

Product Datasheet

Total thyroxine (T4) Chemiluminescent Bulk Reagents

Catalog Number: LS-CLAE-T4

10,000T

INTENDED USE

Total thyroxine (T4) chemiluminescent bulk reagents are designed for the quantitative determination of total thyroxine concentration in human serum and plasma. These bulk packs are intended for use in the production of in vitro diagnostic reagents or devices.

TEST PRINCIPLE

Total thyroxine (T4) assay is a delayed one-step competitive immunoassay with sheep anti-T4 monoclonal antibody coated onto magnetic particles. T4 in the sample competes with acridine sulfonamide-labeled T4-derivative for a limited amount of the binding sites on anti-T4 monoclonal antibody to form an antibody-hapten complex. After reaction, the trigger solution was added and the relative light units (RLUs) from the emitting light of acridine sulfonamide were collected immediately by chemiluminescence analyzer. The concentration of T4 present in the patient samples were inversely proportional to the amount of RLUs.

REAGENTS

- LS-CLAE-T401: Magnetic particles coated with sheep anti-T4 monoclonal antibody in a HEPES buffer with protein stabilizers and 0.1% preservative (1 bottle, 500 mL).
- LS-CLAE-T402: Acridine sulfonamide-labeled T4-derivative in a phosphate buffer with protein stabilizers and 0.1% preservative (1 bottle, 500 mL).
- LS-CLAE-T403: Sample Diluent (1 bottle, 500 mL)

MATERIALS REQUIRED BUT NOT PROVIDED

- LS-CA-T4: Calibrators 6 x 1.0 mL
- LS-HC-AWB: Universal wash buffer
- LS-DW-AT: Trigger solution
- LS-DW-PAT: Pre-trigger solution

STORAGE AND STABILITY

- Up to the stated expiration date if stored unopened at 2-8 °C, and should be used within 4 weeks after opening at 2-8 °C.
- The onboard stability of reagents is 4 weeks.
- Do not freeze.

WARNINGS AND PRECAUTIONS

- The bulk reagents are for further manufacturing use.
- The reagents contain material of biological origin and should be handled as potentially infectious according to universal precautions and good clinical laboratory practice.
- Disposal of waste material shall comply with local regulations.

SPECIMEN

- Serum and plasma (K₂-EDTA, K₃-EDTA, Li-heparin) are acceptable. Blood collection tubes from various manufacturers may contain different materials that could potentially affect the test results.
- Follow the instructions provided by the blood collection tube manufacturers when processing specimens in primary tubes.
- Allow serum specimens to clot completely before centrifugation. Centrifuge samples to remove precipitates prior to analysis.
- Serum and plasma specimens are stable for 24 hours at 2-8°C, 14 days at -20°C. Freeze only once and mix thoroughly after thawing.
- The information provided here is based on data maintained by bulk reagents manufacturer. Kit manufacturers are responsible for using their own studies to establish alternate stability criteria that meet specific needs.

CALIBRATION

Use LS-CA-T4 for calibrating the LinsLink T4 assay.

- Traceability: Calibrator values have been made traceable to Elecsys® T4 assay.

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- Stability: Lyophilized calibrators are stable up to the stated expiration date if stored unopened at 2-8 °C. Reconstituted calibrator materials are stable for 5 days from the date of reconstitution when stored at 2-8°C.
- Calibration frequency: Calibration must be performed after reagent lot change.

QUALITY CONTROL

Use LS-CAL-T4 for quality control of the LinsLink T4 assay.

- Quality control materials, with at least two known concentration levels (low and high), should be tested individually at least once every 24 hours. Results should fall within the defined ranges.
- Quality control ranges should be determined by each laboratory's individual requirements.
- Follow the relevant government requirements and local guidelines.

TEST PROCEDURE

- Ensure the samples, calibrators and controls are at room temperature (20-25 °C) prior to measurement.
- Dispense 10 µL of sample and 50 µL of LS-CLAE-T403 into a cuvette, react for 10 minutes at 37°C.
- Dispense 50 µL of LS-CLAE-T401 and 50 µL of LS-CLAE-T402 into the cuvette, react for 20 minutes at 37°C.
- Separate, aspirate, then wash the cuvette 3 times with universal wash buffer (LS-HC-AWB).
- Dispense 100 µL of pre-trigger solution and incubate for 1 minute, then dispense 100 µL of trigger solution to initiate the chemiluminescent reaction.
- Read the results.

DETECTION CAPABILITY

Measuring Range: 5.4~320 nmol/L

Limit of Blank (LoB): < 2.7 nmol/L

Limit of Detection (LoD): < 5.4 nmol/L

The Limit of Blank and Limit of Detection were determined according to the CLSI (Clinical and Laboratory Standards Institute) document P17-A2 requirements.

METHOD COMPARISON

The comparison of the LinsLink T4 assay with a commercially available T4 assay using clinical samples obtained the following results:

Number of samples tested (N)	66
Comparative Assay (x)	Elecsys® T4 assay
Correlation Coefficient (R)	0.99

PRECISION

Precision was determined using the LinsLink T4 assay reagents, samples and controls according to the CLSI (Clinical and Laboratory Standards Institute) document EP05-A3. Samples were assayed in duplicate in 2 runs per day for 21 days (n=84).

Sample	Mean (nmol/L)	Repeatability		Within-Laboratory Precision	
		sR	CV (%)	sWL	CV (%)
LS-CA-T4 Control 1	9.32	0.52	5.54	0.31	3.31
LS-CA-T4 Control 2	78.25	3.69	4.71	3.00	3.84
Human serum 1	7.67	0.30	3.96	0.26	3.43
Human serum 2	65.49	3.06	4.68	1.88	2.87