Quanterix™
The Science of Precision Health

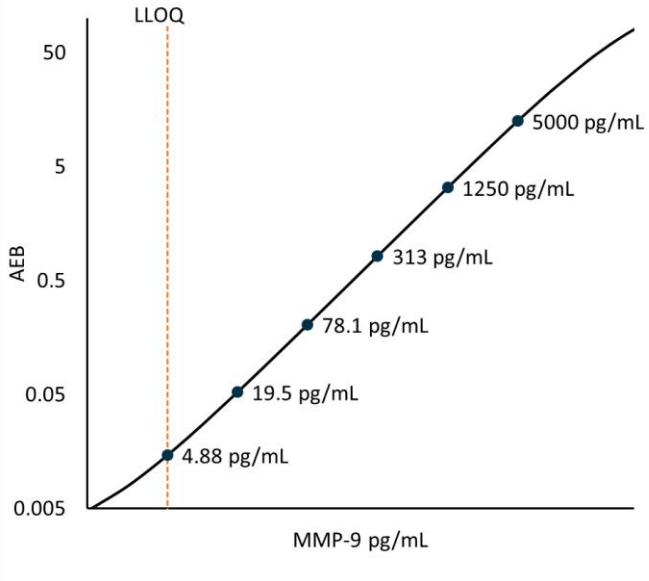
Simoa® MMP-9 Discovery Kit
HD-1/HD-X Data Sheet

Item 102491

Description

Matrix metalloproteinase 9 (Discovery MMP-9) is a 92 kDa secreted protein, belonging to the metzincin (multi domain zinc (II) dependent endopeptidases) superfamily of proteases. It is produced by normal and transformed cells. MMP-9 functions through enzymatic degradation by cleaving extracellular matrix proteins and adhesion molecules (like ICAM-5). These events play major roles in the processes of synaptic plasticity, learning, memory, and morphological reconstruction of targets such as neuronal dendritic spines. MMP-9 has been shown to be linked to various disease states including cancer, cardiovascular disease and arthritis. Specifically, cancer models have shown directly that metastasis/angiogenesis and overall tumor aggression are linked to elevated MMP-9 levels. Cardiovascular issues including myocardial infarction, aneurysms, and atherosclerotic plaques have been shown to be linked to increased MMP-9 levels using knockout and overexpression studies in mice. Allograft studies of renal transplant patients have unearthed links between MMP-9 and immune-mediated tissue rejection (destruction) of the allograft opening up windows for rejection prediction in future transplant cases.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



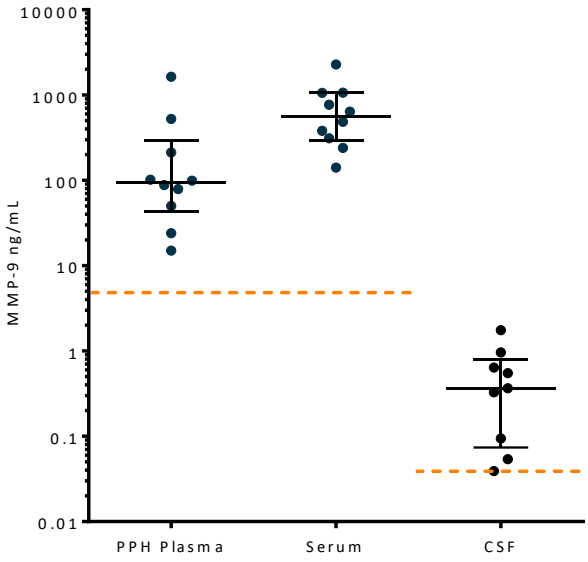
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	**4.88 pg/mL** pooled CV 6% mean recovery 104%
LOD	**0.581 pg/mL** range 0.358-0.805pg/mL
Dynamic range (Serum and Platelet Poor Heparin Plasma)	0–5000 ng/mL
Diluted Sample volume *	100 µL per measurement
Tests per kit	192

***See Kit Instruction for details**

Endogenous Sample Reading: CSF (n=9) samples and healthy donor matched platelet poor heparin plasma (n=10) and serum (n=10) samples were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean MMP-9 ng/mL	Median MMP-9 ng/mL	% Above LLOQ	% Above LOD
Platelet Poor Heparin Plasma	281	93.7	100%	100%
Serum	728	555	100%	100%
CSF	0.477	0.328	100%	100%

Precision: Measurements of controls, endogenous serum, and endogenous platelet poor heparin plasma (PPHP) panels. Triplicate measurements were made for 3 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (ng/mL)	Within run CV	Between run CV	Between inst CV
Control 1	27.8	4.8%	8.1%	2.4%
Control 2	113	2.7%	2.2%	2.0%
Serum 1	23.7	5.3%	10.0%	4.9%
Serum 2	134	4.0%	15.9%	0.7%
PPHP1	19.0	5.5%	8.6%	5.9%
PPHP2	123	2.8%	4.4%	0.6%

Spike and Recovery: 2 serum and 2 platelet poor heparin plasma samples were spiked at high and low concentrations within the range of the assay.

Dilution Linearity: One endogenous platelet poor heparin plasma sample was diluted serially from MRD (1000x) to 4000x with Sample Diluent, one endogenous serum sample was diluted serially from MRD (1000x) to 128000x with Sample Diluent, and one endogenous CSF sample was diluted serially from MRD (8x) to 256x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**97%** Range 90%-102%
Platelet Poor Heparin Plasma Dilution Linearity (4000x)	**Mean = 99%** Range: 98%-101%
Serum Dilution Linearity (128000x)	**Mean = 107%** Range: 97%-116%
CSF Dilution Linearity (256x)	**Mean = 102%** Range: 97%-111%

Specificity: Two normal serum samples and two platelet poor heparin plasma samples were pre-incubated with 20x MMP-9 capture beads. Capture beads were removed and samples were run at MRD in the assay. Average knock-down relative to control without capture bead pre-incubation was **89%**.

The Simoa MMP-9 Discovery 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.