SHD
SCIENCE HEALTH DIAGNOSTICS

8 683981 701252 100 T
8 683981 701276 200 T
8 683981 701290 400 T

High-Sensitivity Cardiac Troponin I (hs-cTnI)
(Magnetic Particle Based Chemiluminescence Immunoassay)

INTENDED USE

High-Sensitivity Cardiac Troponin I Test Kit (Chemiluminescence Immunoassay) is a quantitative test for use on Innoviqure Spectrum Chemiluminescence Immunoassay Analyzer and Innoviqure Nexus Chemiluminescence Immunoassay Analyzer for the determination of cTnI in human serum and plasma. cTnI plays a critical role in the timely diagnosis of myocardial infarction. The test is designed to assist clinicians with the diagnosis and treatment of chest pain patients.

PACKAGING SPECIFICATIONS

100T/200T/400T

SUMMARY AND EXPLANATION

MI is characterized pathologically by the death of myocardial cells resulting from extended ischemia. The initial ultrastructural alterations include reduced cellular glycogen, relaxed myofibrils, and disruption of the sarcolemma, which can be observed as early as 10-15 minutes following the onset of ischemia. (Thygesen et al., 2019). Cardiac troponin levels are significantly higher in patients in whom acute myocardial infarction is the final diagnosis than in patients in whom there is a different final diagnosis. Currently, the key cardiac proteins used in the diagnosis of acute myocardial infarction (AMI) are TnC, TnI, and TnT. TnT and TnI, often referred to as cardiac troponins, are specific to both the heart and skeletal muscle. These proteins are produced and released by cardiac muscle cells. They associate with tropomyosin to form the core structure of striated cardiac muscle. Cardiac troponins (cTn) play a role in myocardial contraction by regulating the calcium-dependent interaction between actin and myosin (Aydin et al., 2019). Cardiac troponin I is a regulatory protein uniquely specific to cardiac injury. It is absent in skeletal muscle during both neonatal development and adulthood, even in cases of acute or chronic skeletal muscle damage. Consequently, its levels in plasma do not rise in patients with skeletal muscle diseases unless there is concurrent acute myocardial injury. Additionally, cardiac troponin I remains elevated in plasma for five to seven days, allowing for flexibility in the timing of blood sample collection (Adams et al., 1994). Additionally, monitoring troponin I levels post-AMI is crucial for assessing the extent of myocardial damage and guiding therapeutic strategies. Elevated troponin I levels correlate with the severity of myocardial injury, allowing clinicians to stratify patients based on risk and tailor their management accordingly. For instance, higher troponin I levels may prompt more aggressive interventions such as early coronary angiography or revascularization procedures. Furthermore, the prognostic value of troponin I extends beyond initial diagnosis; it is a predictor of long-term outcomes, including the risk of future cardiovascular events. Patients with persistently elevated troponin I levels after an AMI are at a higher risk for adverse outcomes, such as heart failure or recurrent myocardial infarction. Therefore, continuous monitoring of troponin I can guide long-term management and rehabilitation strategies, enabling healthcare providers to implement preventative measures for at-risk patients. In summary, troponin I is an indispensable biomarker in the context of acute myocardial infarction, playing a pivotal role in timely diagnosis, risk stratification, and management of patients. Its high sensitivity and specificity, coupled with its prognostic capabilities, underscore its importance in improving patient outcomes and guiding clinical decision-making in the rapidly evolving field of cardiology. As research continues to refine our understanding of troponin I and its role in cardiac health, it remains a cornerstone of contemporary cardiovascular diagnostics.

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PRINCIPLE OF TESTING

The cTnI test utilizing Magnetic Particle-Based Chemiluminescence Immunoassay (CLIA) combines the sensitivity of chemiluminescence with the specificity of magnetic particles to capture and detect cTnI in samples.

1.Sample Introduction and Pre-Coated Magnetic Particles

A solid phase consisting of magnetic particles is pre-coated with monoclonal antibodies specific to human cTnI (Antibody I). When the sample is added, if cTnI is present, it binds to these antibodies on the magnetic particles, forming an immune complex.

