Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

FT4

Free Thyroxine Test Kit
(Fluorescence Immunoassay Method)
Instructions for Use

Version:A/1

REF HP-Palm-FT4-25

Manufacturer

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Product Name

General Name：Free Thyroxine Test Kit
(Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit.

Intended Use

The Hipro Free Thyroxine (FT4) Test Kit is an vitro diagnostic test for the quantitative measurement of Free Thyroxine (FT4) in human serum or plasma.

Serum free thyroxine (FT4) is a sensitive indicator of thyroid function in vitro. It is a relatively accurate indicator of thyroid function even when physiologic and pathologic conditions causechanges in plasma thyroid-binding protein binding and concentration.

(1) Elevated: thyrotoxicosis, synucleinic hyperthyroidism, painless thyroiditis with hyperthyroidism, subacute thyroiditis with hyperthyroidism, overdose of thyroid preparations, thyroid receptor deficiency, chronic thyroiditis with hyperthyroidism.

(2) Reduction: hypothyroidism (primary) pituitary or painless subacute thyroiditis with a transient hypothyroid phase,hypoalbuminemia.

Test Principle

This test kit based on the competitive immunofluorescence method to quantitatively determine the concentration of FT4 in human serum or plasma.

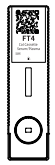
The binding pad contains fluorescent microsphere-labeled-murine anti-human FT4 monoclonal antibody, the nitrocellulose membrane detection area (T) is encapsulated with FT4 recombinant antigen, and the quality control area (C) is encapsulated with sheep anti-mouse IgG polyclonal antibody.During the detection process, the FT4 antigen in the sample competes with the FT4 recombinant antigen encapsulated in the detection zone (T) for the antigen-binding site of fluorescent microsphere-labeled murine anti-human FT4 monoclonal antibody, and the amount of FT4 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 FT4 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

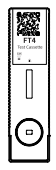
Sample Diluent

Calibration Cassette

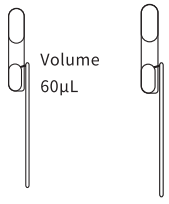


QR code is with built-in parameter for each assay.

Test Cassette



Disposable tube with 60μL&80μL



Material Needed but Not Provided

Timing device

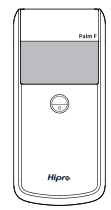
Storage&Validity

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 FT4 test kit is human serum or plasma.
2. Plasma is recommended to use EDTA, lithium heparin anticoagulant.
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.

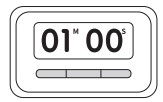
FT4 Test Kit Instructions Guide

Before You Begin

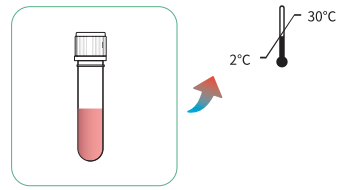
1a Please read the FT4 IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

Before You Begin

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

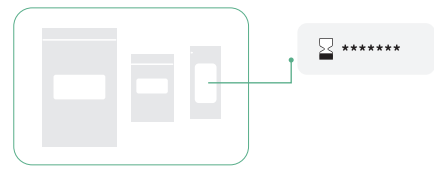


1c Allow the sample back to room temperature.



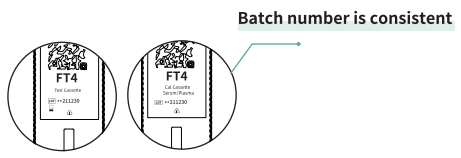
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

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



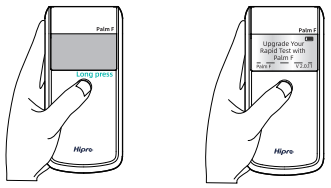
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.

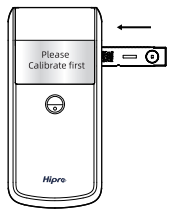


Test Procedures

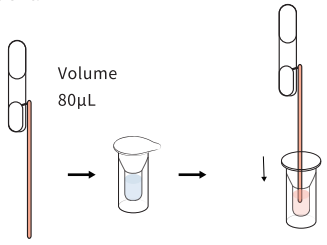
2a Turn on the applicable instrument according to the User Manual.



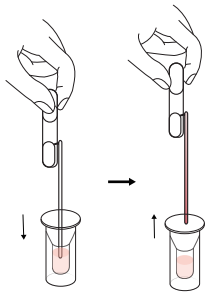
2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.



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



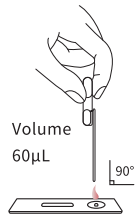
3b Repeated squeezing and absorbing to mix the samples.



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 7.63pmol/L-16.03pmol/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 FT4 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 Thyroxine (FT4) test kit is an vitro diagnostic test for the quantitative measurement of FT4 in human serum,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 <60mg/dL, sodium salicylate <50mg/dL and 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 3.2-77.2pmol/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 ⩽0.5pmol/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, FT4, 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: Jan 28,2022
Revision Date: Dec 22,2023

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