Ab_{(m)} \underset{k_a}{\overset{k_a}{\rightleftharpoons}} {}^{Enz}Ab_{(p)} - Ag_{TSH} - {}^{Btn}Ab_{(m)}$$

$^{Btn}Ab_{(m)}$ = Biotinylated Monoclonal Ab (Excess Quantity)
$Ag_{TSH}$ = Native Ag (Variable Quantity)
$^{Enz}Ab_{(p)}$ = Enzyme labeled Polyclonal Ab (Excess Quantity)
$^{Enz}Ab_{(p)} - Ag_{TSH} - {}^{Btn}Ab_{(m)}$ = Antigen-Antibodies Sandwich Complex
$k_a$ = Rate Constant of Association
$k_{-a}$ = Rate Constant of Dissociation

Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. This interaction is illustrated below:
$^{Enz}Ab_{(p)} - Ag_{TSH} - {}^{Btn}Ab_{(m)} + Streptavidin_{C.W.} \Rightarrow$ immobilized complex
$Streptavidin_{C.W.}$ = Streptavidin immobilized on well
Immobilized complex = sandwich complex bound to the solid surface

After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity, determined by reaction with a signal that generates light, in the antibody-bound fraction is directly proportional to the native antigen concentration. By utilizing several different serum reference calibrators of known antigen values, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

## 4.0 REAGENTS

**Materials Provided:**

**A. TSH Calibrators – 1 ml/vial – Icons A-G**
Seven (7) vials of references for TSH Antigen at levels of 0 (**A**), 0.5 (**B**), 2.5 (**C**), 5.0 (**D**), 10 (**E**), 20 (**F**) and 40 (**G**) µIU/ml. A preservative has been added. Store at 2-8°C.
**Note**: The calibrators, human serum based, were calibrated using a reference preparation, which was assayed against the WHO 2nd IRP 80/558.

**B. TSH Tracer Reagent – 13 ml/vial – Icon**
One (1) vial containing enzyme labeled affinity purified polyclonal goat antibody, biotinylated monoclonal mouse IgG in buffer, dye, and preservative. Store at 2-8°C.

**C. Light Reaction Wells – 96 wells – Icon ⇓**
One 96-well white microplate coated with streptavidin and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

**D. Wash Solution Concentrate – 20 ml/vial – Icon**
One (1) vial containing a surfactant in Buffered Saline. A preservative has been added. Store at 2-8°C.

**E. Signal Reagent A – 7 ml/vial – Icon C[A]**
One (1) vial containing luminol in buffer. Store at 2-8°C.

**F. Signal Reagent B – 7 ml/vial – Icon C[B]**
One (1) vial containing hydrogen peroxide ($H_2O_2$) in buffer. Store at 2-8°C.

**G. Package Insert.**

**Note 1:** Do not use reagents beyond the kit expiration date.
**Note 2:** Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C. Kit and component stability are identified on the label.**
**Note 3:** Above reagents are for a single 96-well microplate.

**4.1 Required But Not Provided:**
1. Pipette(s) capable of delivering 0.050 and 100ml (50 & 100µl) volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100 and 0.350ml (100 & 350µl) volumes with a precision of better than 1.5% (optional).
3. Microplate washer or a squeeze bottle (optional).
4. Microplate luminometer.
5. Absorbent Paper for blotting the microplate wells.
6. Plastic wrap or microplate cover for incubation steps.
7. Vacuum aspirator (optional) for wash steps.
8. Timer.
9. Storage container for storage of wash buffer.
10. Distilled or deionized water.
11. Quality Control Materials.

## 5.0 PRECAUTIONS

***For In Vitro Diagnostic Use***
***Not for Internal or External Use in Humans or Animals***

All products that contain human serum have been found to be non-reactive for Hepatitis B Surface antigen, HIV 1&2 and HCV antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS.