2.Addition of Chemiluminescent-Labeled Antibody

A second reagent containing chemiluminescent-labeled monoclonal antibodies specific to cTnI (Antibody II) is introduced into the reaction mixture. These labeled antibodies bind to the cTnI already captured on the magnetic particles, forming a sandwich immunocomplex.

3.Magnetic Separation and Washing

The magnetic particles are then separated from the solution using a magnet, allowing for the removal of any unbound substances or reagents. The particles are then washed to ensure that only the immune complexes bound to the cTnI are retained.

4.Chemiluminescent Reaction

A chemiluminescent substrate is added to the reaction mixture. The chemiluminescent-labeled antibody conjugates catalyze a reaction that emits light in proportion to the amount of cTnI present in the sample.

5.Detection and Quantification

The emitted light is measured by a chemiluminescence analyzer. The intensity of the light produced is directly correlated with the concentration of cTnI in the sample. A standard curve, created using known concentrations of cTnI, allows for the quantitative determination of cTnI levels.

6.Result Interpretation

The cTnI concentration in the sample is calculated based on the measured light intensity, providing diagnostic information for detecting myocardial injury or acute myocardial infarction (AMI).

MAIN COMPONENTS

This reagent kit consists of Reagent Ra, Reagent Rd, calibrators (optional) and controls (optional).

Characteristics of Reagents

Reagent	For 100 T	Component
Ra	5,50 mL	Magnetic particles coated with recombinant cTnI
Rd	5,50 mL	Acridinium ester conjugated to recombinant cTnI antibody

Characteristics of Calibrators

Calibrator	mL/vial	Component
6 point	1,0 mL	Recombinant cTnI antigen

Characteristics of Controls

Control	mL/vial	Component
2 point	3,0 mL	Recombinant cTnI antigen (Lyophilized)

STORAGE CONDITIONS AND PERIOD OF VALID

The period of validity of the test kit is 18 months while the package is sealed and stored at 2-8 °C.

APPLICABLE INSTRUMENTS

Innoviqure Spectrum Chemiluminescence Immunoassay Analyzer and Innoviqure Nexus Chemiluminescence Immunoassay Analyzer manufactured by Deniz Biyokimya Urunleri Dis. Tic. A.S.

THE REQUIREMENTS OF SAMPLE

This kit is suitable for Serum / Plasma samples.
Serum / Plasma Collection: The serum or plasma should be separated for analysis immediately after blood collection to avoid hemolysis. Use within 8 hours if the sample is stored at room temperature; use within 48 hours if the sample is stored at 2-8 °C; use within 3 months if the sample is stored at -20°C with one cycle of freeze and thaw.

The sample must reach the equilibrium status at room temperature (20~30°C) before use.

TEST METHOD

- When loading Reagent Ra into the instrument for the first time, mix the reagent thoroughly in its bottle to resuspend any magnetic particles that may have settled during transportation.
- Check the sample volume in the sample tube before each test to ensure that the sample volume in the sample tube is always greater than 110 μL.
- If necessary, perform the calibration procedure. Refer to the manual of the device used for information on how to carry out the calibration procedure.
- Gently swirl the calibrator or control bottle 5-10 times to mix thoroughly before use.
- Sample Loading: Refer to the manual of the instrument used for information on sample loading.
- Press the “Run” button to perform the test.

CONFIDENCE INTERVAL

The serum and plasma samples of healthy donors (n=224) were tested using cTnI Test Kit. The results showed that the 95% percentile of cTnI was 5 pg/mL, the 99% percentile of cTnI was 3 pg/mL.
The above reference values are for reference only. Due to the differences in geography, race, gender and age, it is recommended that each laboratory establish its own reference values (reference range) according to the actual situation.

INTERPRETATION OF TEST RESULTS

The test results of this test kits are only for reference in clinical and cannot be used as the sole indicator for the diagnosis or exclusion of disease. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms, medical history, and other laboratory tests result and treatment reactions.

