

HISCL™ FT4 Assay Kit

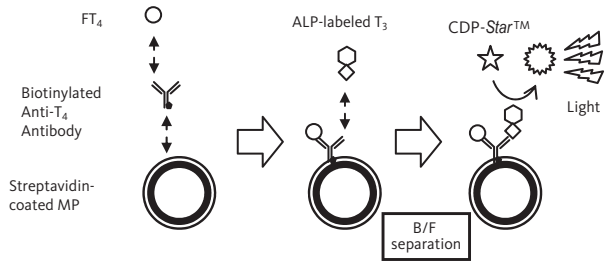
Identification of the IVD reagent
HISCL™ FT4 Assay Kit

[Note 1] R1 reagent and R3 reagent are provided in a two-in-one reagent container.

Intended use
For in vitro diagnostic use only
Measurement of free thyroxine in serum or plasma

Development process and characteristics
T₄ (thyroxine) and T₃ (triiodothyronine) are thyroid hormones which enhance metabolism. Most T₄ and T₃ molecules are bound to serum proteins. Bioactive FT₄ (free thyroxine) and FT₃ (free triiodothyronine), which constitute less than 0.03% and 0.3% of total T₄ and T₃, respectively, are in equilibrium with the corresponding bound forms. Since FT₄ and FT₃ concentrations are independent of bound protein concentrations, FT₄ and FT₃ are commonly measured as indices of thyroid function, and used for the diagnosis and monitoring of thyroid diseases.
This kit measures FT₄ based on the chemiluminescence enzyme immunoassay method with CDP-*Star*™ chemmiluminescent substrate.
This kit is exclusively designed for Sysmex Automated Immunoassay System.

Principles of the examination method
This kit measures FT₄ based on the 1-step competitive chemiluminescent enzyme immunoassay.
1. Biotinylated anti-T₄ monoclonal antibodies (mouse) in R1 reagent specifically react with FT₄ in the sample, and bind to streptavidin-coated MP (magnetic particles) in R2 reagent.
2. ALP (alkaline phosphatase)-labeled T₃ in R3 reagent cross-reacts with unbound antibodies.
3. After B/F separation, ALP on MP breaks down the CDP-*Star*™ substrate in R5 to an excited intermediate, which produces a luminescent signal.
Because the light production decreases in proportion to FT₄ concentration, sample FT₄ concentrations can be obtained with a calibration curve prepared with calibrators.











- Components**
This kit consists of the following reagents. Item 4-6 are sold separately.
1. R1 reagent: contains biotinylated anti-T₄ monoclonal antibodies (mouse) 75 ng/mL
 2. R2 reagent
 3. R3 reagent: contains ALP-labeled T₃ 0.06 U/mL
 4. HISCL Substrate Reagent Set
 - (1) R4 reagent
 - (2) R5 reagent: contains CDP-*Star*™: Disodium 2-chloro-5-(4-methoxy Spiro{1,2-dioxetane-3,2'-(5'-chloro)-tricyclo[3.3.1.1^{3,7}]decan}-4-yl)-1-phenyl phosphate 0.48 mM
 5. HISCL Washing solution
 6. HISCL FT4 Calibrator
 - (1) HISCL FT4 C0
 - (2) HISCL FT4 C1
 - (3) HISCL FT4 C2
 - (4) HISCL FT4 C3
 - (5) HISCL FT4 C4
 - (6) HISCL FT4 C5

