Chuangxingwell

CE

Total Thyroxine (TT4) Rapid Test Kit
Instructions for Use

A rapid test for detecting TT4 quantitative in serum or plasma that with the use of Immunofluorescence Analyzer.

- For *in-vitro* diagnostic use

IVD

PACKING SPECIFICATION
25 Tests/ Kit

INTENDED USE
The Total Thyroxine (TT4) Rapid Test Kit is intended for in-vitro quantitative determination of total Thyroxine (TT4) in serum or plasma. Measurement of TT4 is used as an aid to assessment of thyroid function. The test is intended for healthcare professionals use.

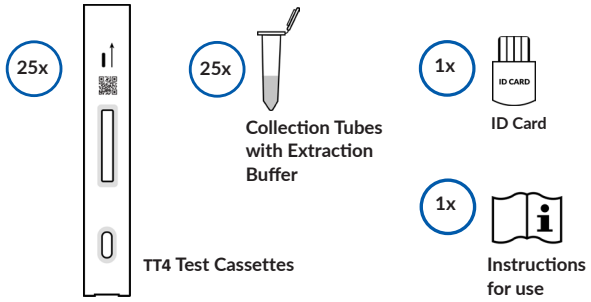
SUMMARY
Thyroid hormones are two hormones produced and released by the thyroid gland, namely triiodothyronine (T3) and thyroxine (T4). They are tyrosine-based hormones that are primarily responsible for regulation of metabolism. The major form of thyroid hormone in the blood is thyroxine (T4), which has a longer half-life than T3.[1] In humans, the ratio of T4 to T3 released into the blood is approximately 14:1.[2] 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 catecholamines (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.

PRINCIPLE
The TT4 Rapid Test Kit detects TT4 based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. TT4 in the sample will compete with the T4 antigen coated on the membrane. The less TT4 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 TT4 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 TT4 in the sample can be calculated by Analyzer to show TT4 concentration in the sample.

REAGENTS
The test include T4 antibody coated particles and T4-BSA antigen coated on the membrane.

MATERIALS PROVIDED



TT4 Test Cassettes

Collection Tubes with Extraction Buffer

ID Card

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer
- Pipette
- Centrifuge
- Timer

PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The TT4 Rapid Test Kit is only operational in the FIA Analyzer. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.

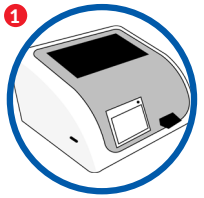
STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch. Shelf life is 24 months.
2. The test must remain in the sealed pouch until use and must be used within 1 hour if opened.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION

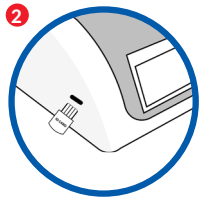
Blood Sample Taking
1. Collect the specimens according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2 - 8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to 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.

Sample Dilution / Sample Stability
1. Transfer **75 µL of serum or plasma** to the buffer tube with the micro pipette.
2. Close the tube and shake the sample by hand forcefully for approximately **10 seconds** so sample and dilution buffer mix well.
3. Let the diluted sample rest for approximately 1 minute.
4. The diluted sample can then be used as soon as possible.

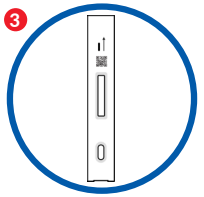
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



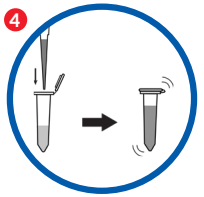
Turn on the Analyzer power.



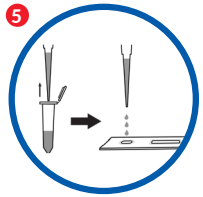
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



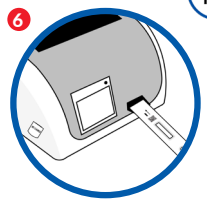
Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.



Place the test on a flat and clean surface.
Serum or plasma: Pipette **75 µL of serum or plasma** into the buffer tube, mix the specimen and the buffer well.



Add diluted specimen with a Pipette: Pipette **75 µL diluted specimen** into the sample well. Start the timer at the same time.



Test results should be interpreted at **10 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of tests for TT4 is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyze.

Working range of TT4 is 12.87 ~ 300 nmol/L.

QUALITY CONTROL

Each TT4 Rapid Test Kit contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer and indicates that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The TT4 Rapid Test Kit is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of TT4.
2. The TT4 Rapid Test Kit will only indicate the presence of T4 antigen in the specimen and should not be used as the sole criteria for evaluating thyroid function.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of Immunofluorescence Analyzer are only for the analysis of the results on the rapid tests. It should not be used as the sole criteria for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
<65 nmol/L	Deficiency
65 ~ 155 nmol/L	Health
>155 nmol/L	Excess

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation is ≤±15%.

2. Assay Range and Detection Limit

- Assay Range: 12.87 ~ 300 nmol/L.
- Detection Limit (Analytical Sensitivity): 12.87 nmol/L.

3. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 different concentration TT4 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 TT4 control, C.V. is ≤15%.

BIBLIOGRAPHY

1. Irizarry L (23 April 2014). "Thyroid Hormone Toxicity". Medscape. WedM LLC. Retrieved 2 May 2014.
2. Pilo A, Iervasi G, Vitek F, Ferdeghini M, Cazzuola F, Bianchi R (April 1990). "Thyroidal and peripheral production of 3,5,3'-triiodothyronine in humans by multicompartmental analysis". The American Journal of Physiology. 258 (4 Pt 1): E715–26. doi:10.1152/ajpendo.1990.258.4.E715. PMID 2333963. Surkset. al.,JAMA 291:228, 2004.

SYMBOLS

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
	Batch Code		Do Not Use if Package is Damaged
	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Consult Instructions for Use		Authorized representative in the European Community

Manufacturer
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