SPECTRUM

The Creative Approach to Bioscience

Cardiac Troponin I Assay (cTnI)

REF: 240 001 R1 1 X 12 ml 50 test
R2 1 X 4 ml

Intended Use

Spectrum Cardiac Troponin I Assay (cTnI) is intended for the in-vitro quantitative, diagnostic determination of Troponin I in human serum and plasma by latex enhanced immunoturbidimetric method

Background

Human troponin I is presented in three isoforms, two isoforms are expressed in skeletal muscle tissue and one isoform is expressed in cardiac muscle tissue. cTnI is expressed in cardiac muscle tissue by a single isoform with molecular weight 23876 Da and it consists of 209 amino acid residues. For more than 15 years cTnI has been known in the literature as a reliable marker of cardiac muscle tissue injury and considered to be more sensitive and significantly more specific in diagnosis of the myocardial infarction than the "golden marker of last decades CK-MB. Published literature states that serum levels of cardiac enzymes and isoenzymes are essential to the diagnosis or exclusion of myocardial damage and that cardiac troponin I is specific for cardiac tissue and is detected in the serum only if myocardial injury has occurred. These reports state that Troponin I determination allows early identification and stratification of patients with chest pain suggestive of ischemia, allows identification of patients that present 48 hours to 6 days after infarction, and identifies patients with false positive elevations in CK-MB1-6.

Method

latex enhanced immunoturbidimetric method.

Assay Principle

An antigen-antibody reaction occurs between cTnI in a sample and anti-cTnI antibody which has been coated to latex particles. This resulting agglutination is detected as an absorbance change , with the magnitude of the change being proportional to the quantity of cTnI in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration

Reagents

Reagent 1 (R1)

Amino acetic acid buffer 50 mmol/l

Reagent 2 (R2)

Latex suspension
super sensitization resistance people cTnI antibodies 0.20%

Reagents Required not included in the kits :

1-Spectrum cTnI Calibrator set (5 levels).
2-Spectrum cTnI control set (2 levels).

Reagent Preparation, Storage and Stability

Spectrum reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored at 2 - 8 ^{O}C.

Precautions and Warnings

1.For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2.Reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush the affected area with copious amounts of water. In case of contact with eyes or ingestion seek immediate medical attention.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(C) - Corrosive
	Temperature Limitation		

3.Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4.All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

Specimen Collection and Preservation

Serum or plasma heparin samples.
If the assay cannot be performed within 24hours, Cap the prepared specimens and freeze them at -20^{O}C or below.

System Parameters

Wavelength	505 nm
Optical path	1 cm
Assay type	Fixed Rate
Direction	Increase
Temperature	37 ^{O}C
Linearity	26.3 ng/mL

Procedure

Sample	30 µl
Reagent 1	225 µl
Mix and incubate for 5 minutes at 37 ^{O}C,then add;	
Reagent 2	75 µl
Mix and incubate for 30 seconds then read intial absorbance A1, after 270 seconds read final absorbance A2	
Calculate ΔA = A2- A1	

Calculation

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of cTnI in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

Quality Control

Normal & abnormal commercial control serum of known concentrations should be analyzed with each run.
Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition precedes technical error, the following steps should be taken:
1.Check instrument settings and light source.
2.Check reaction temperature.
3.Check expiration date of kit and contents.

Performance Characteristics

Precision

Within run (Repeatiblity)

	Level 1	Level 2
n	20	20
Mean (ng/ml)	2.04	4.79
SD	0.03	0.05
CV%	1.52	0.97

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (ng/ml)	2.05	4.77
SD	0.04	0.06
CV%	1.9	1.2

Methods Comparison

A comparison between Spectrum reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.994 was obtained.

Linearity

The reaction is linear up to 26.3 ng/mL.
Specimens showing higher concentration should be diluted with 0.9% Nacl and repeat the assay ,Multiply the result by dilution factor.

Interfering substances

No significant interference up to the levels indicated

Hemoglobin: 500 mg/dl
Heparin: 500 U/ml
Bilirubin: 30 mg/dl
Vitamin C: 50 mg/dl

Expected Values

Up to 1.68 ng/mL.
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

References

1.Adams, J.E., et at, Biochemical markers of myocardial injury. Is MB creatin kinase the choice for the 1990's. Circulation 88:750 (1993).
2.Mair J, Wagner I, Jakob G, Lechleitner P, Dienstl F, Puschendorf B, Michel G: Different time courses of cardiac contractile proteins after acute myocardial infarction. Clin Chim Acta 1994;231:47-60.
3. Bodor, S.G., et al., Development of monoclonal antibody for an assay of cardiac troponin I and preliminary results in suspected cases ofmyocardial infarction. Clin.Chem. 38:2203 (1992).

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
240 001	50 test

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