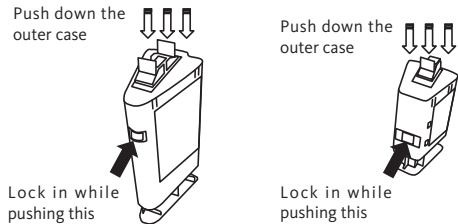
- Warnings and precautions**
1. Use the kit according to the method stipulated in the package insert. The reliability of results cannot be guaranteed if the kit is used with a method or for a purpose other than those stipulated.
 2. Handle each reagent carefully without generating air bubbles, which may produce incorrect analysis results. If bubbles appear, wait until they disappear.
 3. Do not combine reagents from different kits. Do not pool reagents even if the Lot No. of the kits are the same. Use reagents prior to the expiry date. The reliability of results cannot be guaranteed if reagents are used past their expiration date.
 4. Avoid eyes and skin contact with R5 reagent as it is an alkaline solution of pH9.6.
 5. All Calibrator bottles should be quickly closed after dispensing drops of the Calibrator solution, and then stored at 2-8°C. If bottles are left open, Calibrators may become concentrated due to evaporation, resulting in incorrect calibration.
 6. After removing R1-R3 reagent from the analyzer's reagent holder, store them at 2-8°C. Stir R2 reagent according to [Examination procedure] just before you return it to the analyzer. Do not use reagents once they have been frozen, since they may exhibit deterioration.
 7. The calibration curves are valid for 30 days. However, even within this period, calibrate again in the following circumstances:
 - When new R1-R3 reagents with another Lot No. are used.
 - When quality assurance results are abnormal.
 - After specified maintenance and/or repair of the analyzer (see analyzer instruction manual).
 8. R1-R4 reagents and Calibrators contain sodium azide. Since sodium azide reacts with lead tubing and copper tubing to generate metal azides which can explode, use plenty of water when disposing of it. In case of contact with the eyes, mouth, or hands, carry out emergency treatment such as washing with plenty of water. If necessary, consult a physician.
 9. Though the human serum component contained in HISCL FT4 Calibrator (HISCL FT4 C0-C5) has been checked as negative for HBs antigen, HCV antibody, HIV-1 antibody and HIV-2 antibody, exercise care in handling it.
 10. Handle samples carefully. They sometimes contain HBV, HCV, HIV, etc.
 11. Do not use the reagent bottles, etc. for other purposes.
 12. Use only the reagents (R1-R5 reagents, Calibrators, and Washing solution) specified in this package insert.
 13. Be certain to assemble the reagent containers according to [Examination procedure]. Incorrectly assembled containers may result in device errors or cause evaporation of reagents.
 14. Install R4 reagent and R5 reagent carefully to prevent contamination by alkaline phosphatase in saliva or on skin. To prevent absorption of excess CO₂, do not remove R5 reagent from the instrument until its bottle is empty and requires replacement.

- Examination procedure**
1. Preparation for measurement
 - (1) Gently mix R2 reagent thoroughly by circling the container. Look and confirm that the magnetic particles have mixed uniformly.



 REF	Catalogue number		Use by
 IVD	In vitro diagnostic medical device	 LOT	Batch code
	Manufacturer		Sufficient for
	Consult instructions for use		
	Temperature limitation		

- (2)First of all push down the outer cases of reagent containers firmly to tear the aluminum seals on the inner bottles.



- (3)Set the containers at the indicated position in the analyzer.
(4)As a rule, dispense 200μL of the sample to reduce the possible effects of evaporation. Refer to the analyzer instruction manual for the minimum volume.

2. Standard assay method *

- (1) Dispense 50μL of R1 reagent and 10μL of the sample into a reaction cuvette, and then incubate for 2 minutes at 42°C.
(2)Dispense 30μL of R2 reagent into the cuvette, and incubate for 2.5 minutes at 42°C.
(3)Dispense 50μL of R3 reagent into the cuvette, incubate for 2.5 minutes at 42°C, and then perform magnetic separation (contact the magnet with the cuvette, and aspirate liquid).
(4)Dispense 100-700μL of Washing solution, and then perform magnetic separation. Repeat this procedure 3 times.
(5)Dispense 50μL of R4 reagent and mix, dispense 100μL of R5 reagent and mix, incubate for 5 minutes at 42°C, and then measure light intensity.

3. Prepare a calibration curve

- (1) Gently stir each of the calibrators (HISCL FT4 CO-C5) without generating bubbles. Position them according to the analyzer instruction manual.
(2)Carry out procedures according to the "standard assay method", and then measure light intensity.
(3)Plot the intensity of the calibrators on the ordinate and the calibrator concentrations on the abscissa, and then prepare a calibration curve. *

4. Sample measurement

- (1) Position a sample according to the analyzer instruction manual.
(2)Carry out procedures according to the "standard assay method", and then measure light intensity.
(3)Fit the intensity on the calibration curve to obtain the FT4 concentration in the sample. *

* The analyzer automatically carries out these procedures.

