Free Triiodothyronine, Free Thyroxine, Thyrotropin (Free T3/Free T4/TSH VAST®)  
Free Thyroid Panel Test System  
Product Code: 7075-300

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Free Triiodothyronine; Free Thyroxine; Thyrotropin for a comprehensive thyroid status of a Human Serum or Plasma sample by a Microparticle Enzyme Immunoassay, Chemiluminescence.

2.0 SUMMARY AND EXPLANATION OF THE TEST

Measurements of thyroid hormones (T3, T4 and TSH) are generally regarded as invaluable in vitro diagnostic tests for assessing thyroid function. This importance has provided the impetus for the significant improvement in assay methodology that has occurred in recent years. This procedural evolution can be traced from the empirical protein bound iodine (PBI) test to the "theoretically sophisticated radioimmunooassay" and currently used EIA, ELISA, FIA and Chemiluminescence.

The Combination Thyroid Panel (CTP) provides the convenience of combination calibrators, universal plate and flexible receptor selection allowing technicians to perform a variety of assay designs. In this method, a reference calibrator, patient specimen, or control is first added to a microwell plate. Enzyme-T4 (T3) conjugate and biotinylated T4 or T3 antibody are added, and the reactants are mixed. In the case of TSH, the biotinylated and enzyme conjugate are added in one step. A reaction results between the enzyme conjugate, biotinylated conjugate and the native thyroid hormone (T3, T4 or TSH) for the antibody combining sites. Immobilization takes place through the reaction of the incorporated biotin and streptavidin coated on the well. After the completion of the required incubation period, the bound enzyme conjugate is separated from the unbound enzyme conjugate by aspiration or decantation. The activity of the enzyme present on the surface of the bound enzyme is catalyzed by reaction with a suitable substrate to produce light.

The employment of several serum references of known thyroid hormone concentration(s) permits construction of a graph of activity and concentration of said hormone immobilized on the closed response curve(s), an unknown specimen's activity can be correlated with hormone concentration.

3.0 PRINCIPLE

Competitive Enzyme Immunoassay (T3 and T4) – Type 7

The essential reagents required for a chemiluminescence immunoassay include antibody, enzyme-antigen conjugate, native antigen and a substrate that emits light.

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

\[
\text{Ab}_{\text{c}} + \text{Ag} + \text{Ab}_{\text{p}} \rightarrow \text{Ab}_{\text{c}} - \text{Ag} - \text{Ab}_{\text{p}} \rightarrow \text{Ab}_{\text{c}} + \text{Ag} + \text{Ab}_{\text{p}} \rightarrow \text{Ab}_{\text{c}} + \text{Ag} + \text{Ab}_{\text{p}}
\]

\[\text{Ab}_{\text{c}} = \text{Monospecific Immobilized Antibody (Constant Qty)}\]
\[\text{Ag} = \text{Native Antigen (Variable Qty)}\]
\[\text{Ab}_{\text{p}} = \text{Enzyme-Antigen Conjugate (Constant Qty)}\]
\[\text{Ab}_{\text{c}} = \text{Antigen-Antibody Complex}\]
\[k_1 = \text{Rate Constant of Association}\]
\[k_2 = \text{Rate Constant of Dissociation}\]

A simultaneous reaction between the biotin attached to the antibody and the biotinylated enzyme-antigen conjugate results in the microwell occurring. This effect is the separation of the antibody-bound fraction after decantation or aspiration.

Simplified: 
\[\text{EnzAb(p)} + \text{AgTSH} + \text{BtnAb(m)} = \text{Antigen-Antibody Sandwich Complex}\]

The enzyme activity in the antibody-bound fraction, measured by a serum containing the native antigen, a reaction results between the native antigen and the antibodies, without competition or steric hindrance, to form a soluble sandwich complex. The interaction is illustrated by the following equation:

\[
\text{E} + \text{EnzAb(p)} + \text{AgTSH} + \text{BtnAb(m)} + \text{StreptavidinCW} \rightarrow \text{Antigen-Antibody Sandwich Complex}
\]

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\[
\text{E} + \text{EnzAb(p)} + \text{AgTSH} + \text{BtnAb(m)} + \text{StreptavidinCW} \rightarrow \text{Antigen-Antibody Sandwich Complex}
\]

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. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and carefully disposed of. 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 Publication No. (CDC) 88-8395.

