Troponin T

Porrima

Cardiac Troponin T (CLIA)

REF: PM107704 **100**

Intended use
The Porrima Troponin T assay is a Chemiluminescent Immunoassay (CLIA) for the quantitative determination of cardiac troponin T (cTnT) in **Human Serum**. For professional use only.

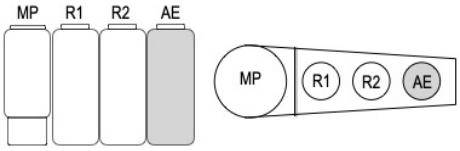
Summary
References[1-5]
Troponin T is a part of the troponin complex, which are proteins integral to the contraction of skeletal and heart muscles. Cardiac troponin T (cTnT) and troponin I (cTnI) are cardiac regulatory proteins that control the calcium mediated interaction between actin and myosin. The cardiac forms of these regulatory proteins are coded by specific genes and theoretically have the potential of being unique to the myocardium. The measurement of serum cTnI and cTnT is superior in terms of sensitivity and specificity to cardiac muscle enzyme measurements in the identification of cardiac muscle damage. Raised cardiac troponin concentrations are now accepted as the standard biochemical marker for the diagnosis of myocardial infarction. The cardiac subtype of troponin T is especially useful in the laboratory diagnosis of heart attack because it is released into the blood-stream when damage to heart muscle occurs.

Test principle
Two-step Sandwich principle. Total duration of assay: **25 minutes**
In the first step, sample and paramagnetic microparticles coated with monoclonal anti-cTnT antibody are added into a reaction vessel to form reaction mixture. After incubation, Microparticle is magnetically captured while other unbound substances are removed by washing.
In the second step, add anti-cTnI antibody acridinium-labeled conjugate to the reaction mixture then form a sandwich complex, the complex becomes bound to the solid phase while the unbound Conjugate are removed by washing.
Pre-Trigger and Trigger Solutions are then added to the reaction mixture, the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of cTnT in the sample and the RLUs detected by the Porrima system.

Materials provided

MP	1 x 5.0 mL, anti-Cardiac troponin T antibody (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (bovine) stabilizers with preservative.
AE	1 x 10 mL, monoclonal anti-Cardiac troponin T antibody (mouse)-acridinium ester labeled conjugate in MES buffer with preservative.
C0	Calibrator, 1 vial, 1.0 mL, ready to use.
C1	Calibrator, 1 vial, 1.0 mL, ready to use.
C2	Calibrator, 1 vial, 1.0 mL, ready to use.

The position of each reagent component is shown in the figure below (front view on the left and top view on the right):



Materials required (but not provided)
- Porrima Chemiluminescent Immunoassay Analyzer
- CT2201 DiaSino ControlSet: 2 levels, L and H
- TR7701 Porrima TriggerPack: ①Pre-Trigger Solution, ②Trigger Solution
- WB7701 Porrima Wash Buffer (20X)
- RV7701 Porrima Reaction Vessels
- PW7701 Porrima Probe Wash Buffer
- SC7701 Porrima Sample Tubes (D13x75mm, D13x100mm or D16x100mm can be acceptable on Porrima system)

Precautions and warnings
- For in vitro diagnostic use only.
- Exercise the normal precautions required for handling all laboratory reagents.
- Disposal of all waste material should be in accordance with local guidelines.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different batch codes.
- All the specimen and reaction wastes should be considered potentially biohazard. The handling of specimens and reaction wastes should be in accordance with the local regulations and guidelines.
- Neutralized acids and other liquid waste should be decontaminated by adding a sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. Exposure to 1.0% sodium hypochlorite for 30 minutes may be necessary to ensure effective decontamination.
- Some reagents contain 0.05% or 0.1% ProClin 300 which may cause sensitization by skin contact, which must therefore be avoided. Reagents and their containers must be disposed of safely. If swallowed, seek medical advice immediately and show this container or label.
- For information on hazardous substances included in the kit please refer to the Materials Safety Data Sheet (MSDS), which is available on request.
- Do not smoke, drink, eat or apply cosmetics in the work area.
- Do not pipette by mouth. Wear protective clothing, disposable gloves and eye/ face protection when handling samples and reagents. Wash hands after use.
- If any of the reagents comes into contact with the skin or eyes, wash the area extensively with water.

