T3 Rapid Test Kit

Cat. No. SF102-01

INTENDED USE

T3 Test Cassetle (Whole Blood/Serum/Plasma) is based on the Flourescence immunoassay for the quantitative detection of total Triiodothyronine (T3) ijn human whole blood, serum or plasma.

SUMMARY &TEST DESCRIPTION

The physiological actions of thyroid hormones can be categorized as growth and development and control of metabolic process in the body. Thyroid hormones play a major role in the growth and development of the brain and central nervous system in humans from the 15nth week of gestation of 3 years of age. The other physiological role of thyroid hormones is to control several metabolic process in the body. These include carbohydrate, fat, protein, vitamin, and mineral metabolism.

Triiodothyronine (T3) is the biologically active thyroid hormone. In normal subjects, approximately 20% of T3 is secreted from the thyroid gland, and approximately 80% of T3 derives from the conversion of thyroxine (T4) to T3 in extra thyroidal peripheral tissue. It has the biological activity of prompting the metabolism of substance and energy, promoting the growth and development of the body. It is an important diagnostic index of thyroid diseases, and also has auxiliary diagnostic value for some non-thyroid diseases.

TEST PRINCIPLE

The T3 Test Cassette (Whole Blood/Serum/Plasma) detects T3 based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad by chromatographic force. If the sample containing T3, it attaches to the T3 antibody which is conjugated with fluorescent microspheres. Then the complex will captured by the T3 antibody coated on the nitrocellulose membrane (Test line).The concentration of the T3 in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of the T3 in the sample can be calculated by the analyzer to show T3 concentration in specimen.

REAGENTS & MATERIALS PROVIDED

1. Each Kit contains 30 test devices, each sealed in a foil pouch containing following items:
    a. One test card
    b. ID card
    c. Assay diluent
    d. Dropper
    e. Desiccant
    f. Analyzer
2. Instruction Leaflet

PRECAUTIONS & WARNINGS

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Do not use with specimen containing precipitates

STORAGE & STABILITY

Store the test kit between 4-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening

SPECIMEN COLLECTION

1. Collect the specimens according to standard procedures.

2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be used within 1 day of collection, Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.

3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens

4. EDTA, Heparin sodium, can be used as the anticoagulant tube for collecting the blood specimen.

TEST PROCEDURE

Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of analyzer. The test should be conducted at room temperature.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

1. Tum on the Analyzer power.
2. Take out the ID card and insert it into the ID Card Slot Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

To use a pipette: Pipette **20 µl of whole blood/serum/plasma** into the buffer tube: mix the specimen and the buffer well.

To use a dropper: Without squeezing the dropper, put the glass capillary tube end in contact with the liquid sample surface tilted. Liquid sample will migrate into the capillary tube automatically. Note: Make sure do not take the plastic part of the dropper in contact with the sample.

Then release the sample into the buffer tube by squeezing the bulb at the top end of the dropper vertically. Wash the tube 2-3 times by squeezing the top bulb. Mix the sample and the buffer well.

5. **To use a pipette**: Pipette **75 µL of diluted specimen** into the sample well. Start the timer at the same time.

To use a dropper, immerse the tube end (plastic tube) into the diluted sample: squeeze the top bulb to absorb the solution into the lower bulb (no more than the lower bulb). Squeeze the top bulb vertically to release the diluted solution into the sample well of the test cassette and start the timer.

6. Test result should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer

INTERPRETATION OF RESULTS

Results read by the Fluorescence Immunoassay Analyzer.

The result of test for T3 is calculated by the Fluorescence Immunoassay Analyzer and displayed on the screen. For additional information, please refer to the user manual of the Fluorescence Immunoassay Analyzer.

Linearity range of T3 is 0.62-9.24 nmol/L (0.4-6.0 ng/mL).

Normal Reference range (adult): 1.23-3.08 nmol/L (0.8-2.0 ng/mL)

Conversion factor as unit of nmol/L (SI unit) = 1.54 x ng/mL EXPECTED RESULTS

CONCENTRATIONS	CLINICAL REFERENCE
< 1.23 nmol/L (0.8ng/ mL)	Hypothyroidism or low T3 syndrome
1.23-3.08 nmol/L (0.8-2.0 ng/ mL)	Healthy
>3.08 nmol/ L (>2.0ng/mL)	Hyperthyroidism

Each laboratory should determine the applicability of the reference range through experiments, and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

sensit RAPID

Cat. No. SF102-01

PERFORMANCE AND CHARACTERESTICS

ACCURACY

The test deviation is ≤±15%

LINEARITY RANGE

0.062-9.24nmol/L (0.4-6.0 ng/mL**) , R**≥0.990

PRECISION

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 different concentrations of T3. C.V. is ≤15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations of T3. C.V. is ≤ 15%.

INTERFERING SUBSTANCES

The following substances do not interfere with the test result at the indicated concentrations : Absorbic acid at 200 mg/L , Haemoglobin at 10g/L , Triglyceride at 30g/L , Bilirubin at 1000mg/Dl , Uric acid at 200mg/L.

CROSS REACTIVITY

The test result Is not higher than 3.1 nmol/L (2ng/ml) when test T4 at 500ng/mL TSH at 20mU /L.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Sensit T3 Rapid Test for the detection of total Triiodothyronine (T3) in human whole blood, serum or plasma are the most common signs appearing on medical devices and their packaging.

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by

ubio Biotechnology Systems Pvt Ltd No 15A Biotechnology Zone
KINFRA Hi-Tech Park, Kalamassery Cochin, Kerala, India 683503
Ph:+91-484-2970043
http://www.ubio.in
e-mail: contact@ubio.co.in

UBD/QA/IFU/ *SF102-01*
Rev. No: A1.1/13-02-2025