

HISCL™ Troponin T hs Assay Kit

Identification of the IVD reagent HISCL™ Troponin T hs Assay Kit

Intended use

For in vitro diagnostic use only
Measurement of cardiac Troponin T in serum or plasma

Development process and characteristics

Troponin complex (troponin I,T&C) is a heteromeric protein that plays an important role in the regulation of skeletal and cardiac muscle contraction.

Troponin T and troponin I are released after cardiac damage alone. Therefore, the presence of cardiac troponin (cTn) in blood serum indicates myocardial damage. Thus, cTn is considered a specific biochemical marker for acute myocardial infarction (AMI).

cTnT (molecular weight, 39.7 kD) is released in to the blood stream within hours of ischemic damage or AMI. Elevated cTnT levels are detected within 3–4 h of onset of chest pain, and may remain elevated for up to 14 days post AMI; therefore, cTnT levels correlate with severity of coronary artery disease.

This kit measures the Troponin T levels based on the chemiluminescence enzyme immunoassay method with the CDP-*Star*™ chemiluminescent substrate.

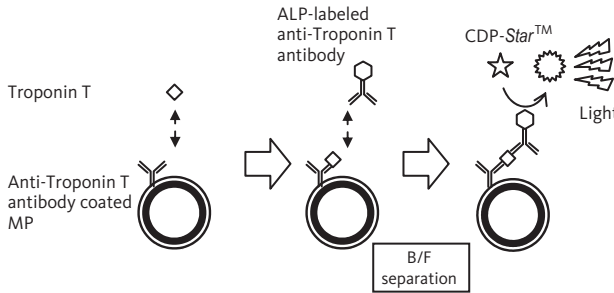
This kit is exclusively designed for Sysmex Automated Immunoassay System.

Principles of the examination method

This kit measures the Troponin T levels using the 1-step sandwich chemiluminescent enzyme immunoassay.

1. Anti-Troponin T antibodies (mouse)-coated magnetic particles (MP) in the R2 reagent specifically reacts with Troponin T in the sample.
2. Alkaline phosphatase (ALP)-labeled anti-Troponin T monoclonal antibodies (mouse) in the R3 reagent specifically bind to Troponin T on the MP.
3. After B/F separation, the ALP on the MP decomposes CDP-*Star*™ substrate in the R5 to an excited intermediate, which produces a luminescent signal.

Because the light production increases in proportion to the Troponin T concentration, sample Troponin T concentrations can be obtained with a calibration curve prepared using calibrators.



Components

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

1. R1 reagent
2. R2 reagent: contains Magnetic Particles coated with anti-Troponin T monoclonal antibodies(mouse) 5 mg/mL
3. R3 reagent: contains ALP-labeled anti-Troponin T monoclonal antibodies (mouse) 4.5 U/mL

4. HISCL Substrate Reagent Set
 - (1) HISCL R4 reagent
 - (2)HISCL 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 0.48mM
5. HISCL Washing solution
6. HISCL Troponin T hs Calibrator
 - (1) HISCL Troponin T hs C0
 - (2)HISCL Troponin T hs C1
 - (3)HISCL Troponin T hs C2
 - (4)HISCL Troponin T hs C3
 - (5)HISCL Troponin T hs C4
 - (6)HISCL Troponin T hs C5
7. HISCL Diluent

