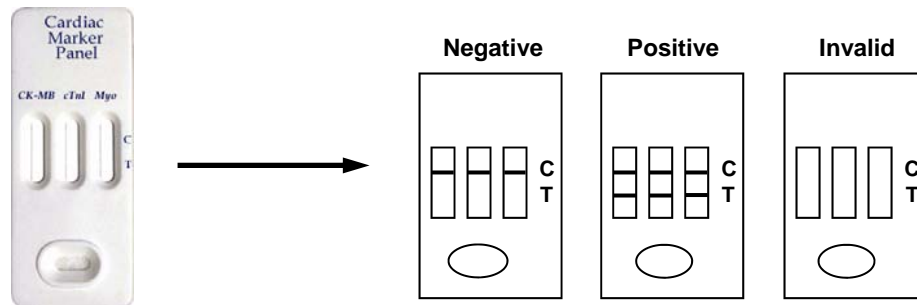




FASTGEN CORPORATION

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