

Calibration

Every Test Device has a bar-coded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

Calibration frequency: Calibration must be performed before new lot of device is used. Renewed calibration is recommended as follows:

- After 90 days (when using the same reagent lot on the analyzer);
- As required: e.g. quality control findings outside the defined limits.

Note: Refer to Instruction of Analyzer for the procedure of calibration.

Quality Control

For quality control, please use Control of REALY or Control Universal.

In addition, other suitable control material can be used. Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Specimen Dilution Procedures

Specimens with a TT4 concentration greater than 250 ng/mL will be flagged as ">250.00 ng/mL" and may be diluted using Manual Dilution Procedure. Use the 1:2 dilutions is recommended. The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution.

EXPECTED VALUES

Normal reference value: 4.4-11.4 µg/dL.

Conversion factors:

$$\text{nmol/L} \times 0.077688 = \mu\text{g/dL}$$

$$\mu\text{g/dL} \times 12.872 = \text{nmol/L}$$

$$\text{nmol/L} \times 0.77688 = \mu\text{g/L} = \text{ng/mL}$$

Results may differ between laboratories due to variations in population and test method.

If necessary, each laboratory should establish its own reference range.

INTERPRETATION OF RESULTS

As interpret the results, the patient's overall clinical situation, including symptoms, medical history and other related data, should be referred to.

LIMITATIONS

- Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results. Procedural directions must be followed exactly and careful technique must be used to obtain valid results.
- If the Total T4 results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Specimens containing HAMA may produce anomalous values when tested with assay kits such as the Total T4 Reagent Kit that employ mouse monoclonal antibodies.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous results may be observed. Additional information may be required for diagnosis.
- Although the Total T4 Reagent Kit is specifically designed to minimize the effects of HAMA and heterophilic antibodies, assay results that are not consistent with other clinical observations may require additional information for diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity

Linearity of the Total T4 (TT4) Assay Reagent Kit (CMIA) was determined by use TT4

calibrator to prepare the 6 different specimens, measuring all these specimens follow the test instruction and then do linear fitting, the results show that the linear correlation coefficient (r) was better than 0.9900.

Precision / Reproducibility

Intra-assay coefficient of variation was evaluated on 3 different levels of control serum.

Repeatedly measured 20 times, calculating the coefficient of variation.

Intra-assay Precision			
Control	Mean (ng/mL)	SD (ng/mL)	CV
Level 1	51.1	1.55	3.03%
Level 2	95.9	3.52	3.67%
Level 3	191.2	11.42	5.97%

Inter-assay coefficient of variation was evaluated on three batches of kits. Repeatedly measured 3 different levels of control serum 30 times, calculating the coefficient of variation.

Inter-assay Precision			
Control	Mean (ng/mL)	SD (ng/mL)	CV
Level 1	50.6	1.83	3.62%
Level 2	96.6	4.64	4.80%
Level 3	192.4	11.97	6.22%

Analytical Sensitivity

The analytical sensitivity is defined as the concentration of Total T4 equivalent to the mean RLU of 20 replicates of the zero standard minus two standard deviations corresponding to the concentration from the standard curve. The analytical sensitivity is typically less than 10 ng/mL.

Specificity

The Total T4 Reagent Kit is designed to have a mean analytical specificity of ≤3.2% cross reactivity with Triiodothyronine (T3) at a concentration of 100 ng/mL.

Interfering Substances

The following compounds in both low-level specimen and high-level specimen show no cross-reactivity when tested with the Total T4 Reagent Kit at a concentration below:

Compound	Concentration
Bilirubin	20 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	1000 mg/dL

Method Comparison

A comparison of the Total T4 Reagent Kit (y) with a commercially available Total T4 test (x) using clinical samples gave the following correlations (ng/mL):

Linear regression

$$y=0.9761x+0.2677$$

$$r=0.9570$$

Number of samples measured: 83

The sample concentrations were between about 11.0 – 214.0 ng/mL.

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Do not use expired or clearly damaged kits.
- Operating according to the steps described, can make the risk of daily handling patients' samples and blood products into a minimum, however, no matter what the source of the products, handling mode or the previous proof, these potentially infectious substances were used shall be in accordance with the unified considerations and Good Laboratory Practice (GLP).
- Proper disinfectant should be used to eliminate pollution.
- Follow local rules and regulations to keep and dispose of these items and containers for these items.
- The ProClin-300 is a potential skin sensitizer. Avoid dumping or splashing this reagent on your skin and clothing. In case of contact with this reagent, wash thoroughly with soap and water.
- Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

➢ Any modification of the procedure is likely to alter the results.

➢ Bacterial contamination or repeated freeze-thaw cycles may affect the test results.

➢ The reagents should be kept away from light, and unused reagents should be put back into the kit in time and be careful to avoid light.

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number		Contains sufficient for <n> tests



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