Safe disposal of kit components must be according to local regulatory and statutory requirement.

1.0 REAGENTS

Materials provided
A. Combi-Cal® III/T3/T4/TSH Calibrators – 1 ml/vial - Icon A  
B. TSH Tracer Reagent — 10ml/vial - Icon C  
C. Strept fT4 Biotin Reagent – 7ml/vial  
D. TSH Tracer Reagent — 10ml/vial - Icon C  
E. Strept fT3 Biotin Reagent – 7ml/vial  
F. Strept fT4 Biotin Reagent – 7ml/vial  
G. Light Reaction Wells – 2 x 96 wells – Icon T  
H. Wash Solution Concentrate – 20ml/vial - Icon H  
I. Signal Reactant A – 2 x 7ml/vial - Icon K  
J. Signal Reactant B – 2 x 7ml/vial - Icon K  
K. Product Insert.

I. Signal Reactant A – 2 x 7ml/vial - Icon K  
J. Signal Reactant B – 2 x 7ml/vial - Icon K  
K. Product Insert.

Note 2:
Do not use reagents beyond the kit expiration date.

Note 3:
Avoid extended exposure to heat and light.  

In patients receiving therapy with high thyroid doses (i.e. levothyroxine), no sample should be taken until at least 4 hours after the last biotin administration, preferably overnight to ensure fasting sampling.

Samples may be refrigerated at 2–8°C for a maximum period of five (5) days. If the specimen(s) cannot be processed within this time period 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 possible in duplicate. 0.05ml (50μl) of the specimen is required for fT4 and TSH and 0.10ml (100μl) for fT3.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the hyperthyroid, euthyroid and hypothyroid range for monitoring assay performance. These controls should be treated as unknowns and their values determined in every test procedure performed. Quality control charts should be used to follow performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set action and performance levels, maximum acceptable values, and management standards. Significant deviations can be used to indicate unexpected 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.

2. Working Signal Reagent Solution  
Store at 2–8°C.  

3. Reagent Preparation  
The reagents should be prepared using mixing equal portions of Signal Reactant A and Signal Reactant B in a clean container. For example, add 1 ml of A and 1 ml of B to two (2) 10ml sterile microtubes. Mix the reagents in a water bath at a suitable temperature. Discard the unused portion if not used within 36 hours after mixing. If complete utilization of the reagents is anticipated, withhold the reagents, mix the reagents and store at 4°C.

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

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, serum 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 calibrator, control and patient specimen to be assayed in duplicate. Replace any unused microtiter strips back into the aluminum bag, seal and store at 4°C.

2. Pipette 0.025ml (25μl) of the appropriate serum reference calibrator, control or specimen into the assigned well for fT4, fT3, fT3 and TSH, and TSH and TSH.

1. Pipette capable of delivering 0.025 & 0.050ml (25 & 50μl) volumes with a precision of better than 1.5%.

2. Dispenser(s) for repetitive deliveries of 0.100ml & 0.350ml (100 & 350μl) volumes with a precision of better than 1.5%.

3. Adjust dilution volume (20-200μl) and (200-1000μl) dispenser(s) for conjugate dilutions.

4. Microplate washer or a squeeze bottle (optional).

5. Test tubes for dilution of enzyme conjugate and Signal reagents A and B.

6. Absorbent Paper for blotting the microplate wells.

7. Plastic wrap or microplate cover for incubation steps.

8. Vacuum aspirator (optional) for wash steps.


10. Quality control materials.

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

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7. Plastic wrap or microplate cover for incubation steps.