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LIMITATIONS OF TEST RESULTS

1. The kit can be used for the determination of serum or plasma, and the reliability for the concentration determination of cTnI needs further confirmation.
2. Plasma samples in this kit are recommended to use EDTA, sodium heparin or sodium citrate as anticoagulants. If other anticoagulants are selected, the effect needs to be further confirmed.
3. The concentrations of cTnI obtained from other methods are not directly comparable with the results obtained from this kit.
4. If the test results of this kit are inconsistent with the clinical evaluations, further examination is required.
5. Operation must be carried out strictly in accordance with operating manual, please operate carefully for getting more accurate results, any modification of the operating manual may affect the results.
6. In the case of false positive results, some non-specific components in the sample with similar antigen-determining clusters might participate in the reaction. In case of false negative results, some unknown components might the antigen-determining cluster and disturb the immune recognition reaction. The detection of cTnI might be unsuccessful if the sample has been taken for too long time or the environmental temperature is causing the degradation of analytes.
7. Other factors may also cause inaccuracy in cTnI test results, including technical problems, inappropriate operation or sample factors, such as wrong sample collection process, preservation and handling.
8. The test results are for reference only and should not be taken as the only indicator for clinical diagnosis.

PRODUCT PERFORMANCE REQUIREMENTS

1. Linear Range: within the range of 3 pg/mL to 50,000 pg/mL, the correlation coefficient R value should be greater than or equal to 0,990.
2. Precision:
2.1 Intra-batch precision: the coefficient of variation CV should not be greater than 10.0 %.
2.2 Inter-batch precision: the coefficient of variation CV should not be greater than 15.0 %.
3. Accuracy: The relative deviation should not be greater than 15.0 %.
4. The Limit of Detection: The limit of detection of this kit is no higher than 3 pg/mL.

PRECAUTIONS

1. This kit is only used for in vitro diagnosis and should not be used for other purposes.
2. The kit is only for use by laboratory medicine professionals.
3. This product is disposable and cannot be reused.
4. Do not use the contaminated or spoiled samples or expired products for testing.
5. Fresh samples are recommended. Hyperlipidemia, jaundice and hemolysis are not recommended.
6. Do not use for detection if the package is not intact.
7. When using the test kit for detection, the environment temperature should not be too high or too low.
8. During the test, the analyzer should avoid strong electromagnetic environment.
9. All wastes shall be disposed in accordance with infectious materials.
10. The test result of this kit is not the only indicator for disease. Judgement should be made by doctors while considering all relevant indications and clinical symptoms.
11. It is recommended to wear gloves without talcum powder, because the powder may lead to wrong results.
12. If you have any questions or suggestions about this reagent, please contact the manufacturer. 13. The longest transportation period for the test kit must not exceed 12 days under 2-8 °C.

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CALIBRATIONS

Use the relevant reagents and calibrators to perform the calibration. Recalibration is required in the following cases:
(1) Reagents with a different lot number;
(2) Reagents with the same lot number have been used in the analyzer for more than 28 days;
(3) The quality control value is outside the allowable range.

QUALITY CONTROL

The controls are used for quality control. If the results are outside the range, the reagents may have deteriorated or there may be technical problems. In this case the results may be invalid and the materials need to be retested. If necessary, perform the calibration again. For information on troubleshooting, refer to the manual of the instrument used.

ASSAY SPECIFICATIONS (Table 1)

Sample Type	Serum, Plasma
Sample Volume	110 µL
Assay Range	3 pg/mL to 50,0 00 pg/mL
Time to First Result	15 minutes
LoB	2 pg/mL
LoD (10% CV)	3 pg/mL
99th Percentile	3 pg/mL

REFERANCES

K. Thygesen, J. S. Alpert, A. S. Jaffe et al., "Fourth universal definition of myocardial infarction European Heart Journal 2019; 40: 3, 237–269.

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Adams, J. E., Sicard, G. A., Allen, B. T., Bridwell, K. H., Lenke, L. G., Davila-Roman, V. G., Bodor, G. S., Ladenson, J. H., & Jaffe, A. S. (1994). Diagnosis of Perioperative Myocardial Infarction with Measurement of Cardiac Troponin I. New England Journal of Medicine, 330(10), 670–674. https://doi.org/10.1056/nejm199403103301003

Deniz Biyokimya

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Index or Symbols

	Attention, see instructions for use	Σ 1	Tests per Kit		Manufacturer
IVD	For *in vitro*		Use by		Do NOT Use Damaged Box
	Store between 2 - 30°C	LOT	Lot Number	REF	Catalogue Number

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