**Safe Disposal of kit components must be according to local regulatory and statutory requirements.**

## 6.0 SPECIMEN COLLECTION AND PREPARATION

The specimens shall be blood, serum in type, and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. The blood should be collected in a plain red-top venipuncture tube with or without gel barrier. Allow the blood to clot. Centrifuge the specimen to separate the serum from the cells.

**In patients receiving therapy with high biotin doses (i.e. >5mg/day), no sample should be taken until at least 8 hours after the last biotin administration, preferably overnight to ensure fasting sample.**

Samples may be refrigerated at 2-8°C for a maximum period of five (5) days. If the specimen(s) can not be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.100ml (100µl) of the specimen is required.

## 7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the hypothyroid, euthyroid and hyperthyroid range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set acceptable assay performance limits. Other parameters that should be monitored include the 80, 50 and 20% intercepts of the dose response curve for run-to-run reproducibility. In addition, maximum light intensity should be consistent with past experience. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

## 8.0 REAGENT PREPARATION

1. **Wash Buffer**
Dilute contents of Wash Concentrate to 1000ml with distilled or deionized water in a suitable storage container. Store diluted buffer at 2-30°C for up to 60 days.
2. **Working Signal Reagent Solution -** Store at 2 - 8°C.
Determine the amount of reagent needed and prepare by mixing equal portions of Signal Reagent A and Signal Reagent B in a clean container. For example, add 1 ml of A and 1ml of B per two (2) eight well strips (A slight excess of solution is made). **Discard the unused portion if not used within 36 hours after mixing.** If complete utilization of the reagents is anticipated, within the above time constraint, pour the contents of Signal Reagent B into Signal Reagent A and label accordingly.

***Note: Do not use reagents that are contaminated or have bacteria growth.***

## 9.0 TEST PROCEDURE

*Before proceeding with the assay, bring all reagents, reference calibrators and controls to room temperature (20 - 27° C).*
*****Test Procedure should be performed by a skilled individual or trained professional*****

1. Format the microplates' wells for each serum reference calibrator, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
2. Pipette 0.050 ml (50µl) of the appropriate serum reference calibrator, control or specimen into the assigned well.
3. Add 0.100 ml (100µl) of the TSH Tracer Reagent to each well. **It is very important to dispense all reagents close to the bottom of the coated well.**
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 45 minutes at room temperature.
6. Discard the contents of the microplate by decantation or aspiration. If decanting, tap and blot the plate dry with absorbent paper.
7. Add (0.350ml) 350µl of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat four (4) additional times for a total of five (5) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat four (4) additional times.**
8. Add 0.100 ml (100µl) of working signal reagent solution to all wells (see Reagent Preparation Section). **Always add reagents in the same order to minimize reaction time differences between wells.**
**DO NOT SHAKE THE PLATE AFTER SIGNAL ADDITION**
9. Incubate for five (5) minutes at room temperature in the dark.
10. Read the RLUs (*Relative Light Units*) in each well in a microplate luminometer for at least 0.2seconds per well. **The results can be read within 30 minutes of adding the signal solution.**

## 10.0 CALCULATION OF RESULTS

A dose response curve is used to ascertain the concentration of TSH in unknown specimens.
1. Record the RLUs obtained from the printout of the microplate reader as outlined in Example 1.
2. Plot the RLUs for each duplicate serum reference calibrator versus the corresponding TSH concentration in µIU/ml on linear graph paper.
3. Draw the best-fit curve through the plotted points.
4. To determine the concentration of TSH for an unknown, locate the average RLUs for each unknown on the vertical axis of the graph, find the intersecting point on the curve, and read the

concentration (in µIU/ml) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the average RLUs (25677) of the unknown intersects the calibration curve at 7.1µIU/ml TSH concentration (See Figure 1).

