Cardiac Troponin I Assay Kit (cTnI)

Method: Latex Enhanced IT

Cat . No.	Size	Instrument
GB290X	R1:1×60ml R2:1×20ml	Hitachi7060/7150, ShimadzuCL7200/8000
GS291X	R1:1×60ml R2:1×20ml	Hitachi7170/7180,Olympus AU640/400/600
GH291X	R1:3×20ml R2:1×20ml	Hitachi 7020
GT291X	R1:3×20ml R2:1×20ml	TOSHIBA
GX291X	R1:1×60ml R2:1×20ml	BeckmanCX5/7/9/LX20
GD291X	R1:24×3.8ml R2:12×2.6 ml	DuPont

INTENDED USE

For the *in vitro* quantitative determination of cTnI in serum or plasma samples.

CLINICAL SIGNIFICANCE

Cardiac troponin consists of three subunits: cTnT, cTnI and cTnC. cTnI, with Molecular weight 21kD is regarded as a high specificity and sensitivity marker of myocardial. cTnI is a unique component of myocardial cells. Blood levels of cTnI in myocardial infarction occurs 4-6 hours and reach a peak in 12-24 hours. Troponin I in the blood has a long duration, the positive results of sustainable to 7-10 days after myocardial infarction. Now cTnI has been more and more used in myocardial ischemic injury such as acute coronary syndrome and other clinical diagnosis, risk degree and prognosis assessment, the area of myocardial infarction predict myocardial infarction thrombolytic efficacy, heart damage, congestive heart failure, severe sepsis caused by left heart failure clinical diagnosis et al. In addition, cTnI on retrospective diagnosis is significant, especially for those visiting time late, myocardial enzyme has returned to normal in patients with myocardial infarction.

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 (500 nm), 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.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Amino acetic acid buffer	50mmol/L
Reagent 2 (R2)	
Latex suspension, super sensitization resistance people cTnI antibodies	0.20%

SPECIMEN COLLECTION AND PREPARATION

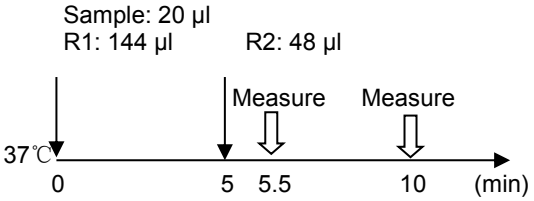
Serum or plasma (heparin) sample.
If the assay cannot be performed within 24hours, Cap the prepared specimens and freeze them at -20℃ or below.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzer (Hitachi 7180)
Assay Mode: 2 Point End, 19 - 34
Wavelength(main) 505 nm



1. Mix 20 µl sample with 144 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 48 µl R2 into cuvette, mix and incubate for 30 seconds at 37℃.
3. Read initial absorbance A_1 and incubate for another 4.5 minutes, read final absorbance A_2.
4. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION

Gcell cTnI calibrators (Cat.No: GC-cTnI).

CALCULATIONS OF RESULTS

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

Gcell cTnI Controls (Cat.No:GQ-cTnI). Quality control materials are intended for use only to monitor accuracy and precision. The values for these controls should fall within specified limits. If the control values fall outside these ranges and repetition precedes technical error the following steps should be taken:

1. Check wavelength setting and light source.
2. Ensure that cuvettes are not dirty and that all glassware in use has been cleaned thoroughly.
3. Check water, contaminants, ie. bacterial growth, may contribute to inaccurate results.
4. Check that assay temperature is accurate.
5. Ensure that reagent pack contents are still within expiry date.

NORMAL VALUE

The unilateral cap of 99% is 1.68ng/ml,by analyzing 100 samples.
It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE version 2014

location.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

The assay is linear up to 26.30 ng/ml. If the concentration in sample is above 26.30 ng/ml, please dilute the sample with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be ≤5%

Intar assay precision		
N=20	level 1	level 2
Mean(ng/ml)	2.04	4.79
SD	0.03	0.05
CV(%)	1.52	0.97%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(ng/ml)	2.07	2.04	2.04
$\bar{x}$	2.05		
(Xmax-Xmin)/$\bar{x}$	(2.07-2.04)/2.05*100=1.46%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

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

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
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. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. 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)
2. Adams, J.E., et at, Biochemical markers of myocardial injury. Is MB creatin kinase the choice for the 1990's. Circulation 88:750 (1993)

INDEX OF SYMBOLS


Manufacture


Catalogue Number


Lot number


Date of manufacture


Use by(Expiration date)


For In-Vitro Diagnostic use only


Stored at 2-8℃


Attention:See instruction for use


Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn