ACCUCARE® Troponin I Turbilatex Kit is intended to Quantitative determination of Troponin I content in human serum or plasma. Only for In Vitro Diagnostic use

ORDER INFORMATION

REF	Cont.
TTI 25	1 X 25 mL
TTI 50	1 X 50 mL

CLINICAL SIGNIFICANCE

Troponin I (TnI) is part of troponin complex, which together with tropomyosin, forms the main component that regulates the Ca+2 – sensitive ATP-ase activity of actomyosin is striated muscle (skeletal and cardiac). The troponin complex consists of three subunit has a distinct function with TnC as the site of Ca+2 binding, TnT the tropomyosin binding, and TnI as the inhibitory subunit. Different isoforms of TnI exists in the skeletal and cardiac muscles (sTnI and cTnI, respectively) with distinct immunologic epitopes that allow the production of cardiac-specific TnI antibodies. The cardiac marker, troponin I has been established as useful tools in the diagnosis of acute myocardial infraction (AMI). Troponin I is found in blood at elevated concentrations approximately 4-6 hours after the onset of chest pain and peak at 12-24 hours. Troponin I levels remain elevated for up to 14 days. The use if this marker is an aid in the diagnosis of AMI after myocardial function.

Method

Latex enhanced immune transmission Turbidimetric

PRINCIPLE

The troponin I in the sample is combined with the specific anti-troponin I antibody coated with the latex microparticles, making the microparticles agglutination with turbidity, and the turbidity change in the reaction fluid is proportional to the troponin I content in the sample. From the standard strain working curve, the concentration of troponin I in the sample is obtained.

REAGENT

Reagent I : PBS Buffer Solution, PEG, NaN_3 Surface active agent
Reagent II : Antigen-sensitized adhesive latex (Troponin I), PBS Buffer Solution, NaN_3 Stabilizer, Surfactant active reagent

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

- This kit of 2~8℃ can be stable for one year. Refrigeration in summer and do not freeze.

WARNING AND PRECAUTIONS

- This product is a latex-enhanced immune transmission ratio turbidity method reagent, and the secondary wavelength is not recommended.
- This product is used for in vitro diagnosis only.
- Different batches of reagents shall not be mixed, and new batch numbers of reagents shall be re-marked.

WASTE MANAGEMENT

Please refer to local legal requirements.

SAMPLE COLLECTION AND PRESERVATION

- Applicable to fresh serum samples. If the samples collected on the Same day cannot be measured in time, please save at-20℃,
- And quickly thaw at 37℃ before temporary use.

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	600 nm
Reaction Temperature	37°C
Reaction Type	Fixed time
Reaction Direction	Increasing
Cuvette	1 cm light path
Measurement	Against Distilled water
Reagent Volume1	400 µl
Reagent Volume2	100 µl
Sample Volume	50 µl
Blank Absorbance	≤2.0
Incubation	300 Seconds
Delay Tine	10 Seconds
Read Time	300 Seconds
Linearity	0.1-10 ng/mL

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	REAGENT BLANK	CALIBRATOR	SAMPLE
REAGENT I	400 µl	400 µl	400 µl
Cali.(C0,C1,C2, C3,C4,C5,C6)	-	50 µl	-
SAMPLE	-	-	50 µl
Mix well and incubate for 5 mins at 37°C & Immediately Add			
REAGENT II	100 µl	100 µl	100 µl
Mix well, and read the absorbance immediately A1 and after 5 minutes A2 of the sample addition.			

LINEARITY

Linearity Range: 0.1-10 ng/ml

REFERENCE VALUES

Serum / Plasma	Up to 0.6ng/mL.

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- When the concentration of ≥10ng/mL exceeds the detection limit, it should be diluted in normal saline for determination.
- Only matching calibrations are used with this kit and within the applicable inspection system used in this kit.

INTERFERENCE

- This kit is linearly dependent on the ratio of specimen and reagent. Reducing the specimen dosage can increase the linearity, but the reagent sensitivity decreases; the excessive sample size affects the standard curve.
- The first photometry should be performed at 40 seconds after the addition of R2, and the second one at 300 seconds after the addition of R2. When used for diagnostic and therapeutic purposes, the test results should always be interpreted in conjunction with the patient's medical history, clinical symptoms, and other outcomes.

BIBLIOGRAPHY

1. In the Clinical Laboratory Management and Technical Regulations, Lu Yongsui and Zhang Weiming
2. Notice No.17 of the Guidelines for the Compilation of National Food and Drug Administration [2014]

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
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