Reagent handling
The reagents in the kit have been assembled into a ready-for-use unit that cannot be separated.
All information required for correct operation is read in from the respective reagent barcodes.

Storage and stability
- Store at 2-8°C. Do not freeze.
- Store the Porrima reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.
- The Porrima Cardiac troponin T reagent kit can be stored onboard and used for a maximum of 28 days after opening at 2-8°C.

Specimen collection and preparation
- Human serum is recommended for this assay.
- Centrifuge the specimens after clot formation is complete. Transfer the supernatants into tubes for storage or test within two hours after centrifugation.
- Specimens should be tested as soon as possible after sample collection. If testing is not completed within 8 hours, specimens should be tightly capped and refrigerated at 2-8°C. If testing will be delayed for more than 72 hours, specimens should be frozen at -20°C or below.
- Avoid repeated freeze and thaw cycles.

Assay procedure
- For optimal performance of this assay, operators should read the Porrima CLIA system operation manual carefully, to get sufficient information such as operation instructions, sample preservation and management, safety precaution, and maintenance. Prepare all required materials for the assay as well.
- Before loading the reagent kit on the machine for the first time, unopened reagent bottle should be inverted gently for at least 30 times to resuspend the microparticles that have settled during shipment or storage.
- Visually inspect the bottle to ensure the microparticles have been resuspended. If the microparticles remain adhered to the bottle, continue inverting until the microparticles have been completely resuspended.
- If the microparticles cannot be resuspended, **DO NOT USE**. Contact DiaSino Technical Support for help. Do not invert opened reagent bottle.
- This assay requires 50 µL of sample for a single test. This volume does not include the dead volume of the sample container. Additional volume is required when performing additional tests from the same sample. Operators should refer to the system operation manual and specific requirement of the assay to determine the minimum sample volume.

Calibration
The specific information of master calibration curve of Cardiac troponin T CLIA reagent kit is stored in the barcode attached in the reagent pack. It's used together with calibrators for the calibration of the specific reagent lot. When performing the calibration, scan the information of master calibration curve from the barcode into the system first, and then use the calibrators at two levels. Valid calibration curve is required before any Cardiac troponin T test. Recalibration is recommended every 28 days, or when a new reagent lot is used, or the quality controls are out of specified range. For detailed instruction of calibration, refer to the system operations manual.

Quality control
For quality control, use DiaSino ControlSet. In addition, other suitable control material can be used.

IVD

Troponin T

Porrima

Cardiac Troponin T (CLIA)

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.
Quality control results should be within the acceptable ranges. If a control is out of its specified range, the associated test results are invalid and the samples must be retested. Recalibration may be required. Examine the assay system referring to the system operation manual. If the quality control results are still out of the specified range, please contact DiaSino Technical Support for help.

Calculation
The analyzer automatically calculates the analyte concentration of each sample.

Limitations - interference
- Falsely depressed results are obtained when using samples with hemoglobin concentrations > 0.1 g/dL.
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- No interference was observed from rheumatoid factors up to a concentration of 1500 IU/mL.
- There is no high-dose hook effect at troponin T concentrations up to 100000 ng/L (pg/mL).
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies or ruthenium can occur. These effects are minimized by suitable test design.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range
10-10000 pg/mL or ng/L (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 10 pg/mL. Values above the measuring range are reported as > 10000 pg/mL.

Lower detection limit
10 pg/mL (ng/L)
The lower detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values