[Note 1] The 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 described in the package insert. The reliability of results cannot be guaranteed a method other than that described is followed or if the kit used for a purpose other than those mentioned.
2. Handle each reagent carefully without generating air bubbles, which may produce incorrect results of the analysis. If bubbles appear, wait until they disappear.
3. Do not combine reagents from different kits. Do not pool reagents even if the Lot Nos. of the kits are the same. Use reagents before their expiry date. The reliability of results cannot be guaranteed if the reagents are beyond their expiration date.
4. Avoid contact of the R5 reagent with the skin and eyes, because the R5 is an alkaline solution with pH9.6.
5. The rest of the calibrator solution should be quickly closed and frozen. With regard to the reconstituted Troponin T calibrators, the Troponin T concentration may change due to evaporation, resulting in incorrect calibration.
6. When the reagents are out of the reagent holder of the analyzer, store R1-R3 reagents at 2-8°C. Stir the R2 reagent according to the [Examination procedure] just before you return it to the analyzer. Do not use reagents once they have frozen, because they may be deteriorated.
7. The calibration curves are valid for 30 days. However, even within this period, calibrate again in the following cases:
 - When new R1-R3 reagents belonging to another Lot No. are used.
 - When the quality assurance results are abnormal.
 - After specified maintenance and/or repair of the analyzer (see instruction manual of analyzer).
8. The R4 reagent and Diluent contain sodium azide. Because sodium azide reacts with lead tubing and copper tubing to generate metal azides which can explode, use a large quantity of water when disposing them. In case of contact with the eyes, mouth, or hands, perform emergency treatment such as washing with a large quantity of water. If necessary, consult a physician.
9. HISCL Troponin T hs C1-C5 contain human serum. Handle with care as potentially infectious, though the calibrator material has been checked as negative for HBs antigen, HCV antibody, HIV antibody.
- 10.Handle samples carefully. They sometimes contain hepatitis B virus(HBV), HCV, human immunodeficiency virus (HIV), etc. In case of contact with eyes, mouth, or hands, perform emergency treatment such as washing with a large quantity of water. If necessary, consult a physician or follow in-hospital infection manual.
11. Do not use the reagent bottles, etc. for other purposes.
12. Use only the reagents (R1-R5 reagents, Calibrators, Diluent and Washing solution) specified in this package insert.
13. Ensure that the reagent containers are assemble according to the [Examination procedure]. Incorrectly assembled containers may result in device errors or cause evaporation of reagents.

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

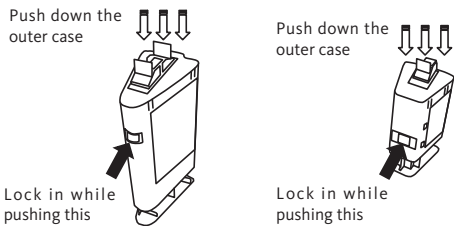
14. Install the R4 reagent and R5 reagent carefully to prevent contamination by ALP in the saliva or on skin. To prevent absorption of excess CO₂, do not remove the R5 reagent from the instrument until its bottle is empty and requires replacement.
15. Dispense 200 µL of sample to reduce possible effects of evaporation. Refer to the analyzer instruction manual for the minimum volume.

Examination procedure

1. Preparation for measurement
- (1) Gently mix the R2 reagent thoroughly by circling the container. See and confirm that the MP have mixed uniformly. Do not invert the container.



- (2) At first, certainly push down the outer cases of the reagent containers to tear aluminum seals on the inner bottles.



- (3) Set the containers at the indicated position of the analyzer.
- (4) In general, dispense 200 µL of sample to reduce possible effects of evaporation. Refer to the instruction manual of the analyzer for the minimum volume.
2. Standard assay method *
- (1) Dispense 30 µL of the R1 reagent and 30 µL of sample into a reaction cuvette, and then incubate for 2 min at 42°C.
- (2) Dispense 30 µL of the R2 reagent into the cuvette, incubate for 2.5 min at 42°C.
- (3) Dispense 30 µL of the R3 reagent into the cuvette, incubate for 2.5 min at 42°C, and then perform magnetic separation (bring the magnet in contact with the cuvette, and aspirate liquid).
- (4) Dispense 100-700 µL of Washing solution, and perform magnetic separation. This washing cycles are performed for a total of 4 times.
- (5) Dispense 50 µL of the R4 reagent and mix, dispense 100 µL of the R5 reagent and mix, incubate for 5 min at 42°C, and then measure light intensity.
3. Preparation of the Calibration curve
- (1) Gently stir each of the calibrators (HISCL Troponin T hs C0-C5) without generating bubbles. Position them according to the instruction manual for the analyzer.
- (2) Perform procedures according to the "2. Standard assay method", and then measure light intensity.
- (3) Prepare a calibration curve by plotting the intensity of the calibrators on the ordinate and the calibrator concentrations on the abscissa. *
4. Sample measurement
- (1) Position a sample according to that mentioned in the instruction manual for the analyzer.
- (2) Perform procedures according to the "2. Standard assay method", and then measure light intensity.
- (3) Fit the intensity on the calibration curve to obtain the Troponin T concentration in the sample. *

* The analyzer automatically performs these procedures.

