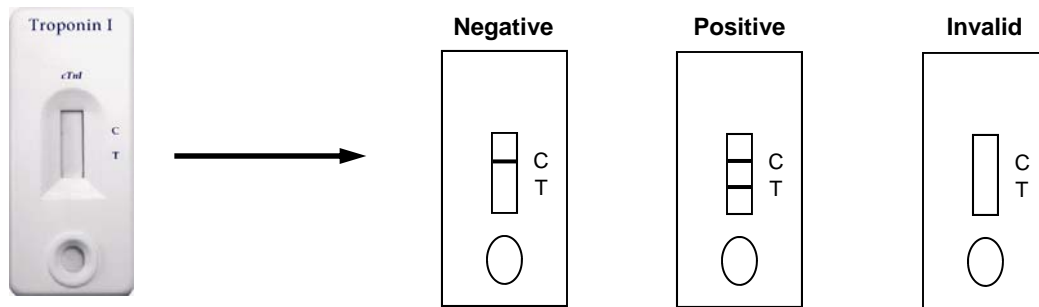




**FASTGEN CORPORATION**

**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
<b>Total</b>	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



## **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.*

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:**

Cummins, B., Auckland, M.L., and Cummins, P., *Am. Heart J.*, 113:1333-1344 (1987)  
Larue, C. et. al., *Clin. Chem.*, 39:972 (1993)  
Adams, III, J.E. et. al., *Clin. Chem.*, 40:1291 (1994)  
Mair, J. et. al., *Lancet* 341:838-839 (1993)  
Antman, E.M. et. al., *N. Engl. J. Med.*, 335:1342-1349 (1996)  
Myocardial Infarction redefined—a consensus document of the Joint European Society of cardiology/American College of Cardiology Committee for the re-definition of myocardial infarction. *Eur. Heart J.*, 21:1502 and *J. Am. Coll. Cardiol.*, 36:959 (2000)

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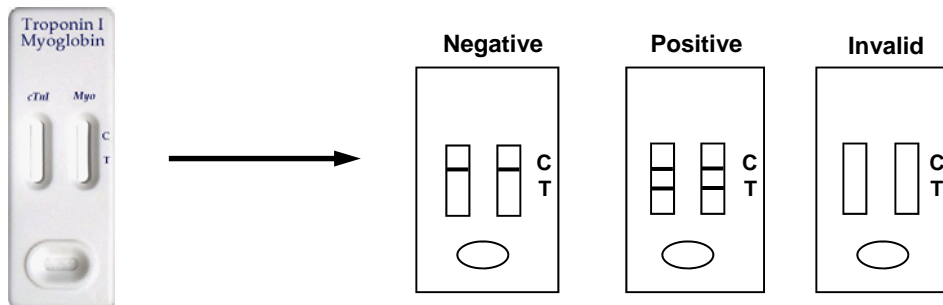


# FASTGEN CORPORATION

## Cardiac-2 Rapid Test

### For the Qualitative Test of Cardiac Troponin I and Myoglobin in Human Serum

*INTENDED USE:* The Cardiac-2 Rapid Test is intended for the in vitro diagnostic use in the qualitative detection of cardiac Troponin I and myoglobin in human serum samples.



#### Features and Advantages of Cardiac-2 Rapid Test:

- Highly sensitive chromatographic immunoassay\* offers the same features in the detection of Troponin I marker
- This test provides simultaneous detection of myoglobin, the first marker to rise above normal levels following cardiac necrosis associated with myocardial infarction (MI)
- Negative result in myoglobin detection may be used as a diagnostic aid in ruling out MI
- Rapid test format delivers results in minutes

*\*US FDA 510(K) approval pending*

#### Performance Characteristics:

- Cut-off positivity concentrations — Troponin I 1.5 ng/ml  
Myoglobin 100 ng/ml

#### • Accuracy

##### - Troponin I

	Negative (0 ng/ml)	Troponin I (0.3-0.8 ng/ml)	Troponin I (≥1.1 ng/ml)
# Samples	105	23	67
Negative	104	23	0
Positive	1	0	67
Agreement	99.1%	100%	100%

##### - Myoglobin

	Negative (0 ng/ml)	Myoglobin (13-66 ng/ml)	Myoglobin (> 100 ng/ml)
# Samples	70	50	101
Negative	70	42	0
Positive	0	8	101
Agreement	100%	84%	100%

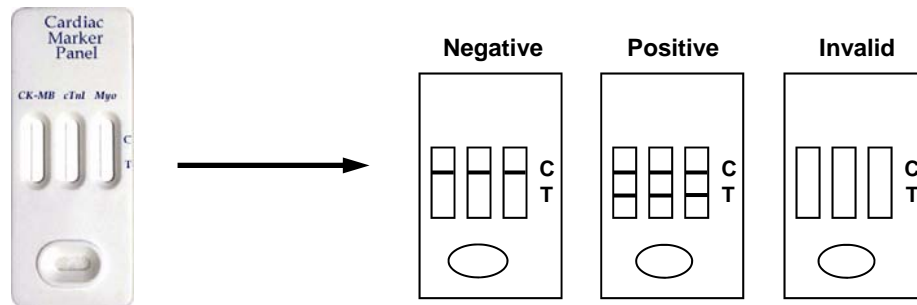
To Order: Catalog No. FGD0003 Cardiac-2 Rapid Test Not available for sale in the US



# FASTGEN CORPORATION

## Cardiac-3 Panel Rapid Test For the Qualitative Test of Cardiac Troponin I, Myoglobin and CK-MB in Human Serum

*INTENDED USE: The Cardiac-3 Panel Rapid Test is intended for the in vitro diagnostic use in the qualitative detection of cardiac Troponin I, myoglobin, and CK-MB in human serum samples.*



### Features and Advantages of Cardiac-3 Panel Rapid Test:

- Highly sensitive chromatographic immunoassay\* detects the levels of all three critical cardiac markers for the diagnosis or exclusion of acute myocardial infarction (AMI)
- Incorporates measurement of CK-MB used in the WHO criteria for MI diagnosis
- Provides complete biochemical data in one test
- Rapid test format delivers results in minutes

*\*US FDA 510(K) approval pending*

### Performance Characteristics:

- Cut-off positivity concentrations — Troponin I 1.5 ng/ml  
Myoglobin 100 ng/ml  
CK-MB 7.0 ng/ml

### • Accuracy

#### - Troponin I

	Concentration (ng/ml)		
	Negative	Troponin I (0.3-0.8)	Troponin I (≥1.1)
# Samples	105	23	67
Negative	104	23	0
Positive	1	0	67
Agreement	99.1%	100%	100%

#### - Myoglobin

	Concentration (ng/ml)		
	Negative	Myoglobin (13-66)	Myoglobin (>100)
# Samples	70	50	101
Negative	70	42	0
Positive	0	8	101
Agreement	100%	84%	100%

#### - CK-MB

	Concentration (ng/ml)		
	Negative	CK-MB (0.8-6.9)	CK-MB (≥7.5)
# Samples	79	30	58
Negative	79	26	0
Positive	0	4	58
Agreement	100%	86.7%	100%

To Order: Catalog No. FGD0004 Cardiac-3 Panel Rapid Test Not available for sale in the US