Quanterix™
The Science of Precision Health

Simoa® Troponin-I Advantage Kit

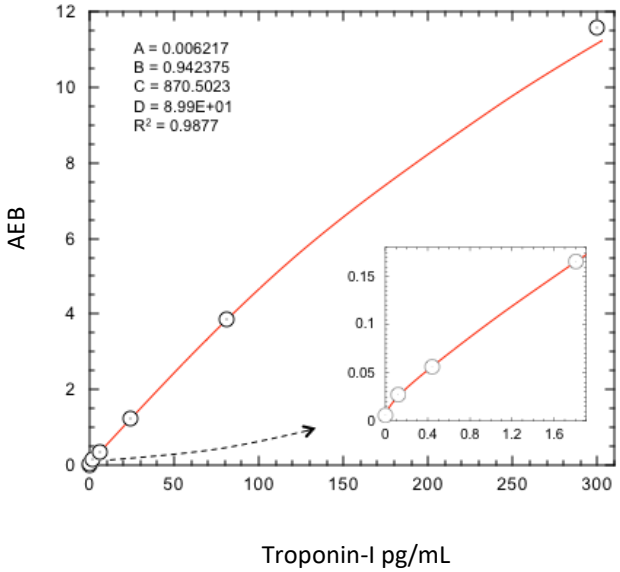
HD-1/HD-X Data Sheet

Item 101588

Description

Cardiac Troponin-I (cTnI) is a 23.8 kD regulatory subunit of the troponin complex that is associated with the actin thin filament within cardiac muscle cells. The troponin complex is composed of troponin-C and troponin-T, and it plays an integral role in the regulation of cardiac muscle contraction. Extensive clinical studies have demonstrated that cTnI is slowly released into the blood within hours of myocardial infarction (MI) or ischemic damage. cTnI elevation is detectable in serum within 4-6 hours after the onset of chest pain, and can remain elevated for up to 10 days following MI. cTnI measurements are highly specific for myocardial damage, and can be useful for identifying cardiac injury from different sources, including surgery, trauma, and intensive exercise. Clinical studies have also shown the patients with acute coronary syndromes (ACS) were at greater risk of progressing to MI if cTnI is elevated relative to an upper reference limit for healthy individuals. This has spurred increasing attention in recent years on high sensitivity cTnI measurement. Potential benefits include more rapid diagnosis in ACS, population screening, prognostic information in stable patients, and clinical drug development.

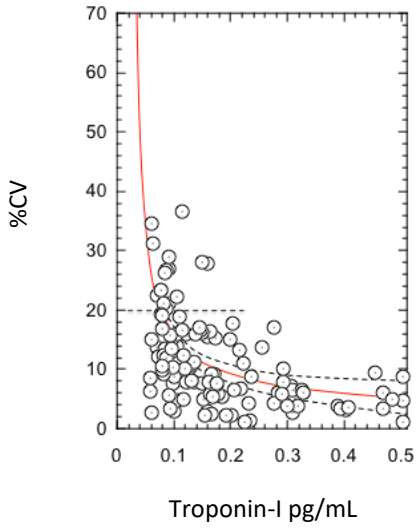
Calibration Curve: Four-parameter curve fit parameters are depicted.



Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (12 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 2 reagent lots across 3 instruments (12 runs total).

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (144 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



LLOQ (see CV Profile above)	**0.079 pg/mL**
LLOQ (fit for purpose)	**0.075 pg/mL** pooled CV 18.3% mean recovery 98.6%
LOD	**0.013 pg/mL** range 0.003–0.044 pg/mL
Dynamic range (serum and plasma)	0–1200 pg/mL
Diluted Sample volume*	168 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

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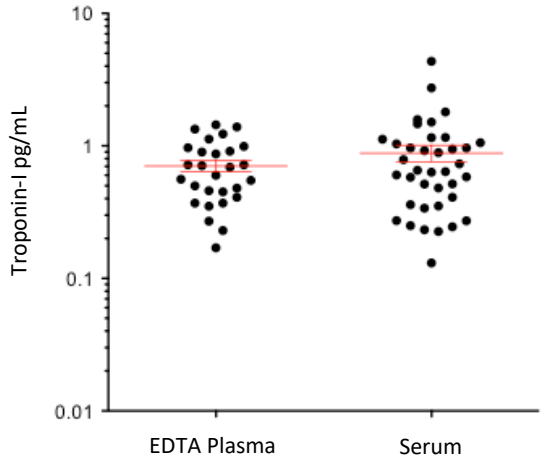
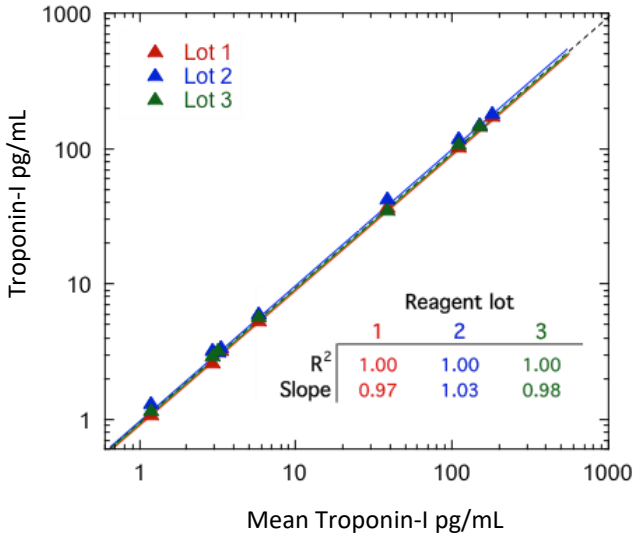
Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=28) and serum (n=38) were measured. Error bars depict mean and SEM.