Storage and shelf life after first opening

Store at 2-8°C. The shelf life is 30 days after opening.
Do not freeze.

Control procedure

Analyze control materials as samples according to [Examination procedure].

Biological reference intervals

Reference interval: 0.77-1.59 ng/dL ⁽²⁾

[Note 2] Samples from patients with autoimmune disease frequently exhibit non-specific responses on immunoassay.

[Note 3] Do not dilute samples. Dilution may cause incorrect results, since equilibration between free and bound T4 may be affected.

[Note 4] Each laboratory should conduct transference analysis using the local population samples and if necessary to establish its own reference intervals.

Performance characteristics

1. Sensitivity

- (1)When HISCL FT4 CO is analyzed, the light intensity is 1,000,000 - 10,000,000 counts.
(2)When half of the light intensity of HISCL FT4 CO is converted using the calibration curve, the concentration is 0.10 - 0.50 ng/dL.

2. Accuracy

When FT4 control sera (L, M, and H) are analyzed, the result is within the labeled concentration ±20%.

3. Reproducibility

When all FT4 control sera (L, M, and H) are analyzed simultaneously 10 times, the CV of result is 15% or less.

4. Measurement range

0.25 - 8.00 ng/dL

[Note 5] Counts :

Unit of light intensity on Sysmex Automated Immunoassay System.

[Note 6] FT4 control sera:

L :	0.25	-	0.50 ng/dL
M:	0.70	-	1.50 ng/dL
H:	5.00	-	8.00 ng/dL

Limitations of the examination procedure

Limitation-Interference

Hemoglobin (486 mg/dL or lower), bilirubin (bilirubin F: 20.3 mg/dL or lower, bilirubin C: 20.2 mg/dL or lower), chylo-microns (1,460 formazine turbidity units or lower) and RF (500 IU/mL or lower) each have almost no effect on measurements.⁽¹⁾

Reagent preparation

All reagents are ready-to-use.

Primary sample collection, handling and storage

Human serum or plasma.

- Plasma should be collected using EDTA or heparin as an anticoagulant. Do not use liquid anticoagulant, since it dilutes samples and causes incorrect results. Do not use sodium fluoride, since it yields incorrectly high results.
- If samples must be stored, freeze at -20°C or lower. Do not repeat freezing and thawing of samples, which may induce formation of particulates and cause incorrect results.
- Fibrin-clotted samples should be centrifuged at 2,000xg for 10 minutes to remove insoluble matter.

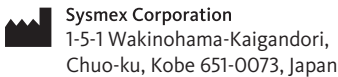
Disposal procedures

- Incinerate used sample tubes or reagent bottles, or dispose of them as medical waste or industrial waste according to the rules stipulated for waste materials.
- When apparatus that has come in contact with any specimens, perform sterilization using one of the following methods:
 - Immerse in 0.05% formalin solution at 37°C for 72 hours or longer.
 - Immerse in 2% glutaraldehyde solution for 1 hour or longer.
 - Immerse in a solution containing 0.1% or more sodium hypochlorite for 1 hour or longer.
 - Autoclave at 121°C for at least 1 hour.

Literature references

- (1) In-house data
(2)Shinji Morita, et al.: Fundamental and Clinical Evaluation of FT4, FT3, TSH Measurement in Blood by Automated Chemiluminescent Enzyme Immunoassay System.: Japanese Journal of Clinical Laboratory Automation, **32(5)**, 843 (2007)

Manufacturer



Authorized representatives

Asia-Pacific: **Sysmex Asia Pacific Pte Ltd.**
9 Tampines Grande #06-18, Singapore 528735

Product information

HISCL FT4 Assay Kit For 50 tests
 For 100 tests

Traceability of values assigned to calibrators

HISCL FT4 Calibrator has been adjusted by in-house standard materials.

Date of issue or revision

01/2020

Printed in Japan