8. Vacuum aspirator (optional) for wash steps.


10. Quality control materials.

Note: Do not use reagents that are contaminated or have bacteria growth.
3. Add 0.050ml (50µl) of T4 or fT3 Tracer Reagent to the appropriate wells. For TSH, add 0.010 ml of TSH Tracer Reagent and skip steps 4 and 5.

4. Swirl the microplate gently for 20-30 seconds to mix.

5. Add 0.050ml (50µl) of a T4 or (a-T3) Biotin Reagent solution to the appropriate wells.

6. Swirl the microplate gently for 20-30 seconds to mix and cover.

7. Incubate 90 minutes at room temperature.

8. Discord the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.

9. Add 3.00ml (300µl) of Wash Buffer (see Reagent Preparation Section), decant (tap and blot) and 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 instructions 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 two (2) additional times.

10. Add 0.100ml (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.

11. Incubate for five (5) minutes at room temperature in the dark.

12. Read the Relative Light Units (RLUs) in each well in a fluorometer. (the duplicates of the unknown may be averaged as indicated).

**Note:** Do not shake plate after signal addition.

1. The dose response curve should be within established ranges, which can be expected to be found by a given method for a patient or specimen.

2. Pipetting of samples should not extend beyond ten (10) minutes.

3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) must be discarded.

4. It is important to keep in mind that establishment of a range of expected values, which can be expected to be found by a given method for a patient or specimen, is extremely important.

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 sequence to eliminate any time-deviation during reaction.

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 reagents prescribed are essential. Any deviation from Monobind’s IFU may yield inaccurate results.

9. All applicable national standards, regulations and laws, including but not limited to, good laboratory practices, 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.

12.1 Interpretation

1. Measurement 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 status and should not be the sole basis for therapy, particularly if the results conflict with other determinations.

3. The reagents for AccuLite® CLIA procedure have been formulated to minimize interactions; 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 a problem for all kinds of immunoassays. (Boccaz, 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 used in combination with clinical examination, patient history and all other clinical findings.

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. Total serum thyroxine concentration is dependent on a multiplicity of factors: thyroid gland function and its regulation, thyroxine binding to TBG (TBG) concentration, and the presence or absence of thyroid antibodies to TBG. Thus, total thyroxine alone is not sufficient to assess clinical status.

8. Total serum thyroxine values may be elevated under conditions such as pregnancy or administration of oral contraceptives. A T3 uptake test may be performed to estimate the relative TBG concentration in order to determine if the elevated T4 is caused by TBG variation.

9. A decrease in total thyroxine values is found with pregnancy, obesity, some liver diseases, and administration of testosterone, diphenylhydantoin or salicylates. A table of interfering drugs and conditions, which affects total thyroxine values, has been compiled by the Journal of the American Association of Clinical Chemists.

**NOT INTENDED FOR NEWBORN SCREENING**

13.0 EXPECTED RANGES OF VALUES

A study of euthyroid adult population was undertaken to determine expected values. The mean (R) values, standard deviations (σ) and expected ranges (±2σ) are presented in Table 1 for T4 and Table 2 for T3. A nonparametric method (95% Percentile Estimate) was used for TSH in Table 3.