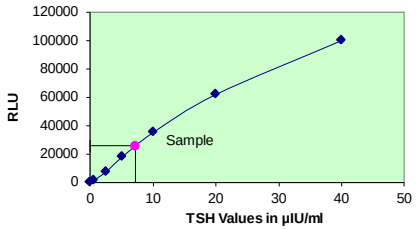
**Note**: Computer data reduction software designed for chemiluminescence assays may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

**EXAMPLE 1**

| Sample I.D. | Well Number | RLU (A) | Mean RLU (B) | Value (µIU/ml) |
|---|---|---|---|---|
| Cal A | A1 | 100 | 102 | 0 |
| | B1 | 105 | | |
| Cal B | C1 | 1290 | 1325 | 0.5 |
| | D1 | 1350 | | |
| Cal C | E1 | 7663 | 7631 | 2.5 |
| | F1 | 7600 | | |
| Cal D | G1 | 17878 | 17761 | 5.0 |
| | H1 | 17645 | | |
| Cal E | A2 | 36315 | 35231 | 10.0 |
| | B2 | 34147 | | |
| Cal F | C2 | 61811 | 62071 | 20.0 |
| | D2 | 62331 | | |
| Cal G | E2 | 99820 | 100000 | 40.0 |
| | F2 | 100180 | | |
| Ctrl 1 | G2 | 907 | 905 | 0.34 |
| | H2 | 902 | | |
| Ctrl 2 | A3 | 21870 | 21669 | 6.0 |
| | B3 | 21468 | | |
| Sample | C3 | 26231 | 25677 | 7.1 |
| | D3 | 25124 | | |

The data presented in Example 1 and Figure 1 is for illustration only and **should not** be used in lieu of a dose response curve prepared with each assay. In addition, the RLU's of the calibrators have been normalized to 100,000 RLU's for the G calibrator (greatest light output). This conversion minimizes differences caused by efficiency of the various instruments that can be used to measure light.

**Figure 1**




## 11.0 Q.C. PARAMETERS

**In order for the assay results to be considered valid the following criteria should be met:**

1. The Dose Response Curve should be within established parameters.
2. Four out of six quality control pools should be within established ranges.

## 12.0 RISK ANALYSIS

*The MSDS and Risk Analysis Form for this product is available on request from Monobind Inc.*

**12.1 Assay Performance**

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the dose response curve.
5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.
6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
7. Use components from the same lot. No intermixing of reagents from different batches.
8. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from IFU may yield inaccurate results.
9. All applicable national standards, regulations and laws, including good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
10. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
11. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

**12.2 Interpretation**

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. The reagents for the test system have been formulated to eliminate maximal interference; however, potential interaction between rare serum specimens and test reagents can cause erroneous results. Heterophilic antibodies often cause these interactions and have been known to be problems for all kinds of immunoassays (Boscato LM, Stuart MC. 'Heterophilic antibodies: a problem for all immunoassays' Clin. Chem. 1988:3427-33). For diagnostic purposes, the results from this assay should be in combination with clinical examination, patient history and all other clinical findings. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
4. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
6. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
7. Serum TSH concentration is dependent upon a multiplicity of factors: hypothalamus gland function, thyroid gland function, and the responsiveness of pituitary to TRH. **Thus, thyrotropin concentration alone is not sufficient to assess clinical status.**
8. Serum TSH values may be elevated by pharmacological intervention. Domperiodone, amiodazon, iodide, phenobarbital, and phenytoin have been reported to increase TSH levels.
9. A decrease in thyrotropin values has been reported with the administration of propranolol, methimazol, dopamine and d-thyroxine.[4]
10. Genetic variations or degradation of intact TSH into subunits may affect the biding characteristics of the antibodies and influence the final result. Such samples normally exhibit different results among various assay systems due to the reactivity of the antibodies involved.

**"NOT INTENDED FOR NEWBORN SCREENING"**

## 13.0 EXPECTED RANGES OF VALUES

A study of euthyroid adult population was undertaken to determine expected values for the TSH AccuLite® CLIA Test System. The number and determined range are given in Table 1. A nonparametric method (95% Percentile Estimate) was used.

