Diagnostic Kit for Free Triiodothyronine (fluorescence immunochromatographic assay)

Instructions for Use

INTENDED USE

This kit is applicable to in vitro quantitative detection of free triiodothyronine (FT3) in human serum/plasma/whole blood sample, which's mainly used for assessment of thyroid function. This kit only provides free triiodothyronine (FT3) test results, and results obtained shall be used in combination with other clinical information for analysis. It must only be used by healthcare professionals.

SUMMARY

Triiodothyronine is one of thyroid hormones that regulate metabolism in serum. Determination of triiodothyronine concentration can be used for diagnosis and identification of normal thyroid function, hyperthyroidism, and hypothyroidism. Main parts of total triiodothyronine bonds with transport proteins (TBG, prealbumin and albumin). Free triiodothyronine (FT3) is a form of biological activity of the thyroid hormone of triiodothyronine (T3). Free T3 assay has the strength of not affected by changes in concentration and binding properties of binding protein.

PRINCIPLE OF DETECTION

This kit uses competitive immunoassay and fluorescence immunochromatographic assay of high specificity for quantitative detection of free triiodothyronine (FT3) in human serum/plasma/whole blood sample. Test strip contains conjugate coated with FT3 and BSA pre-fixed to test area (T) on membrane and goat anti-chicken IgY antibody prefixed to control area (C), and marker pad contains pre-coated fluorescently labeled anti-FT3 antibody and chicken IgY antibody. During detection, free FT3 will bond with fluorescently labeled anti-FT3 antibody and form immune complex first. The immune complex and unbound fluorescence marker flow towards the direction of bibulous paper inside nitrocellulose membrane under chromatographic effect. Unbound fluorescence marker bonds with coated conjugate on membrane when the complex passes test area (T), fluorescently labeled chicken IgY antibody bonds with coated goat anti-chicken IgY antibody when the complex passes control area (C) and forms the complex of "goat anti-chicken IgY antibody - fluorescently labeled chicken IgY antibody", and agglutinates. Since FT3 in sample has competitive relation with conjugate of FT3 and BSA, FT3 concentration in sample is negatively correlated with fluorescence intensity, and FT3 concentration in sample can be detected by fluorescence immunoanalyzer.

MAIN KIT COMPONENTS

Catalogue number	52311701	52311705	52311720	52311725
specification / Components	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Test device	1	5	20	25
Sample diluents	1	5	20	25

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Note: The volume of sample diluent is 160 µL per vial.

MAIN ACTIVE INGREDIENTS

1 Test line (T line): T line area of nitrocellulose membrane is coated with conjugate of FT3 and BSA.

2 Control line (C line): C line area of nitrocellulose membrane is coated with goat anti-chicken IgY antibody.

3 Marking pad: It is coated with fluorescent-microsphere-marker anti-FT3 antibody and chicken IgY antibody.

4. Main component of sample diluent is 20mM, pH7.4 PBS solution.

Warning：The diluent includes 0.1% Proclin300

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

P280: Wear protective gloves/protective clothing/face protection.

P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2℃~30℃. The shell life of the kit is 24 months.
2. Do not use the kit after the expiration date

APPLICABLE INSTRUMENT

The test must be quantified with Igloo Reader Pro, available from goodscare GmbH or Dx365 GmbH, Germany.

SAMPLE COLLECTION AND STORAGE

1.This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as heparin, and sodium citrate.

2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedure.

3. To avoid interferencewith the test result, do not use hyperlipidemic, hemolytic or turbid sample.

4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2℃~8℃ for up to 2 days

5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be tested immediately. If test cannot be performed in time, the separated samples can be stored at 2℃~8℃ for 7 days. If frozen below -15℃, samples can be stored for 6 months.

6.Fresh terminal blood of fingertips should be used immediately after collection.

7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.

