Diagnostic Kit for Free T4

A Fluorescence Immunoassay test for quantitative detection of Free Thyroxine (FT4) in human serum or plasma with the use of a Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

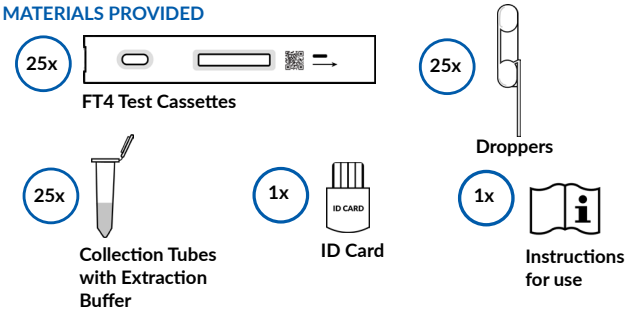
PACKING SPECIFICATION
25 Tests/ Kit (07FT45025)

INTENDED USE
The FT4 Test Cassette (Serum/Plasma) is intended for *in-vitro* quantitative determination of free Thyroxine (FT4) in human serum or plasma. Measurement of FT4 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.
Most of the thyroid hormone circulating in the blood is bound to transport proteins, and only a very small fraction is unbound and biologically active. Therefore, triiodothyronine (T3) and thyroxine (T4) measured as free T3 and free T4 can more accurately reflect the functional status of the thyroid.

PRINCIPLE
The FT4 Test Cassette (Serum/Plasma) detects FT4 based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. FT4 in the sample will compete with the T4 antigen coated on the membrane. The less FT4 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 FT4 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 FT4 in the sample can be calculated by the Immunofluorescence Analyzer to show FT4 concentration in the sample.

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

MATERIALS PROVIDED


MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Centrifuge
- Specimen Collection Containers
- 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. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. 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.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The FT4 Test Cassette 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.
2. The test must remain in the sealed pouch until use.
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.

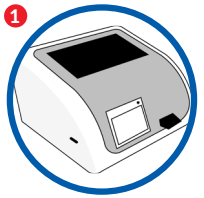
SAMPLE COLLECTION AND PREPARATION

Specimen Collection
Collect the specimens according to standard procedures.
EDTA K2, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the plasma specimens.
A clean tube without anticoagulants can be used to collect serum specimens.

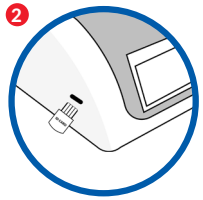
Specimen Storage and Shipping
Serum and plasma specimens may be stored at 2 - 8 °C for up to 7 days, and -20 °C for long term. Frozen specimens should be thawed and mixed before testing. Specimens should not be frozen and thawed repeatedly.
If specimens are to be shipped, these should be packed in compliance with local regulations covering the transportation of etiological agents.

Preparation
Before performing the test, please balance the sample to room temperature (15 - 30 °C). Frozen specimens must be completely thawed and mixed well prior to testing

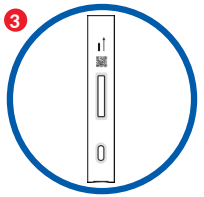
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions on use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



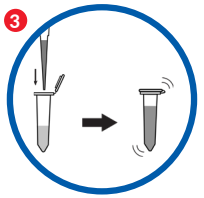
Turn on the Analyzer power.



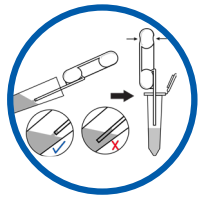
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



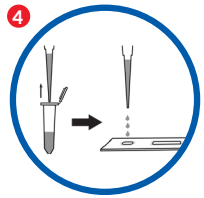
Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
Place the test on a flat and clean surface.



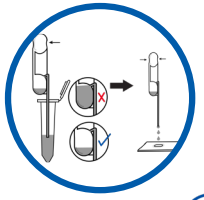
Use a pipette: Pipette **75 µL of serum or plasma** into the buffer tube, mix the specimen and the buffer well.



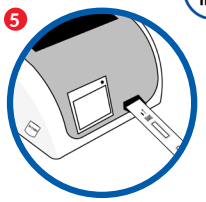
Use a dropper: Immerse the tube end into the sample; squeeze the top bulb to absorb the sample into the lower bulb (no more than the lower bulb). Then release the sample into the buffer tube by squeezing the bulb at the top end of the dropper vertically. Wash the tube 2-3 times by squeezing the top bulb. Mix the sample and the buffer well.



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



Immerse the tube end 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.



Test results should be interpreted at **15 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 test result of FT4 is calculated by Analyzer and displayed on the screen with concentration range of 1 ~ 100 pmol/L (0.08 ~ 7.75 ng/dL).
The normal reference range is 9 - 19.05 pmol/L (0.7 - 1.48 ng/dL).
(Concentration in ng/dL) x (12.87) = Concentration in pmol/L
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.

QUALITY CONTROL

Each FT4 Test Cassette contains internal control that satisfies routing 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 the Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on the 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 FT4 Test Cassette should be used only with the Immunofluorescence Analyzer.
2. The test should preferably be performed on freshly collected samples. For stored specimens, please refer to specimen storage.
3. The FT4 Test Cassette (Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of FT4.
4. The test may yield low results due to T4 epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of FT4 antigen with time and temperature.
5. Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test samples.
6. The FT4 Test Cassette (Serum/Plasma) will only indicate the presence of FT4 in the specimen and should not be used as the sole criteria for evaluating thyroid disease.
7. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
8. The results of Analyzer are only for the concentration of FT4. It should not be used as the sole criterion for treatment decisions. If the result is abnormal (low or high), other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
<9 pmol/L (0.7 ng/dL)	Hypothyroidism
9 - 19.05 pmol/L (0.7 - 1.48 ng/dL)	Healthy
>19.05 pmol/L (1.48 ng/dL)	Hyperthyroidism

PERFORMANCE CHARACTERISTICS

1. Method comparison
For 105 specimens, the test results of FT4 test cassettes were consistent with a commercial FT4 test kits and the correlation coefficient (R^2) is 0.9877.

2. Accuracy
The test deviation ≤ ±15%.

3. Assay Range
Assay Range is 1 ~ 100 pmol/L.

4. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 different concentration FT4 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 FT4 control. C.V. is ≤15%.

BIBLIOGRAPHY

1. Irizarry L (23 April 2014). "Thyroid Hormone Toxicity". Medscape. WedMD LLC. Retrieved 2 May 2014.
2. 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.

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
4℃ 30 ℃	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
LOT	Lot Number	CE	European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date	Σ	Tests per Kit
UDI	Unique Device Identifier		

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