Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

FT3

Free Triiodothyronine Test Kit
(Fluorescence Immunoassay Method)

Instructions for Use

Version:A/0

REF HP-Palm-FT3-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.

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Product Name

General Name：Free Triiodothyronine Test Kit.

(Fluorescence Immunoassay Method) .

Package Specification

25 Tests/Kit.

Intended Use

The Hipro Free Triiodothyronine(FT3) Test Kit is an vitro diagnostic test for the quantitative measurement of Free Triiodothyronine (FT3) in human serum or plasma.

FT3 is the physiologically active portion of thyroxine.FT3 is measured together with FT4 (free thyroxine) and TSH (thyrotropin) when thyroid dysfunction is suspected. It is indicated for monitoring antithyroid therapy. Triiodothyronine (T3) is one of the serum thyroid hormones that plays a role in regulating metabolism.

Measurement of the level of this hormone is important in the differential diagnosis of normal, hyper- or hypothyroidism. The majority of T3 is bound to its transport proteins (TBG, prealbumin,albumin), and FT3 is the physiologically active form of T3.The advantage of FT3 measurement is that it is unaffected by changes in the concentration and binding properties of its binding proteins.FT3 is a sensitive indicator for the diagnosis of hyperthyroidism, and the early onset of or precursor to Graves disease, with an elevation of FT3 earlier than that of FT4, can help to confirm the diagnosis of Graves disease. Confirmation of the diagnosis. Autonomous thyroid nodule T3 secretion is higher, this case FT4 can be normal, but often accompanied by FT3 elevation, the measurement of FT3 in patients with thyroid nodules can help to determine the function of the thyroid gland. It is not as valuable as FT4 in the diagnosis of hypothyroidism.

Clinical studies have shown that progesterone plays a role in promoting ovulation and maintaining the normal function of corpus luteum in non-pregnant women. Insufficient progesterone production by the corpus luteum may indicate the presence of corpus luteum insufficiency (LPD), which is associated with infertility and early miscarriage. In women who take oral contraceptives, progesterone levels are suppressed. Decreased progesterone is common in luteal insufficiency, polycystic ovary syndrome, fetal growth retardation, stillbirth, primary and secondary amenorrhea, anovulatory uterus, functional bleeding, etc.

Test Principle

This test kit based on the competitive immunofluorescence

method to quantitatively determine the concentration of FT3 in human serum or plasma.

The binding pad contains fluorescent microsphere-labeled murine anti-human FT3 monoclonal antibody, the nitrocellulose membrane detection area (T) is encapsulated with FT3 recombinant antigen, and the quality control area (C) is encapsulated with sheep anti-mouse IgG polyclonal antibody.

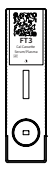
During the detection process, the FT3 antigen in the sample competes with the FT3 recombinant antigen encapsulated in the detection zone (T) for the antigen-binding site of the fluorescent microsphere-labeled murine anti-human FT3 monoclonal antibody, and the amount of FT3 in the sample is inversely proportional to the amount of the fluorescent complex formed in the detection zone (T). The excess labeled antibody specifically binds to the sheep anti-mouse IgG polyclonal antibody encapsulated in the quality control area (C) to form a fluorescent complex. After the reaction, the fluorescence immunoassay analyzer will calculate the total FT3 concentration by detecting the fluorescence intensity of T and C line.

Material Provided

Component	25Kits
Sample Diluent	25
Calibration Cassette	1
Test Cassette	25
Instructions for Use	1
Disposable tube with 60μL	25
Disposable tube with 80μl	25

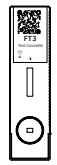
Sample Diluent

Calibration Cassette

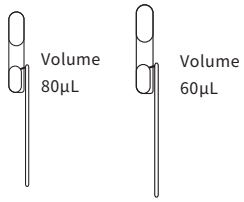


QR code is with built-in parameter for each assay.

Test Cassette



Disposable tube with 80μL&60μL



Material Needed but Not Provided

1. Timing device

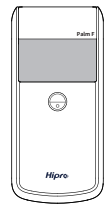
Storage&Validity

Store test kit at: 2°C-30°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.