8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.
2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

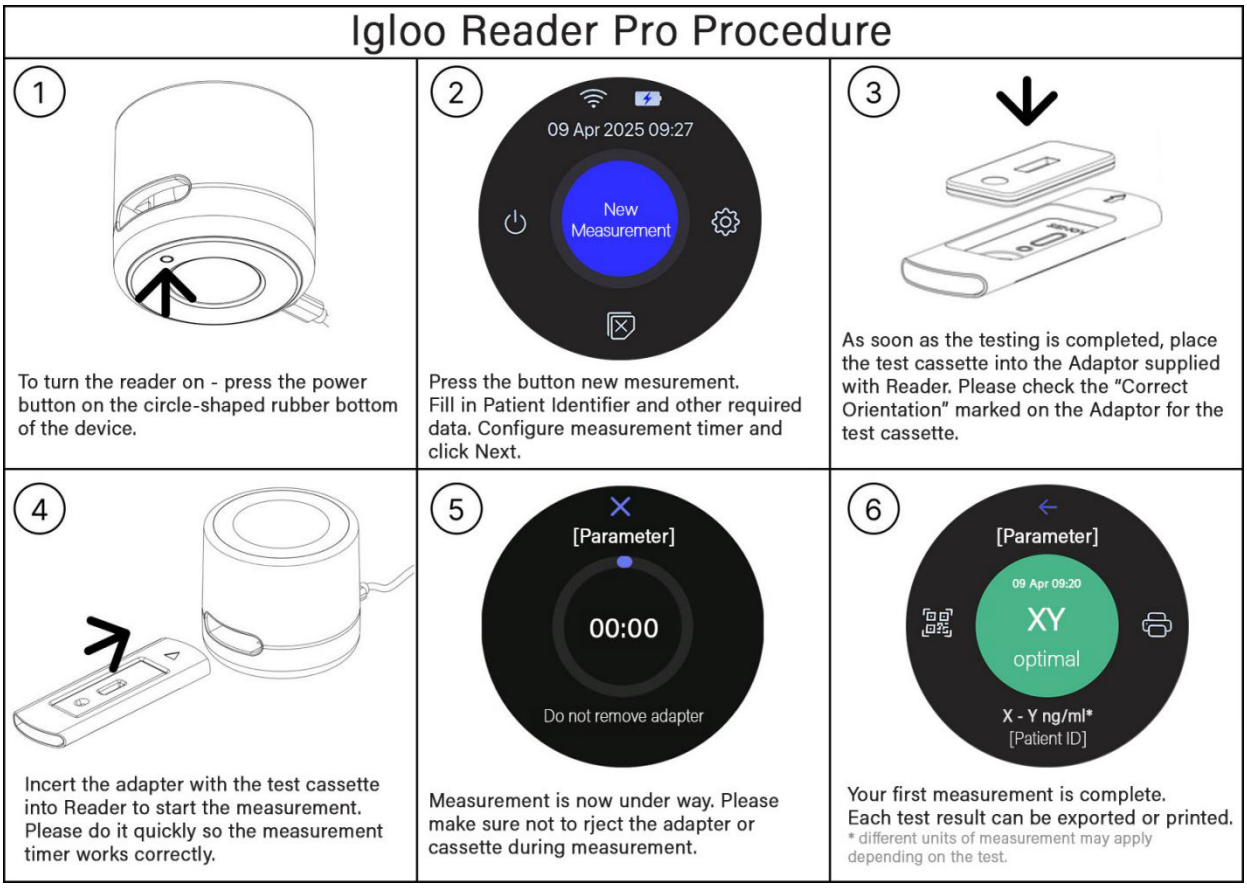
1: Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;

(2) Take out sample diluents, add 20μL of serum/plasma/whole blood/fresh finger terminal blood sample and mix;

(3) Add 80μL of above mixed solution into the sample hole of test device;

(4) Reaction time is 15 minutes.



REFERENCE INTERVAL

1. Through study on reference interval of FT3 based on C28-A2 Define and Determine Reference Intervals in the Clinical Laboratory - Second Edition released by Clinical and Laboratory Standards Institute (CLSI) and WST 402-2012 Define and Determine the Reference Intervals in Clinical Laboratory, the reference interval of FT3 obtained

is: 2.8-7.1 pmol/L.

2. Given geographical, race and age difference, different laboratories are recommended to develop FT3 reference intervals of related clinical significance that suit populations of their own areas.

INTERPRETATION OF THE RESULT

1. Aforesaid data are reference intervals established for detection data of this kit, and different laboratories are recommended to develop reference intervals of related clinical significance for populations of their own areas.
2. Physiological change, stress reaction and other statuses shall be excluded in case of measured concentration of sample FT3 more than reference interval. Clinical symptom diagnosis shall be taken into consideration in case of real abnormalities. Aforesaid results are for reference only.
3. Measured results of this method are only applicable to judgment by reference interval established by this method, which are not directly comparable with results of other methods.
4. Other factors may also give rise to incorrect detection results, which include technical reasons, operational errors and other sample related factors.