### TABLE 1 - Expected Values – (T3 - in ng/ml)

<table>
<thead>
<tr>
<th>Sample LD.</th>
<th>Well Number</th>
<th>RLUs</th>
<th>Mean RLUs</th>
<th>Value (µg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cal A</td>
<td>A1</td>
<td>97385</td>
<td>100000</td>
<td>0.0</td>
</tr>
<tr>
<td>Cal B</td>
<td>B1</td>
<td>102615</td>
<td>104180</td>
<td>1.3</td>
</tr>
<tr>
<td>Cal C</td>
<td>C1</td>
<td>8317</td>
<td>84180</td>
<td>0.9</td>
</tr>
<tr>
<td>Cal D</td>
<td>D1</td>
<td>63612</td>
<td>63489</td>
<td>8.0</td>
</tr>
<tr>
<td>Cal E</td>
<td>E1</td>
<td>46600</td>
<td>46418</td>
<td>0.3</td>
</tr>
<tr>
<td>Cal F</td>
<td>F1</td>
<td>36361</td>
<td>36361</td>
<td>0.0</td>
</tr>
<tr>
<td>Cal G</td>
<td>G1</td>
<td>23863</td>
<td>23324</td>
<td>12.0</td>
</tr>
<tr>
<td>Cal H</td>
<td>H1</td>
<td>23863</td>
<td>23324</td>
<td>12.0</td>
</tr>
<tr>
<td>Cal I</td>
<td>I1</td>
<td>23863</td>
<td>23324</td>
<td>12.0</td>
</tr>
<tr>
<td>Patient</td>
<td>E2</td>
<td>49780</td>
<td>53560</td>
<td>5.2</td>
</tr>
</tbody>
</table>

### TABLE 2 - Expected Values – (T4 - in ng/ml)

<table>
<thead>
<tr>
<th>Sample LD.</th>
<th>Well Number</th>
<th>RLUs</th>
<th>Mean RLUs</th>
<th>Value (µg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cal A</td>
<td>A1</td>
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<td>100000</td>
<td>0.0</td>
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<td>84180</td>
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</tr>
<tr>
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<td>D1</td>
<td>63612</td>
<td>63489</td>
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</tr>
<tr>
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<td>E1</td>
<td>46600</td>
<td>46418</td>
<td>0.3</td>
</tr>
<tr>
<td>Cal F</td>
<td>F1</td>
<td>36361</td>
<td>36361</td>
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<tr>
<td>Cal G</td>
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<tr>
<td>Patient</td>
<td>E2</td>
<td>49780</td>
<td>53560</td>
<td>5.2</td>
</tr>
</tbody>
</table>

### TABLE 3 - Expected Values – (TSH - in µIU/ml)

<table>
<thead>
<tr>
<th>Sample LD.</th>
<th>Well Number</th>
<th>RLUs</th>
<th>Mean RLUs</th>
<th>Value (µg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>97385</td>
<td>100000</td>
<td>0.0</td>
</tr>
<tr>
<td>Cal B</td>
<td>B1</td>
<td>102615</td>
<td>104180</td>
<td>1.3</td>
</tr>
<tr>
<td>Cal C</td>
<td>C1</td>
<td>8317</td>
<td>84180</td>
<td>0.9</td>
</tr>
<tr>
<td>Cal D</td>
<td>D1</td>
<td>63612</td>
<td>63489</td>
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</tr>
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<td>46600</td>
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</tr>
<tr>
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<td>F1</td>
<td>36361</td>
<td>36361</td>
<td>0.0</td>
</tr>
<tr>
<td>Cal G</td>
<td>G1</td>
<td>23863</td>
<td>23324</td>
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<tr>
<td>Cal H</td>
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</tr>
<tr>
<td>Patient</td>
<td>E2</td>
<td>49780</td>
<td>53560</td>
<td>5.2</td>
</tr>
</tbody>
</table>

### 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 the established ranges.

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product are available on request from Monobind Inc.
tracer.
to dose of thyroid hormone needed to displace the same amount of

calculated by deriving a ratio between dose of interfering substance
dose:
to calculate the minimum dose.

14.4 Specificity

The Free T3 test system procedure has a specificity of 0.04 pg/ml.