Perform the test within 1 hour when opened.

Applicable Instrument



Palm F Fluorescence Immunoassay Analyzer

Specimen type

1. The specimen type of FT3 test kit is human serum or plasma.
2. Plasma is recommended to use EDTA, lithium heparin.
3. Fresh collected specimen should be measured within 2 hours otherwise should be stored at 2°C~8°C up to 24 hours.
4. Avoid hemolysate. Ensure the test kits are back to room temperature before use.

Storage

1. For long-term storage the serum or plasma should stored at -20 °C up to 3 months.
2. Avoid repeated freezing and thawing.

Required volume

80μL is required for serum,plasma , used for dilution.

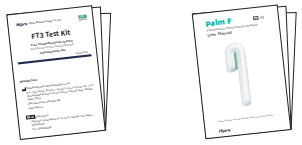
60μL is required of diluted sample for each determination.

This volume does not include the dead volume(unusable volume inthe sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

FT3 Test Kit Instructions Guide

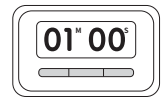
Before You Begin

1a Please read the FT3 IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

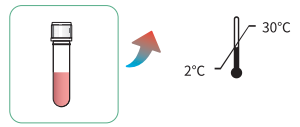


Before You Begin

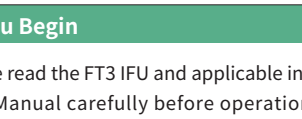
1b A timing device (phone, clock or timer) is required but not provided.



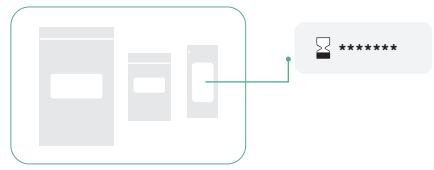
1c Allow the sample back to room temperature.



1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

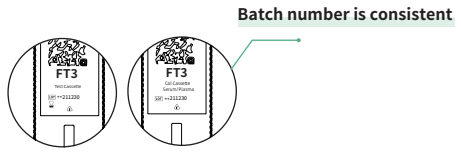


1e Check on the expiration date on labels of different component.



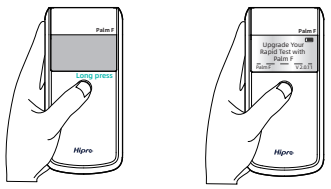
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.



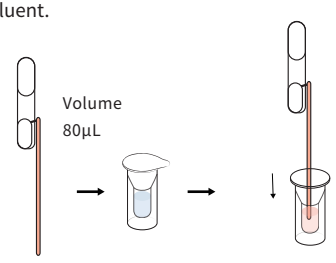
Test Procedures

2a Turn on the applicable instrument according to the User Manual.

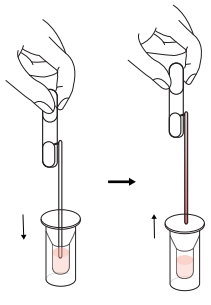


2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.

3a Use the disposable tube to collect and add 80μL specimen (serum/plasma) into the sample diluent.



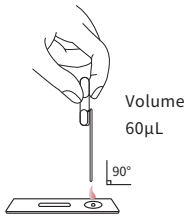
3b Repeated squeezing and absorbing to mix the samples.



Note:Do not make the liquid entering into the balloon interior during the squeezing and absorbing process.

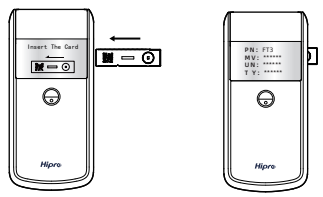
Test Procedures

3c Use a 60μL disposable tube to collect and add the mixed liquid onto the sample well of test cassette.



3d Wait for 15 minutes .

3e Insert the test cassette into the analyzer and the analyzer will display the results automatically.



! Avoid bubbles when collecting samples.

Reference Value

The normal reference range is 3.5pmol/L-6.57pmol/L.

159 healthy patients' serum were measured and the results (95%) meets the linearity range.

Recommended that each laboratory establish its own reference range.