Storage and shelf life after first opening

1. HISCL Troponin T hs Calibrator
- Store at 2–8°C before reconstitution.
Store below -20°C after reconstitution.
The shelf life is 90 days after reconstitution.
Freezing and thawing can be repeated 3 times.
2. Other reagents
- Store at 2-8°C.
The shelf life is 30 days after opening.

Control procedure

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

Interpretation of results

Reference interval: ≤ 0.016 ng/mL (317 samples) ⁽¹⁾

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

[Note 3] For specimens which showed high values exceeding the upper limit of measurement range, or those which are predicted to show high values beforehand, dilute the specimens appropriately using the HISCL Diluent (triethanolamine buffer, pH 7.5, containing 1% BSA) and measure the values. When diluting, dilute specimens so that their values measured after dilution are not less than 3.5 ng/mL.

Performance characteristics

1. Sensitivity
- (1) When HISCL Troponin T hs C0 is analyzed, the light intensity is ≤20,000 counts.
- (2) When HISCL Troponin T hs C2 is analyzed, the light intensity is 40,000 - 300,000 counts per 0.100 ng/mL Troponin T.
2. Accuracy
- When all Troponin T control sera (L, M, and H) are analyzed, the result is within the labeled concentration ±20%.
3. Reproducibility
- When all Troponin T control sera (L, M, and H) are analyzed simultaneously 10 times, the CV of each result is 10% or less.
4. Measurement range
- 0.002 – 10.000 ng/mL

[Note 4] HISCL Troponin T hs C0 : 0.000 ng/mL
HISCL Troponin T hs C2 : 0.158-0.254 ng/mL
The indicated concentrations may differ among batches.

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

[Note 6] Troponin T control sera:
L : 0.050 - 0.200 ng/mL
M : 0.500 - 1.000 ng/mL
H : 5.000 - 10.000 ng/mL

Limitations of the examination procedure

1. Limitation-interference
- Hemoglobin level (100 mg/dL above) has an effect on measurements. Bilirubin (bilirubin F: 18.7 mg/dL or lower, bilirubin C: 19.7 mg/dL or lower), and chylomicrons (1,440 formazine turbidity units or lower) each have almost no effect on measurements.
2. Incorrect results rarely occur for dilution because of specimens properties.

Reagent preparation

1. Add 1 mL of distilled water to Troponin T hs C0-C5, put the cap on them, and leave for 15 minutes. Mix by inversion with care not to foam the solution to dissolve the content into the solution completely.
2. The other 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, because it dilutes samples and causes incorrect results. For best results, test freshly collected samples.
2. For storing samples, freeze them 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 2,000×g for 10 min 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. For apparatus that has come in contact with any specimens is sterilized, perform sterilization using one of the following methods:
- Immerse in 0.05% formalin solution at 37°C for 72 h or more.
 - Immerse in 2% glutaraldehyde solution for 1 h or more.
 - Immerse in a solution containing 0.1% or more sodium hypochlorite for 1 h or more.
 - Autoclave at 121°C for at least 1 h.
3. In case of spillage of samples, liquid wastes or any other biohazard materials, wipe and disinfect the area with 2 % glutaraldehyde solution 0.1 % or more sodium hypochlorite.

Literature references

(1) In-house data

Manufacturer

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

Authorized representatives

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

Product information

HISCL Troponin T hs Assay Kit For 50 tests

Traceability of values assigned to calibrators

HISCL Troponin T hs C1-C5 have been adjusted by in-house standard materials.

Date of issue or revision

09/2020

Printed in Japan