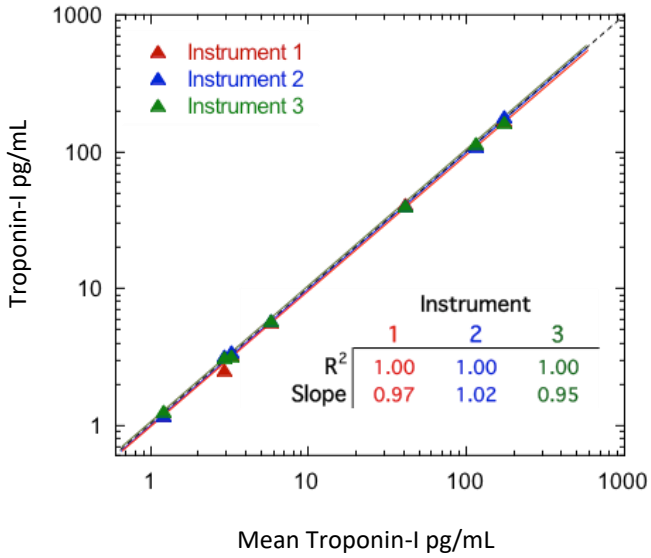


Sample Type	Median Troponin-I pg/mL	% Above LOD
EDTA Plasma	0.646	100%
Serum	0.647	100%

Reproducibility Across Reagent Lots: Nine native and spiked serum and plasma troponin-I samples tested across 2 runs x 3 instruments each lot. Data points depict means for each sample. Regression statistics reflect linear analysis.



Reproducibility Across Instruments: Seven native and spiked serum and plasma troponin-I samples tested across 2 runs x 2 reagent lots each instrument. Data points depict means for each sample. Regression statistics reflect linear analysis.



Inter Lot CV: Pool of CVs from 9 samples (range: 1.08–185 pg/mL) tested with 3 reagent lots across 2 runs x 3 instruments.

Inter Instrument CV: Pool of CVs from 7 samples (range: 1.08–185 pg/mL) tested with 3 instruments across 2 runs x 2 reagent lots.

Endogenous Interferences: Bilirubin (20 mg/dL), hemoglobin (500 mg/dL), protein (12 g/dL), triglycerides (1000 mg/dL), mean of 6 samples.

Inter Lot CV	**9.3%**
Inter Instrument CV	**6.7%**
Endogenous Interferences	**<20%**

Reproducibility Precision: Six samples consisting of four serum panels and two troponin-I controls were assayed in replicates of three for two runs on each of three instruments and two reagent lots. Analysis of variance (nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between Lot	Between Instrument
Control 1	3.25	7.7%	7.6%	0.0%	4.3%
Control 2	160	4.7%	8.3%	9.4%	0.0%
Panel 1	1.11	9.9%	4.3%	2.3%	2.2%
Panel 2	2.79	11.3%	0.0%	7.4%	0.0%
Panel 3	5.61	4.5%	7.0%	4.4%	0.0%
Panel 4	37.5	4.0%	7.7%	0.0%	0.0%
Panel 5	109	4.6%	12.3%	0.0%	1.1%

Repeatability Precision: Five samples consisting of two serum-based panels, one plasma-based panel, and two troponin-I controls were assayed in replicates of three at two separate times per day for five days using a single stored calibration curve and a single lot of reagents. Analysis of variance (fully nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between Day
Control 1	2.55	7.6%	5.1%	7.2%
Control 2	115	5.4%	8.1%	9.7%
Panel 1	2.04	9.7%	3.0%	0.0%
Panel 2	5.73	5.9%	0.0%	1.0%
Panel 3	54.4	4.8%	3.8%	1.8%

Spike and Recovery: cTnI spiked into 28 serum samples at varying concentrations.

Admixture Linearity: High cTnI serum sample admixed with low TnI sample, mean of 10 levels.

Dilution Linearity: Serum sample diluted serially from MRD (4x) to 64x with Sample Diluent.

Spike and Recovery (Serum)	**Mean = 75.5%** Range: 40.4–104%
Admixture Linearity	**Mean = 85.9%** Range: 88.2–105%
Dilution Linearity (64x)	**Mean = 89.5%** Range: 82.0–101%

The Simoa Troponin-I Advantage assay kit is formulated for use on the SR-X®, HD-1, or HD-X® platform. Data in this document was obtained from runs on the HD-1 platform unless otherwise noted. Some differences in performance claims between SR-X and HD-1/HD-X may be observed when comparing datasheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples, or it may be due to minor differences in antibody and analyte behavior in the different assay formats.