Interpretation

1. The Hipro FT3 Test Kit is for in vitro diagnostic use only.

The data obtained by this test should be used in conjunction with other clinical findings and testing methods.

2. Dilution is not recommended for samples in the superlinear range.

3. If the test results are different from clinical symptoms, retesting is recommended.

Precautions and limitations

1. The Hipro Free Triiodothyronine (FT3) test kit is an vitro diagnostic test for the quantitative measurement of FT3 in human serum or plasma.
2. For terminal purposes, the results obtained from this assay should always be used in combination with the clinical examination,patient medical history, and other findings.
3. Testing the same sample with test kits from different manufacturers may result in different test results due to methodological or antibody specificity reasons, so results from testing with different test kits should not be directly compared with each other to avoid incorrect

   medical interpretation.
4. The results of this test can be influenced by factors present in some patients' specimens. The factors include hemoglobin>6mg/mL, bilirubin >0.6mg/mL, triglyceride>10mg/mL.
5. This product is not influenced by aspirin <75mg/dL, sodium salicylate <75mg/dL, Ibuprofen <750 mg/dL, acetaminophen <200 mg/dLand methimazole <0.4mg/dL.
6. This product is not influenced by 3,5,3,,-Triiodothyronine ⩽200ng/mL, 3,3,,5,-Triiodothyronine⩽100ng/mL, 3,3,-Diiodothyronine⩽200ng/mL.

Performance Characteristics

1.Appearance

The inside package should be sealed tightly and no air leakage; the information on label is complete and clear. The surface of the test cassette should be smooth.

2.Strip width

The width of strip should be ⩾2.5mm.

3.Liquid flow speed

The speed should be ⩾10mm/min.

4.Linearity

Within range 1.4-45pmol/L, the correlation coefficient (r) should be ⩾0.990.

5.Within-lot precision

The coefficient of variation (CV) should be ⩽15%.

6.Between-lot precision

The coefficient of variation (CV) should be ⩽15%.

7.Accuracy

The relative deviation should be ⩽15%.

8.Limit of detection(LoD)

The LoB should be ⩽0.35pmol/L.

Precautions

1.For in vitro diagnostic us, do not reuse, do not use expired product.

2.All samples should be considered potentially infectious and suitable protective measures should be taken. Laboratory gloves should be worn while handling patient' sample,disposal of waste, storage, mixing and testing. Disposal of all wast material should be in accordance with local guidelines.

3.Do not use damaged test kits, or expired test cassette.

4.Make sure the lot number on calibration card and test cassette are same. Do not misuse the reagents with different lot.

5.The desiccant inside the package not to be used for other purposes.

6.The test cassette and the components are only match with the suitable fluorescence immunoassay analyzer.

7.Avoid electromagnetic or vibration environment for analyzer; The vibration of the instrument is normal when it working.

8.Do not insert the polluted cassette into analyzer. Please dispose the used test cassette properly.

9.Any questions or suggestions about the test kits, please contact the manufacturer.

Symbols used on labels

Symbol	Usage
	Use-By date
LOT	Batch code
	Manufacturer
	Keep Away from Sunlight
2°C 30°C	Temperature Limit
IVD	In Vitro Diagnostic Medical device
EC REP	Authorized Representative in the European Community
CE	CE Mark
	Consult Instructions for use
	Do not freeze
Σ	Contains sufficient for <n> tests
	Biological risks
	Do not use if package is damaged
	Date of manufacture
	Do Not Reuse

Reference

1.Li S, He YN, Hu QW. Exploration of the clinical application of measuring serum T3, T4, FT3, FT4 and sTSH concentrations in hyperthyroid patients[J].Radioimmunology impurity, 2010,2(4):443-444.

2.Umar H,Muallima N,Adam J M,et al.Hashimoto' s thyroiditis following Graves' s disease[J].Acta Med Indones,2010,42 (1):31-45.

Approval Date &Revision Date

Approval Date: Mar 4,2022

CE IVD

工艺：70g双胶纸，双面印刷，横向4折页，竖向对折　展开尺寸：32*25cm，第一页的左上角项目名称为封面