Troponin T level (pg/mL)	Comment
< 50 pg/mL	Acute myocardial infarction not likely, but still possible; in context of clinical assessment repeat the test (e.g. after 3-6 h) to detect rising Troponin T levels.
Between 50-100 pg/mL	Acute myocardial infarction possible, repeat the test to detect rising Troponin T levels in context of clinical assessment according to guidelines; search for differential diagnosis and other causes of Troponin T elevation.
Between 100-2000 pg/mL	Acute myocardial infarction likely; consider differential diagnosis for other causes of Troponin T elevation.
> 2000 pg/mL	Acute myocardial infarction very likely; consider differential diagnosis for other causes of Troponin T elevation.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Interpretation of results
A typical pattern of rise and fall together with an elevation of the troponin T concentration above the test's detection limit of 50 ng/L is regarded as an acute MI,[6] if one additional out of several criteria for evidence of myocardial ischemia as given in the Universal Definition of Myocardial Infarction is fulfilled.[7]
Result < 50 ng/L: Due to the release kinetics of troponin T, even a result of less than 50 ng/L does not rule out cardiac infarction or myocardial cell damage with certainty. If suspicion of an infarction persists, the test should be repeated at suitable time intervals in keeping with the guidelines from the professional cardiology societies. A troponin T result must not be used as the sole diagnostic criterion.

Specific performance data
Representative performance data on the instruments are given below. Results obtained in individual laboratories may differ.

Precision
Precision was determined using DiaSino reagents, pooled human sera, and controls in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute): 2 times daily for 20 days (n = 40). The following results were obtained:

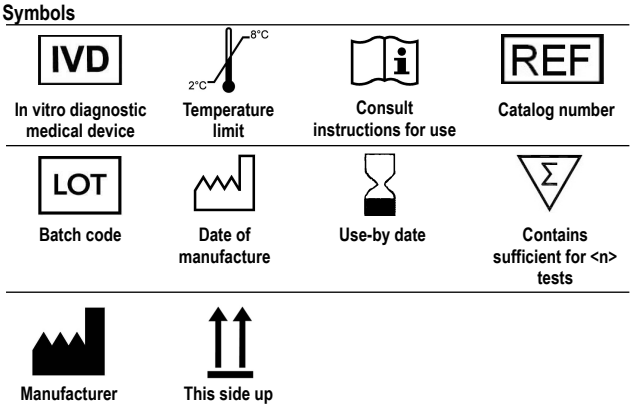
		Repeatability		Intermediate precision	
Sample	Mean pg/mL	SD pg/mL	CV %	SD pg/mL	CV %
Human Serum 1	47.72	3.064	6.42%	3.326	6.97%
Human Serum 2	169.45	9.201	5.43%	9.947	5.87%
Human Serum 3	864.92	34.251	3.96%	34.770	4.02%
ControlSet 1	98.42	5.403	5.49%	5.433	5.52%
ControlSet 2	1652.33	51.387	3.11%	51.553	3.12%

Method comparison
A comparison of the Porrima Troponin T assay (y) with the Roche Elecsys cTnT-hs (x) using 78 clinical samples gave the correlations > 0.95.

References

1. Jin, Jian-Ping (2016-01-01), Jeon, Kwang W. (ed.), "Chapter One - Evolution, Regulation, and Function of N-terminal Variable Region of Troponin T: Modulation of Muscle Contractility and Beyond", International Review of Cell and Molecular Biology, Academic Press, vol. 321, pp. 1–28, retrieved 2020-06-19
2. Bodor GS, Porterfield D, Voss EM, et al. Cardiac troponin-I is not expressed in fetal and healthy or diseased adult human skeletal muscle tissue. Clin Chem 1995;41:1710.
3. Collinson PO, Boa FG, Gaze DC. Measurement of cardiac troponins. Ann Clin Biochem 2001;38:423–9.
4. Braunwald E , Antmann EM, Beasley JW, et al. ACC/AHA guidelines for the management of patients with unstable angina and non ST elevation myocardial infarction: executive summary and recommendations.
5. Bertrand ME, Simoons ML, Fox KA, et al. Management of acute coronary syndromes: acute coronary syndromes without persistent ST segment elevation.
6. Giannitsis E, Katus HA. Current recommendations for interpretation of the highly sensitive troponin T assay for diagnostic, therapeutic and prognostic purposes in patients with a non-ST-segment-elevation acute coronary syndrome. European Cardiology 2010;5:44-47.
7. ThygesenK,AlpertJS,WhiteHD,onbehalfoftheJoint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. Universal definition of myocardial infarction. Eur Heart J 2007;28:2525-2538.

Symbols



diasino
DiaSino Laboratories Co., Ltd
No.68 Jingnansi Road National Eco & Tech Development Area
Zhengzhou 450000, P.R. China. info@diasino.com

IVD