T4 Rapid Test Kit

Cat. No. SF104-01

INTENDED USE

T4 Test Cassetle (Whole Blood/Serum/Plasma) is intended for in vitro quantitative detection of total Thyroxine (T4) in human whole blood, serum or plasma as an aid to assessment of thyroid function.

SUMMARY &TEST DESCRIPTION

Thyroid hormones are two hormones produced and released by the thyroid gland, namely triodothyronine (T3) and thyroxine (T4). They are tyrosine-based hormones that are primarily responsible for regulation of metabolism. The major form of thyroid hormone in the blood is Thyroxine (T4), which has a longer half-life than T3. In humans, the ratio of T4 to T3 released into the blood is approximately 14:1. so the thyroxine (T4) is a primary diagnostic marker for thyroid function

The thyroid hormones act on nearly every cell in the body. They act to increase the basal metabolic rate, affect protein synthesis, help regulate long bone growth (synergy with growth hormone) and neural maturation, and increase the body's sensitivity to catecholamine's (such as adrenaline) by permissiveness. The thyroid hormones are essential to proper development and differentiation of all cells of the human body .These hormones also regulate protein, fat, and carbohydrate metabolism, affecting how human cells use energetic compounds. They also stimulate vitamin metabolism. Numerous physiological and pathological stimuli influence thyroid hormone synthesis.

TEST PRINCIPLE

The T4 Test Cassette (Whole Blood/Serum/Plasma) detects T4 based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. T4 in the sample will compete with the T4 antigen coated on the membrane. The less T4 in the sample, the more fluorescent microspheres conjugated with anti-T4 antibodies can be captured by the T4 antigen coated on the membrane (Test line). The concentration of T4 in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of T4 in the sample can be calculated by analyzer to show T4 concentration in the sample.

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 T4 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.

Normal Reference range : 65-155 nmol/L

CONCENTRATIONS	CLINICAL REFERENCE
< 65 nmol/L	Deficency
65 ~155 nmol/L	Healthy
> 155 nmol/ L	Excess

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.

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PERFORMANCE AND CHARACTERESTICS

1.ACCURACY

The test deviation is ≤±15%

2. ASSAY RANGE AND DETECTION LIMIT

Assay Range: 12.87-300 nmol/L

Detection Limit (Analytical Sensitivity): 12.87nmol/L

3. PRECISION

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 different concentrations of T4 control. 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 T4 control. C.V. is ≤ 15%.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Sensit T4 Rapid Test for the detection of total Thyroxine (T4) 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
Σ X	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

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ubio Biotechnology Systems Pvt Ltd No 15A Biotechnology Zone KINFRA Hi-Tech Park, Kalamassery Cochin, Kerala, India 683503
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