**TABLE I**
**Expected Values for the TSH CLIA (in µIU/ml)**

| | |
|---|---|
| Number | 85 |
| Low Normal Range | 0.42 |
| High Normal Range | 5.45 |
| **70% Confidence Intervals for 2.5 Percentile** | |
| Low Range | 0.30 – 0.55 |
| High Range | 5.05 – 6.02 |

It is important to keep in mind that expected values for normal population is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

## 14.0 PERFORMANCE CHARACTERISTICS

**14.1 Precision**

The within and between assay precision of the TSH AccuLite® CLIA Test System were determined by analyses on three different levels of pool control sera. The number, mean value, standard deviation and coefficient of variation for each of these control sera are presented in Table 2 and Table 3.

**TABLE 2**
Within Assay Precision (Values in µIU/ml)

| Sample | N | X | σ | C.V.% |
|---|---|---|---|---|
| Level 1 | 20 | 0.26 | 0.03 | 11.9 |
| Level 2 | 20 | 5.15 | 0.27 | 5.3 |
| Level 3 | 20 | 32.00 | 2.15 | 6.7 |

**TABLE 3**
Between Assay Precision* (Values in µIU/ml)

| Sample | N | X | σ | C.V.% |
|---|---|---|---|---|
| Level 1 | 20 | 0.35 | 0.05 | 13.9 |
| Level 2 | 20 | 5.42 | 0.52 | 9.6 |
| Level 3 | 20 | 37.18 | 2.14 | 5.8 |

*As measured in ten experiments in duplicate over ten days.

**14.2 Sensitivity**

The sensitivity (detection limit) was ascertained by determining the variability of the 0 µIU/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose. It was determined to be 0.0062 µIU/ml.

**14.3 Accuracy**

The TSH AccuLite® CLIA Test System was compared with a reference assay. Biological specimens from hypothyroid, euthyroid and hyperthyroid populations were used (The values ranged from 0.01µIU/ml – 41µIU/ml). The total number of such specimens was 181. The least square regression equation and the correlation coefficient were computed for this method in comparison with the reference method. The data obtained is displayed in Table 4.

**TABLE 4**

| Method | Mean (x) | Least Square Regression Analysis | Correlation Coefficient |
|---|---|---|---|
| This Method | 14.97 | y = 1.15 + 0.956 (x) | 0.973 |
| Reference | 14.44 | | |

Only slight amounts of bias between TSH AccuLite® CLIA Test System and the reference method are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

**14.4 Specificity**

The cross-reactivity of this method to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of thyrotropin needed to produce the same light intensity.

| Substance | Cross Reactivity | Concentration |
|---|---|---|
| Thyrotropin (hTSH) | 1.0000 | - |
| Follitropin (hFSH) | < 0.0001 | 1000ng/ml |
| Lutropin Hormone (hLH) | < 0.0001 | 1000ng/ml |
| Chorionic Gonadotropin (hCG) | < 0.0001 | 1000ng/ml |

## 15.0 REFERENCES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**MP375** **Product Code: 375-300**


| Size | | 96(A) | 192(B) | 480(D) | 960(E) |
|---|---|---|---|---|---|
| Reagent (fill) | A) | 1ml set | 1ml set | 2ml set | 2ml set x2 |
| | B) | 1 (13ml) | 2 (13ml) | 1(60ml) | 2 (60ml) |
| | C) | 1 plate | 2 plates | 5 plates | 10 plates |
| | D) | 1 (20ml) | 1 (20ml) | 1 (60ml) | 2 (60ml) |
| | E) | 1 (7ml) | 2 (7ml) | 1 (30ml) | 2 (30ml) |
| | F) | 1 (7ml) | 2 (7ml) | 1 (30ml) | 2 (30ml) |


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**Glossary of Symbols**
(EN 980/ISO 15223)

IVD — In Vitro - Diagnostic Medical Device
Temperature Limitation Storage Condition (2-8° C)
Consult Instructions for Use
REF — Catalogue Number
Contains Sufficient Test for Σ
LOT — Batch Code
Used By (Expiration Day)
Date of Manufacturer
Manufacturer
EC REP — Authorized Rep in European Country
CE — European Conformity