The sensitivity was ascertained by determining the variability of the 0 µIU/ml serum calibrator and using the 2
sensitivity was ascertained by determining the variability of the 0 pg/ml serum calibrator and using the 2

σ(95% certainty) statistic to
ng/dl serum calibrator and using the 2

15.0 REFERENCES

4. Sterling L, Diagnosis and Treatment of Thyroid Disease, Cleveland CRC Press, 19-51 (1975).

Revision: 4 Date: 2019-Jul-16 DCO: 1353

MP7075 Product Code: 7075-300

Phenytoin < 0.0001 10µg/ml
Sodium Salicylate < 0.0001 10µg/ml

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cross Reactivity</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-iodothyronine</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>I-Thyroxine</td>
<td>&lt; 0.0002</td>
<td>10µg/ml</td>
</tr>
<tr>
<td>lodothyronine</td>
<td>&lt; 0.0001</td>
<td>10µg/ml</td>
</tr>
<tr>
<td>Diiodothyronine</td>
<td>&lt; 0.0001</td>
<td>10µg/ml</td>
</tr>
</tbody>
</table>

TABLE 4
Within Assay Precision T4 & T3

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>X</th>
<th>σ</th>
<th>C.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>24</td>
<td>0.46</td>
<td>0.430</td>
<td>9.4%</td>
</tr>
<tr>
<td>Pool 2</td>
<td>24</td>
<td>2.1</td>
<td>0.159</td>
<td>7.1%</td>
</tr>
<tr>
<td>Pool 3</td>
<td>24</td>
<td>1.50</td>
<td>0.062</td>
<td>5.5%</td>
</tr>
<tr>
<td>Pool 4</td>
<td>24</td>
<td>5.3</td>
<td>0.220</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

T3 values in ng/dl – T3 values in pg/ml

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cross Reactivity</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSH VALUES in µIU/ml)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean (x)</th>
<th>Least Square Regression Analysis</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monobind</td>
<td>3.11</td>
<td>y = 0.11+ 0.97(x)</td>
<td>0.985</td>
</tr>
<tr>
<td>Reference</td>
<td>3.20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number: 65</td>
<td>Range of values</td>
<td>0.8 – 12.5</td>
<td></td>
</tr>
</tbody>
</table>

TABLE 8 (FT3)

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean (x)</th>
<th>Least Square Regression Analysis</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monobind</td>
<td>1.38</td>
<td>y = 0.02+ 0.964(x)</td>
<td>0.160</td>
</tr>
<tr>
<td>Reference</td>
<td>1.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number: 65</td>
<td>Range of values</td>
<td>0.15 – 9.5</td>
<td></td>
</tr>
</tbody>
</table>

TABLE 9 (FT4)

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean (x)</th>
<th>Least Square Regression Analysis</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monobind</td>
<td>4.32</td>
<td>y = 0.34+ 0.961(x)</td>
<td>0.989</td>
</tr>
<tr>
<td>Reference</td>
<td>4.49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number: 65</td>
<td>Range of values</td>
<td>0.01 – 61</td>
<td></td>
</tr>
</tbody>
</table>

Only slight amounts of bias between this method 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 the antibodies used 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 thyroid hormone needed to displace the same amount of tracer.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cross Reactivity</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-iodothyronine</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>I-Thyroxine</td>
<td>&lt; 0.0002</td>
<td>10µg/ml</td>
</tr>
<tr>
<td>lodothyronine</td>
<td>&lt; 0.0001</td>
<td>10µg/ml</td>
</tr>
<tr>
<td>Diiodothyronine</td>
<td>&lt; 0.0001</td>
<td>10µg/ml</td>
</tr>
<tr>
<td>Diiodothyronine</td>
<td>&lt; 0.0001</td>
<td>10µg/ml</td>
</tr>
</tbody>
</table>

TABLE 10 (TSH)

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean (x)</th>
<th>Least Square Regression Analysis</th>
<th>Correlation Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monobind</td>
<td>3.38</td>
<td>y = 0.01+ 0.964(x)</td>
<td>0.992</td>
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<tr>
<td>Reference</td>
<td>3.40</td>
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</tr>
<tr>
<td>Number: 65</td>
<td>Range of values</td>
<td>0.01 – 61</td>
<td></td>
</tr>
</tbody>
</table>

15.0 REFERENCES

4. Sterling L, Diagnosis and Treatment of Thyroid Disease, Cleveland CRC Press, 19-51 (1975).