

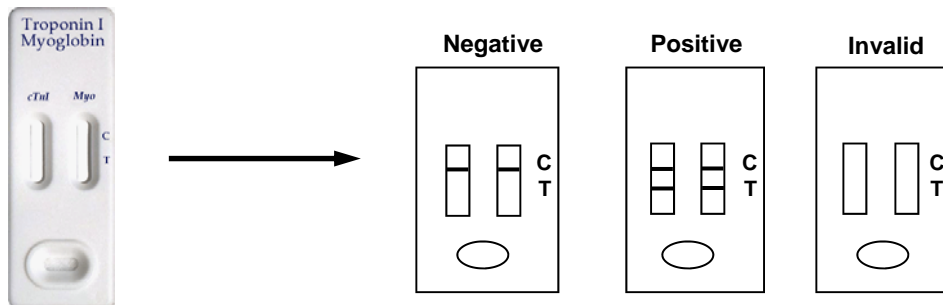


FASTGEN CORPORATION

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