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

sysmex

HISCL™ FT3 Assay Kit

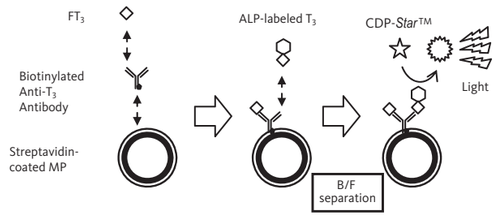
Identification of the IVD reagent
HISCL™ FT3 Assay Kit

Intended use
For In Vitro Diagnostic Use
Measurement of free triiodothyronine in serum or plasma

Development process and characteristics
T_4 (thyroxine) and T_3 (triiodothyronine) are thyroid hormones which enhance metabolism. Most T_4 and T_3 molecules are bound to serum proteins. Bioactive FT_4 (free thyroxine) and FT_3 (free triiodothyronine), which constitute less than 0.03‰ and 0.3‰ of total T_4 and T_3, respectively, are in equilibrium with the corresponding bound forms. Since FT_4 and FT_3 concentrations are independent of bound protein concentrations, FT_4 and FT_3 are commonly measured as indices of thyroid function, and used for the diagnosis and monitoring of thyroid diseases.
This kit measures FT_3 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 FT_3 based on the 1-step competitive chemiluminescent enzyme immunoassay.
1. Biotinylated anti-T_3 monoclonal antibodies (sheep) in R1 reagent specifically react to FT_3 in the sample, and bind to streptavidin-coated MP (magnetic particles) in R2 reagent.
2. ALP (alkaline phosphatase)-labeled T_3 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 FT_3 concentration, sample FT_3 concentrations can be obtained with a calibration curve prepared with calibrators.



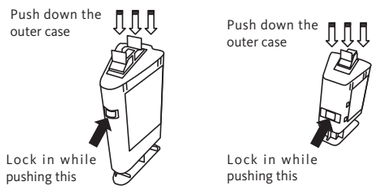
Components
This kit consists of the following reagents. Item 4-6 are sold separately.
1. R1 reagent: contains biotinylated anti-T_3 monoclonal antibodies (sheep) 6 ng/mL
2. R2 reagent
3. R3 reagent: contains ALP-labeled T_3 0.04 U/mL
4. HISCL Substrate Reagent Set
   (1) R4 reagent
   (2)R5 reagent: contains CDP-*Star*™:
   Disodium 2-chloro-5-(4-methoxyspiro{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 FT3 Calibrator
   (1) HISCL FT3 C0
   (2)HISCL FT3 C1
   (3)HISCL FT3 C2
   (4)HISCL FT3 C3
   (5)HISCL FT3 C4
   (6)HISCL FT3 C5

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

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 FT3 Calibrator (HISCL FT3 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 CO_2, 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.

(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 FT3 C0-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 FT_3 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: 2.24-3.94 pg/mL[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 T_3 may be affected.

Performance characteristics
1. Sensitivity
   (1) When HISCL FT3 C0 is analyzed, the light intensity is 500,000 - 5,000,000 counts.
   (2)When half of the light intensity of HISCL FT3 C0 is converted using the calibration curve, the concentration is 1.00 - 4.00 pg/mL.
2. Accuracy
   When FT_3 control sera (L, M, and H) are analyzed, the result is within the labeled concentration ±20%.
3. Reproducibility
   When all FT_3 control sera (L, M, and H) are analyzed simultaneously 10 times, the CV of result is 15% or less.
4. Measurement range
   1.00 - 30.00 pg/mL

[Note 4] Counts :
Unit of light intensity on Sysmex Automated Immunoassay System.
[Note 5] FT_3 control sera:

L :	1.00	-	1.50 pg/mL
M:	2.00	-	5.00 pg/mL
H:	20.00	-	30.00 pg/mL

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), and chylo-microns (1,460 formazin turbidity units or lower) each have almost no effect on the measurements.[1]

Reagent preparation
All reagents are ready-to-use.

Primary sample collection, handling and storage
Human serum or plasma.
1. 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.
2. 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.
3. Fibrin-clotted samples should be centrifuged at 2,000xg for 10 minutes to remove insoluble matter.

Disposal procedures
1. 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.
2. 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
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Product information
HISCL FT3 Assay Kit For 50 tests
For 100 tests

Traceability of values assigned to calibrators
HISCL FT3 Calibrator has been adjusted by in-house standard materials.

Date of issue or revision
01/2016