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Troponin I

This reagent is used for in vitro determination of troponin I (cTnI) in human serum samples for clinical diagnostic purposes.

REF: BS.1/TR01.025.0025	25 test	REF: BS.1/TR01.100.0100	100 test
REF: BS.1/TR01.050.0050	50 test		

CLINICAL SIGNIFICANCE

Troponins are regulatory proteins that form the cornerstone of muscle contraction. The amino acid sequences of cardiac troponins differentiate them from that of skeletal muscles, allowing for the development of monoclonal antibody-based assay of troponin I (TnI) and troponin T (TnT). Along with the patient history, physical examination and electrocardiography, the measurement of highly sensitive and specific cardiac troponin has supplanted the former gold standard biomarker (creatine kinase-MB) to detect myocardial damage and estimate the prognosis of patients with ischemic heart disease. The current guidelines for the diagnosis of non-ST segment elevation myocardial infarction are largely based on an elevated troponin level. The implementation of these new guidelines in clinical practice has led to a substantial increase in the frequency of myocardial infarction diagnosis.

METHOD PRINCIPLE

Troponin I in sample serum binds to the specific antitroponin I antibody in the reagent and binds as an antigenantibody complex to form a certain turbidity. The level of this turbidity in the presence of sufficient antibody is proportional to the concentration of troponin I in the sample. The turbidity was measured at 505nm to yield the concentration of troponin I in the sample serum when compared with the calibration material.

REAGENT COMPOSITION

Reagents:	Composition
R1 Reagent	PBS buffer solution 0.1mol/L PEG appropriate amount anticorrosive 1‰ surface active agent appropriate amount
R2 Reagent	Antibody sensitized latex (Antitroponin I antibody) >0.05g/L PBS buffer solution 0.1mol/L anticorrosive 1‰ stabilizer appropriate amount surface active agent appropriate amount
CALIBRATOR SET	Troponin I concentration is stated on the vial label.

Both reagents contain Sodium azide as a preservative.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Troponin I reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Bioscien Troponin I reagents are stable up to the expiry date labeled on the bottles when properly stored
refrigerated at 2–8°C. Opened vials are stable for one month.
NOTE: working reagent must be freshly mixed (stable for only 2 mins.)

Deterioration

The ***BioScien*** Troponin I reagent can be damaged due to Presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION

Serum, K2-EDTA plasma, K3-EDTA plasma or Li-heparin plasma samples can be used for the assay. If the sample is refrigerated at 2-8°C, testing should be completed within 3 days.

SYSTEM PARAMETERS

Wavelength	600 nm
Optical path	1 cm
Assay type	Fixed Rate
Temperature	37 ˚C
Direction	Increasing

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Automatic analyzer

ASSAY PROCEDURE

	Calibrator	Sample
R1	240 µl	240 µl
R2	60 µl	60 µl
Calibrator	30 µl	
Sample		30 µl

Mix and read the initial absorbance after 300 seconds (A1), then after 300 seconds read the absorbance (A2).

CALCULATION

Calculate the absorbance difference (A2-A1) of each point of the calibration curve and plot the values obtained against the troponin I concentration of each calibrator concentration. troponin I concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.
For more information please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

1. **Sensetivity:** 0.45 ng/mL
2. **Precision:** repeatability CV≤10%;batch variations R≤10%.
3. **Accuracy:** relative deviation ≤10%.
4. **Linearity range:** 24 ng/mL

If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.

INTERFERING SUBSTANCES

Heterophilic antibodies (HA) and rheumatoid factor (RF) typically produce false-positive cardiac troponin (cTn) or NT-proBNP levels by bridging capture and detection antibodies. False-positive results could also occur in the presence of macroforms that decrease the renal clearance of cardiac biomarkers. Outliers, also called fliers, are encountered when the results obtained between two successive analyses of the same sample vary significantly.

LIMITATIONS OF PROCEDURE

1. When the sample concentration is> 24ng/mL, exceeding the detection limit,dilute with saline.
2. Supporting calibrators are when used and within the applicable inspection system used in this kit.

EXPECTED VALUES

Normal reference range: 0-1.68ng/mL. It was determined from 95% of the distribution areas of normal people. It is recommended that each laboratory verify this reference range or establish their own reference range.

REFERENCES

1. Wick M, Pinnggera W, Lehmann P. Ferritin in iron metabolism. Diagnosis of anemias. 2nd ed. Springer-Verlag. Wien 1994.
2. Rodriguez Perez J et al. Revista Clinica Española 1980: 156 (1): 39-43
3. Milman N et al. Eur J Haematol 1994: 53: 16-20.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		