*Invalid result: If the assay result is invalid, the Igloo Reader Pro will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result is obtained If it reappears, please contact the device manufacturer.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.
9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.
18. Sample cannot be diluted during test, T3 can be free, and protein bound in blood, which are in equilibrium.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal reference material of the enterprise demonstrates that all performance indexes of this kit conform to standard. Specific performance indexes are as below:

1. Linearity range: linearity of reagent (kit) shall be within the range from 2.0 pmol/L～50.0 pmol/L. Analytical performance meets following requirements:

a) Linear correlation coefficient (r) shall be ≥0.9900.

2. Accuracy: recovery shall be within the range of [85%～115%];

3. Detection limit: ≤1.5pmol/L;

4. Repeatability: CV≤15%;

5. Specificity: The following substances were tested at the concentrations shown in the table and did not produce nonspecific responses.

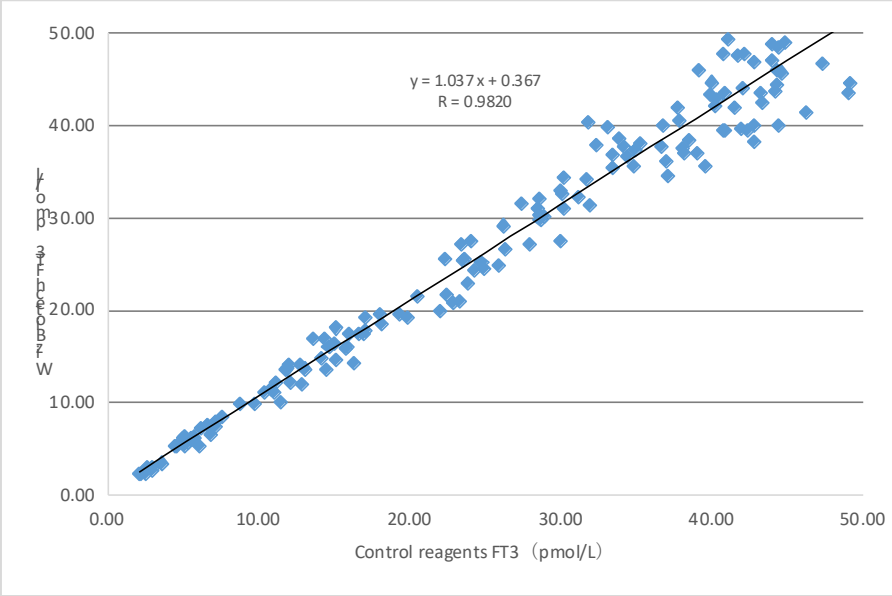
Substance	Concentration	Substance	Concentration
rT3	100ng/mL	T4	200ng/mL

8. Interfering substance: Following substances are found to cause no interference when they are tested at the given concentration.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2 mg/mL	Triglyceride	40.0 mg/mL
Hemoglobin	200μg/mL	Rheumatoid factor	1500 IU/mL
Transferrin	100μg/mL	-	-

9. Clinical performance

Clinical performance of this product's assessed through collection of 161 cases of clinical samples. Corresponding marketed kit of electrochemiluminescence assay's used as reference reagent, detection results have been compared and their comparability has been studied through linear regression, and correlation coefficients of the two assays are Y=1.037X+0.367 and R=0.9820 respectively.



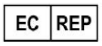
LIMITATION

1. This reagent is only used for testing human whole blood, serum, and plasma.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
5. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
6. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
7. If the obtained result is questionable, immediately re-test or use other method to test the sample.
8. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

[1] Ortega E, Koska J, Pannacciulli N, etc. Free triiodothyronine plasma concentrations are positively associated with insulin secretion in euthyroid individuals. Eur J Endocrinol. 2008;158(2):217-221.
[2] GOOLDEN AW, BURRELL CD. The clinical applications of triiodothyronine. Br Med J. 1957;2(5052):1028-1032.
[3] Li L, Guo CY, Yang J, etc. Negative association between free triiodothyronine level and international normalized ratio in euthyroid subjects with acute myocardial infarction. Acta Pharmacol Sin. 2011;32(11):1351-1356.
[4] Falkowski B, Rogowicz-Frontczak A, Grzelka A, etc. Higher free triiodothyronine concentration is associated with lower prevalence of microangiopathic complications and better metabolic control in adult euthyroid people with type 1 diabetes. Endocrine. 2018;60(3):458-465.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer
	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2℃～30℃		Catalogue number		Batch code
	Authorized Representative in the European Community		Caution		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