# Product Datasheet

## Free triiodothyronine (FT3) Chemiluminescent Bulk Reagents

### Catalog Number: LS-CLAE-FT3 10,000T

#### INTENDED USE

Free triiodothyronine (3,5,3'-triiodothyronine or FT3) chemiluminescent bulk reagents are designed for the quantitative determination of free triiodothyronine 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

Free triiodothyronine (FT3) assay is a delayed one-step competitive immunoassay with sheep anti-T3 monoclonal antibody coated onto magnetic particles. FT3 in the sample competes with acridine sulfonamide-labeled T3-derivative for a limited amount of the binding sites on anti-T3 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 FT3 present in the patient samples were inversely proportional to the amount of RLUs.

#### REAGENTS

- LS-CLAE-FT301: Magnetic particles coated with sheep anti-T3 monoclonal antibody in a HEPES buffer with protein stabilizers and 0.1% preservative (1 bottle, 500 mL).
- LS-CLAE-FT302: Acridine sulfonamide-labeled T3-derivative in a phosphate buffer with protein stabilizers and 0.1% preservative (1 bottle, 500 mL).

#### MATERIALS REQUIRED BUT NOT PROVIDED

- LS-CA-FT3: 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 ($K_2$-EDTA, $K_3$-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 2-8ºC, 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-FT3 for calibrating the LinsLink free triiodothyronine (FT3) assay.

- Traceability: Calibrator values have been made traceable to Elecsys® FT3 assay.
- 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-FT3 for quality control of the LinsLink free triiodothyronine (FT3) 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 30 µL of sample and 50 µL of LS-CLAE-FT301 into a cuvette, react for 20 minutes at 37°C.
- Dispense 50 µL of LS-CLAE-FT302 into the cuvette, react for 10 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: 0.6~50 pmol/L

Limit of Blank (LoB): < 0.4 pmol/L

Limit of Detection (LoD): < 0.6 pmol/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 free triiodothyronine (FT3) assay with a commercially available human free triiodothyronine (FT3) assay using clinical samples obtained the following results:

| | |
|---|---|
| Number of samples tested (N) | 76 |
| Comparative Assay (x) | Elecsys® FT3 assay |
| Correlation Coefficient (R) | 0.99 |

## PRECISION

Precision was determined using the LinsLink free triiodothyronine (FT3) 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 (pmol/L) | Repeatability | | Within-Laboratory Precision | |
|---|---|---|---|---|---|
| | | sR | CV（%） | sWL | CV（%） |
| LS-CA-FT3 Control 1 | 3.15 | 0.15 | 4.75 | 0.10 | 3.07 |
| LS-CA-FT3 Control 2 | 24.58 | 0.90 | 3.68 | 0.77 | 3.12 |
| Human serum 1 | 4.78 | 0.20 | 4.21 | 0.14 | 2.96 |
| Human serum 2 | 22.64 | 0.75 | 3.32 | 0.53 | 2.35 |