Quanterix™
The Science of Precision Health

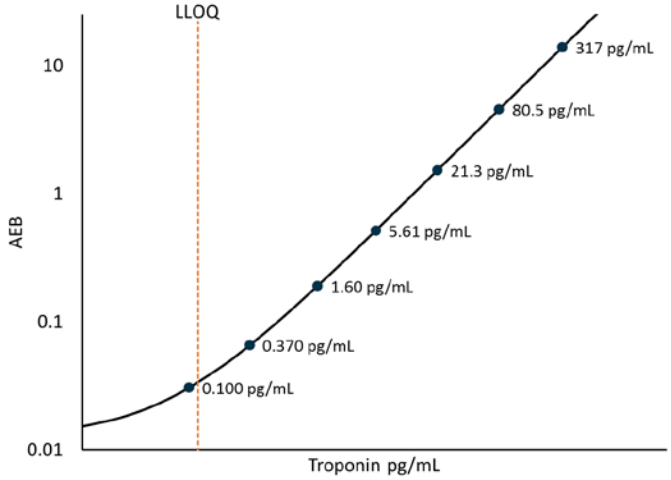
Simoa™ Troponin-I Advantage Kit
SR-X™ Data Sheet

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: Calibrator concentrations and Lower Limit of Quantification depicted.



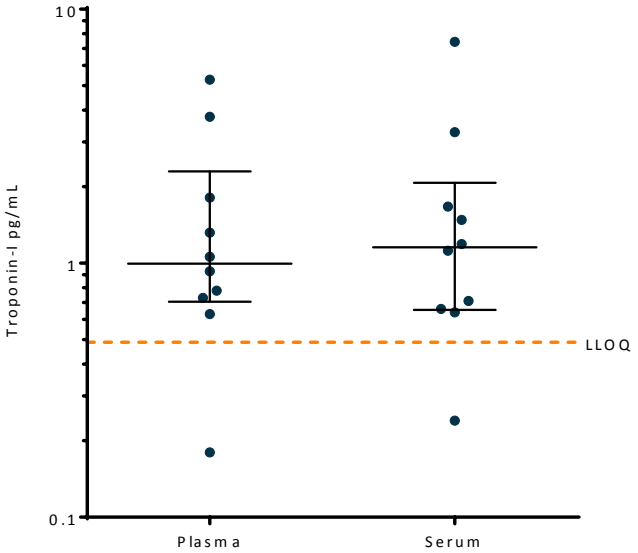
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	**0.122 pg/mL** pooled CV 17% mean recovery 114%
LOD	**0.021 pg/mL** range 0.013-0.038 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**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10), and serum (n=10) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean Troponin-I pg/mL	Median Troponin-I pg/mL	% Above LLOQ	% Above LOD
Serum	1.81*	1.15	90%	100%
Plasma	2.02*	0.986	90%	100%

*Values below LLOQ are not included in the mean

Quanterix Corporation
113 Hartwell Avenue, Lexington, MA 02421
techsupport@quanterix.com

Assay designed by Muriel

Precision: Measurements of 3 panels, 2 serum-based and 1 plasma-based and 1 calibrator-based control. Triplicate measurements were made for 6 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control	158	10.9%	10.2%	4.9%
Panel 1	2.07	10.4%	14.4%	10.7%
Panel 2	6.28	12.9%	13.5%	2.3%
Panel 3	113	9.6%	7.0%	7.1%

Spike and Recovery: 4 serum and 4 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on SR-X.

Dilution Linearity: 1 endogenous EDTA plasma and 1 spiked serum sample were diluted 2X serially from MRD (4x) to 128x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**Mean = 63%** Range: 52-87%
Dilution Linearity (128x)	**Mean = 89%** Range: 72–114%

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

Quanterix Corporation
113 Hartwell Avenue, Lexington, MA 02421
techsupport@quanterix.com

Assay designed by Muriel