CE

Diagnostic Kit for Free T3

A rapid test for for quantitative detection of FT3 in human serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

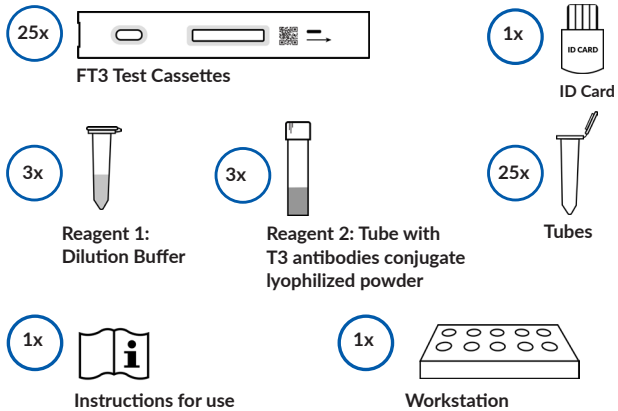
PACKING SPECIFICATION
25 Tests/ Kit (07FT35025)

INTENDED USE
The FT3 Test Cassette (Serum/Plasma) is based on Fluorescence Immunoassay for the quantitative detection of free Triiodothyronine (FT3) in human serum or plasma. The test is intended for healthcare professionals use.

SUMMARY
The physiological actions of thyroid hormones can be categorized as growth and development and control of metabolic processes in the body. Hypothalamic-pituitarythyroid axis can control the synthesis, release and function of thyroid hormone. It's secreted from the hypothalamus Thyrotropin releasing hormone (TRH) stimulates the synthesis and release of thyrotropin or TSH. In turn, TSH Stimulate the synthesis, storage, secretion and metabolism of thyroxine (T4) and triiodothyronine (T3). In the blood, there are free and combined forms of T4 and T3. In blood circulation, more than 99% of T4 and T3 bind to carrier proteins. The remaining Less than 1% of T4 and T3 are free. Such unbound or free hormone levels are associated with thyroid function in most humans. It depends on the energy state.[1, 2]
Free T3 and free T4 regulate normal growth and development by maintaining body temperature and stimulating heat generation. In addition, FT4 with FT3 also affects all aspects of carbohydrate metabolism and some aspects of fat and vitamin metabolism. Fetal and Thyroid hormones are also needed for newborn development.[1,2]

PRINCIPLE
The FT3 Test Cassette (Serum/Plasma) detects FT3 based on Fluorescence Immunoassay. The specimen moves through the strip from sample pad to absorbent pad. FT3 in the specimen will compete with the T3 antigen coated on the strip. The less FT3 in the specimen, the more fluorescent microspheres conjugated with anti-T3 antibodies can be captured by the T3 antigen coated on the strip. The concentration of FT3 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 FT3 in the sample can be calculated by analyzer to show FT3 concentration in the specimen.

REAGENTS
The test cassette contains T3 antigen and T3 antibody.

MATERIALS PROVIDED


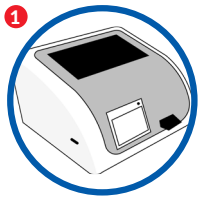
MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipettes
- Centrifuge
- Specimen Collection Containers
- Timer

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 FT3 Test Cassette should only be used with the analyzer by approved medical professionals.

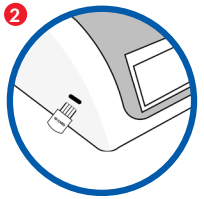
STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiration date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence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

SAMPLE COLLECTION AND PREPARATION
1. Collect the specimen 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 7 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 K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.
5. 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.

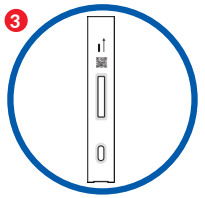
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions on use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



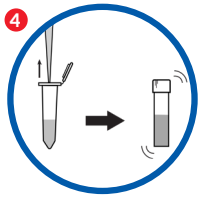
Turn on the Analyzer power.



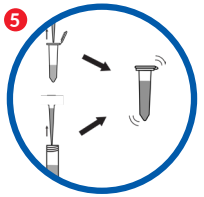
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



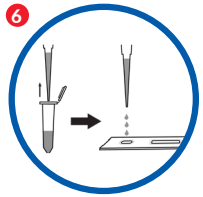
Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch. Place the test on a flat and clean surface.



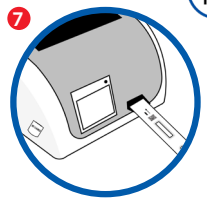
Pipette **900 µL of reagent 1** into the reagent 2 tube and dissolve the lyophilized powder thoroughly.
Note: After dissolution, the dissolved reagent 2 could be stored at 2-8 °C for 30 days or stored at -20 °C for long period.



Pipette **75 µL** of the dissolved reagent 2 and **75 µL** of serum or plasma into empty tube to mix the specimen and the dissolved reagent 2 well. Leave the mixture for reaction of 5 minutes.



Then pipette **75 µL diluted sample** into the sample well of the cassette. Start the timer at the same time.



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 result of test for FT3 is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

Linearity range of FT3 is 1.5 - 46 pmol/L (0.97 - 29.8 pg/mL).

Normal Reference range (adult): 2.6 - 5.7 pmol/L (1.7 - 3.7 pg/mL).

Conversion factor as unit of pmol/L (SI unit) = 1.54*pg/mL.

QUALITY CONTROL

Each FT3 Test Cassette (Serum/Plasma) 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 inserted and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer. 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 FT3 Test Cassette (Serum/Plasma) is for *in-vitro* diagnostic use only.
2. The test should be used for the detection of Triiodothyronine (Free T3) in serum or plasma specimens only.
3. The FT3 Test Cassette (Serum/Plasma) will only indicate the presence of FT3 in the specimen and should not be used as the sole criteria of diagnosis of hyperthyroidism or hypothyroidism.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. For patients receiving high-dose biotin (ie >5 mg/day), samples can be collected at least 8 hours after the last biotin dose.

EXPECTED VALUES

Concentrations	Clinical Reference
<2.6 pmol/L (1.71 pg/mL)	Low
2.6 - 5.7 pmol/L (1.71 - 3.7 pg/mL)	Normal
>5.7 pmol/L (3.7 pg/mL)	High

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.

PERFORMANCE CHARACTERISTICS

1. Method comparison

The assay was compared with commercial CLIA test kit with 140 samples. The correlation coefficient (R^2) is 0.9925

2. Accuracy

The test deviation is ≤±15%.

3. Linearity range

1.5 - 46 pmol/L (0.88 - 29.8 pg/mL), R≥0.990

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 different concentration of FT3. 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 concentration of FT3. C.V. is ≤15%.

5. Interfering substances

The following substances do not interfere with the test results at the indicated concentrations: Ascorbic Acid at 200 mg/L, Hemoglobin at 10 g/L, Triglyceride at 30 g/L, Bilirubin at 1,000 mg/dL, Uric Acid at 200 mg/L.

BIBLIOGRAPHY

1. Gornall, AG, Luxton, AW, Bhavnani, BR. Endocrine Disorders. In Applied biochemistry of clinical disorders. 1986; 305-318. Philadelphia, PA: J. B. Lippincott Co.
2. White, GH. Recent advances in routine thyroid function testing. CRC - Critical Reviews in Clinical Laboratory Sciences. 1987; 24: 315-362.

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
	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		Tests per Kit
UDI	Unique Device Identifier		

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