

Description

Matrix metalloproteinase 9 (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.

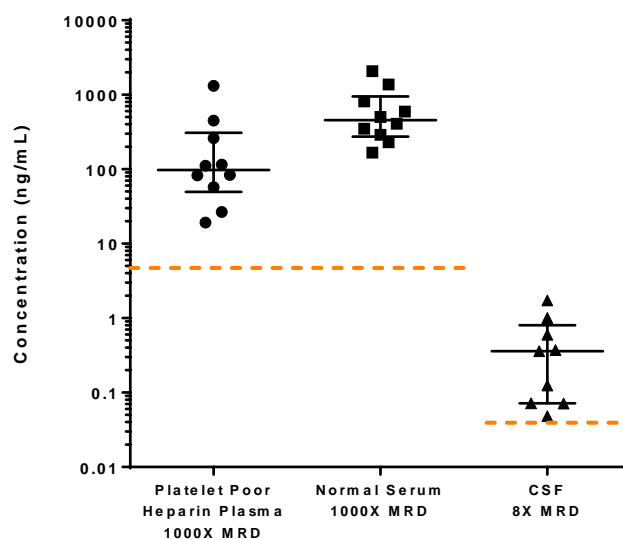
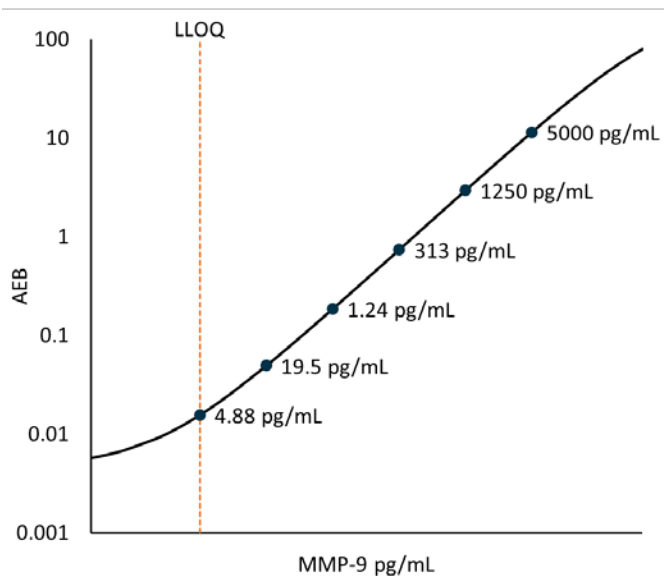
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrators were read back on the calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

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	4.88 pg/mL pooled CV 9.6% mean recovery 97%
LOD	1.09 pg/mL range 0.37-2.54 pg/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), serum (n=10) were measured. Orange line represents functional LLOQ. Error bars depict median with interquartile range.



Sample Type	Mean MMP-9 ng/mL	Median MMP-9 ng/mL	% Above LOD	% Above LLOQ
Platelet Poor Heparin Plasma	253	98	100%	100%
Serum	680	456	100%	100%
CSF	0.486	0.360	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	29.0	5.6%	8.8%	1.0%
Control 2	115.9	10.0%	5.0%	4.5%
Panel 1	144.2	6.3%	8.6%	0.5%
Panel 2	20.5	8.4%	8.8%	4.3%
Panel 3	132.3	12.1%	5.5%	5.1%

Dilution Linearity: One endogenous platelet poor heparin plasma sample and one endogenous serum sample were diluted 2x serially from MRD (1000x) to 64x MRD with Sample Diluent. One endogenous CSF sample was diluted serially from MRD (8x) to 16x MRD with sample diluent.

Platelet Poor Heparin Plasma Dilution Linearity (64x MRD)	Mean = 94.4% Range: 83%-103.5%
Serum Dilution Linearity (64x MRD)	Mean = 105% Range: 88%–116%
CSF Dilution Linearity (16x MRD)	Mean = 101.2% Range: 95.5%-109%

The Simoa Discovery MMP-9 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.