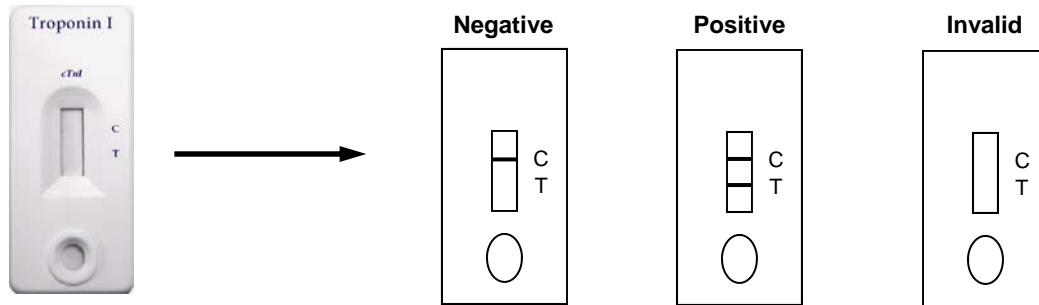




FASTGEN CORPORATION

Cardiac-1 Rapid Test
For the Qualitative Test of Cardiac Troponin I in Human Serum, Plasma, or Whole Blood

INTENDED USE: The Cardiac-1 Rapid Test is intended for the in vitro diagnostic use in the qualitative detection of cardiac Troponin I in human serum, plasma and whole blood samples.



Features and Advantages of Cardiac –1 Rapid Test:

- Highly sensitive chromatographic immunoassay
- US FDA 510(K) approved test
- Specific detection of cardiac Troponin I, the current gold standard biochemical indicator for acute myocardial infarction (AMI)
- Rapid test format delivers results in minutes
- Strong prognostic value in unstable angina

Performance Characteristics:

- Cut-off positivity concentrations—1.5 ng/ml free Troponin I or 5 ng/ml ternary complex
- Excellent correlation with commercially available ELISA assay:

Fastgen Troponin I Rapid Test	Troponin I ELISA Test	
	≥ 1.5 ng/ml	≤ 1.5 ng/ml
+	149	4
-	1	146
Total	150	150

Sensitivity 149/150 = 99.3%
 Specificity 146/150 = 97.3%
 Overall Accuracy 295/300 = 98.3%

- 100% agreement between protocols using whole blood samples and homologous plasma isolated

To Order:
 Catalog No. FGD0001 For use with serum samples
 Catalog No. FGD0002 For use with whole blood, plasma, or serum samples
Not available for sale in the US

Fastgen Corporation
 366 Lakeside Drive
 Foster City, CA 94404
 USA
 tel: 1.650.356.1112
 fax: 1.650.356.0555
 www.fastgencorp.com



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Potential Utilities in the following Clinical Presentations:

- Chest pain with nondiagnostic ECG
 - elevation in Troponin I specific indicator for acute myocardial infarction (AMI)
 - negative assay results in sequential testing may allow rule-out of infarction
- Chest pain, abnormal ECG with creatine kinase (CK) elevation following trauma or surgery
 - cardiac Troponin I helps differentiate true or false positive for myocardial cell damage
- Persistent chest pain prior to office/hospital presentation
 - prolonged elevation renders Troponin I sensitive indicator of AMI for up to 7 days
- Decompensated heart failure, acute myocarditis, hypotension, syncope or prolonged tachyarrhythmia
 - Troponin I assay able to detect small amounts of myocardial necrosis

Advantages of cardiac Troponin I as a cardiac Marker:

- ***More sensitive and specific indicator of AMI than CK-MB***
- ***Allows timely triage of chest pain patients into appropriate treatment and risk categories***
- ***Levels elevated for 5-7 days, providing a longer diagnostic window***
- ***Strong prognostic value in unstable angina***

References:

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366 Lakeside Drive
Foster City, CA 94404
USA
tel: 1.650.356.1112
fax: 1.650.356.0555
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