Quanterix
The Science of Precision Health

Simoa™ Troponin-I 2.0 Kit
Certificate of Analysis

Product Number:	101588
Lot Number:	501898
Expiration:	26-Mar-2020
Platform(s):	HD-1/HD-x & SR-X

Component	Part Number	Lot Number
Bead Reagent	101590	910813
Detector Reagent	101589	909802
SBG Reagent	101591	908515
Sample Diluent	101592	908516
Calibrators	101110	906404, 907901
Controls	100551-100552	907902
SBG Diluent (SR-X)†	103158	N/A[1]
RGP Reagent	103159	N/A[1]

[1] RGP is not Kit Lot Specific

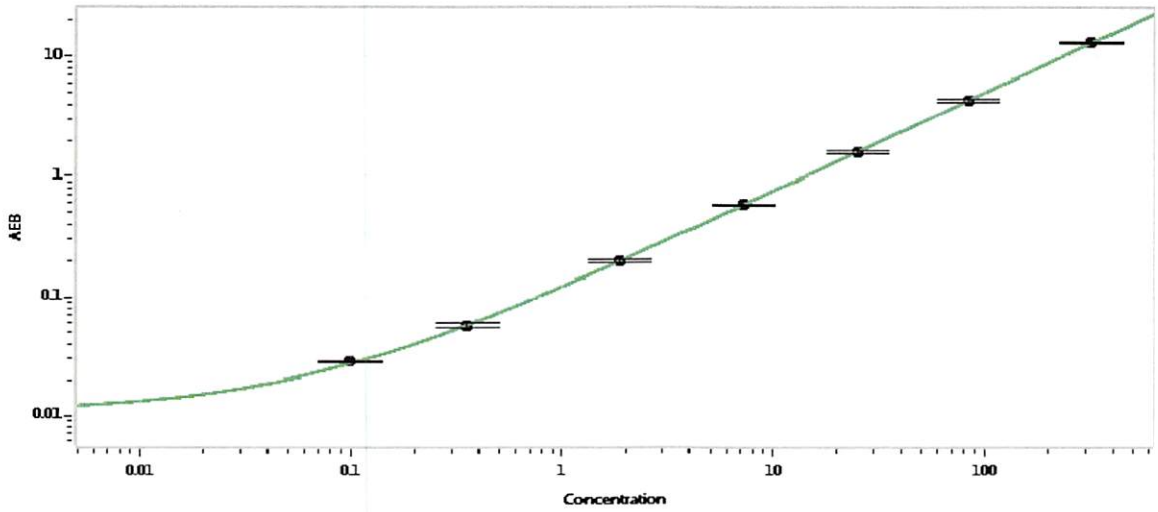
† Specific for use on the SR-X platform - refer to the Simoa™ Troponin-I Advantage SR-X Kit Instructions (KI-0098).

Data below represents results generated on the Simoa™ HD-1 Analyzer.

Release Materials*			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	907902	3.60	2.80-4.20
Control 2	907902	166	135-202
Panel 1	MF-031918-01	0.934	0.642-1.22
Panel 2	MF-031918-02	5.95	4.78-7.17
Panel 3	MF-031918-03	115	91.2-160

* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.098
C	0.355
D	1.88
E	7.20
F	25.2
G	84.1
H	319

Review/Approval	Patrizia Stadler	Assoc.Director, QC	P. Stadler	16 JUL 2019
	Name	Title	Signature/Date	

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