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

HISCL™ TSH Assay Kit

Identification of the IVD reagent

HISCL™ TSH Assay Kit

Intended use

For In Vitro Diagnostic Use
Measurement of thyroid stimulating hormone (TSH) in serum or plasma

Development process and characteristics

TSH (Thyroid Stimulating Hormone) is a pituitary hormone which stimulates the thyroid and promotes thyroid hormone secretion. TSH plays an important role in homeostasis of thyroid hormone by participating in a negative feedback mechanism. High level of thyroid hormone suppresses TSH production. It is therefore widely measured as an index of the mechanism of control of thyroid hormone, and used for the diagnosis and monitoring of thyroid diseases.
This kit measures TSH based on the chemiluminescence enzyme immunoassay method with CDP-*Star*™ chemiluminescent substrate, and has the following characteristics.

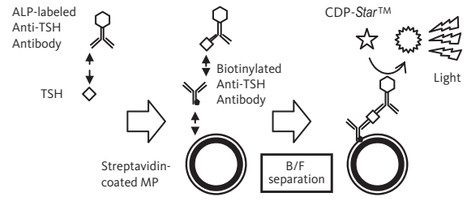
1. This kit is exclusively designed for Sysmex Automated Immunoassay System.
2. Calibrators contain non-infective recombinant antigen, and none of the calibrator components contain human-derived materials.

Principles of the examination method

This kit measures TSH based on the 1-step sandwich chemiluminescent enzyme immunoassay.

1. ALP (alkaline phosphatase)-labeled anti-TSH monoclonal antibodies (mouse) in R1 reagent specifically react with TSH in the sample.
2. Biotinylated anti-TSH monoclonal antibodies (mouse) in R3 reagent specifically bind to TSH, and bind to streptavidin-coated MP (magnetic particles) in R2 reagent.
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 increases in proportion to TSH concentration, sample TSH concentrations can be obtained with a calibration curve prepared with calibrators.



Components

This kit consists of the following reagents. Item 4-7 are sold separately.

1. R1 reagent: contains ALP-labeled anti-TSH monoclonal antibodies (mouse) 0.4 U/mL
2. R2 reagent
3. R3 reagent: contains biotinylated anti-TSH monoclonal antibodies (mouse) 9 µg/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 TSH Calibrator
   (1) HISCL TSH C0
   (2) HISCL TSH C1
   (3) HISCL TSH C2
   (4) HISCL TSH C3
   (5) HISCL TSH C4
   (6) HISCL TSH C5
7. HISCL Diluent

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

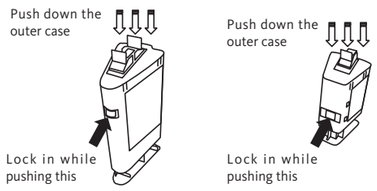
Warnings and precautions

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, Calibrators, and Diluent 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. Handle samples carefully. They sometimes contain HBV, HCV, HIV, etc.
10. Do not use the reagent bottles, etc. for other purpose.
11. Use only the reagents (R1-R5 reagents, Calibrators, Diluent and Washing solution) specified in this package insert.
12. Be certain to assemble the reagent containers according to [Examination procedure]. Incorrectly assembled containers may result in device errors or cause evaporation of reagents.
13. 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 30µL of R1 reagent and 30µL 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, incubate for 2.5 minutes at 42°C.
   (3)Dispense 30µL 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 TSH 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 TSH 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: 0.34 - 4.22 µIU/mL(1)

[Note 2] Samples from patients with autoimmune disease frequently exhibit non-specific responses on immunoassay.
[Note 3] Use HISCL Diluent in case of dilution test.

Performance characteristics
1. Sensitivity
   (1) When HISCL TSH C0 is analyzed, the light intensity is ≤5,000 counts.
   (2)When HISCL TSH C1 is analyzed, the light intensity is 300,000 - 2,200,000 counts.
2. Accuracy
   When all TSH control sera (L, M, and H) are analyzed, the result is within the labeled concentration±20%.
3. Reproducibility
   When all TSH control sera (L, M, and H) are analyzed simultaneously 10 times, the CV of each result is 15% or less.
4. Measurement range
   0.002 - 200 µIU/mL

[Note 4] HISCL TSH C0 : 0 µIU/mL
HISCL TSH C1 : 2 µIU/mL
[Note 5] Counts :
Unit of light intensity on Sysmex Automated Immunoassay System.
[Note 6] IU :
International unit of TSH concentration based on the WHO standard.
[Note 7] TSH control sera:

L :	0.050	-	0.200 µIU/mL
M:	1.00	-	3.00 µIU/mL
H:	10.0	-	50.0 µIU/mL

Limitations of the examination procedure
1. Limitation-Interference
   Hemoglobin (482 mg/dL or lower), bilirubin (bilirubin F, 18.0 mg/dL or lower, bilirubin C, 19.3 mg/dL or lower), chylo-microns (1,430 formazine turbidity units or lower) and RF (500 IU/mL or lower) each have almost no effect on measurements.(1)
2. Rarely, incorrect results can occur for dilution because of the specimen's properties.

Reagent preparation
All reagents are ready-to-use.

Primary sample collection, handling and storage
Human serum or plasma.
1. Plasma should be collected using heparin as an anticoagulant. Do not use liquid anticoagulant, since it dilutes samples and causes incorrect 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

Manufacturer
Sysmex Corporation
1-5-1, Wakinohama-Kaigandori,
Chuo-ku, Kobe 651-0073, Japan

Authorized representative / Distributors
Asia-Pacific: Sysmex Asia Pacific Pte Ltd.
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Product information
HISCL TSH Assay Kit For 50 tests
For 100 tests

Traceability of values assigned to calibrators
HISCL TSH Calibrator has been adjusted by in-house standard materials based on WHO Standard 80/558.

Date of issue or revision
01/2016

Printed in Japan