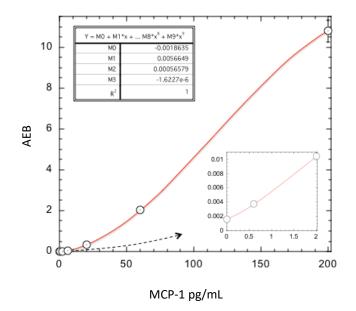
Simoa® MCP-1 Advantage Kit HD-1/HD-X Data Sheet Item 101154

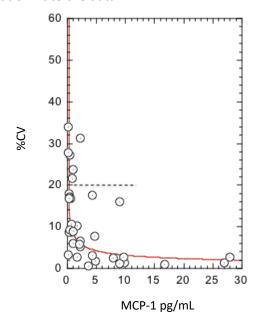
Description

Monocyte chemoattractant protein-1 (MCP-1) is a 13 kDa chemokine that regulates migration and infiltration of monocytes/macrophages. The idiopathic inflammatory including dermatomyositis myopathies, (DM), polymyosititis and inclusion body myositis, are a group of autoimmune diseases characterized by chronic lymphocytic and macrophagic infiltration in muscle. MCP-1 is believed to play a major role in the recruitment of these cells, especially in DM. Plasma levels of MCP-1 have also been shown to be increased in patients with high viral load compared with HIV-seropositive subjects with undetectable plasma viral RNA and healthy controls.

Calibration Curve: Cubic fit parameters are depicted.



Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (33 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



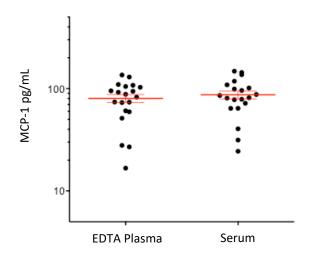
| LLOQ | 0.153 pg/mL | |
|----------------------------------|---------------------------------------|--|
| LOD | 0.212 pg/mL SD 0.1311 pg/mL | |
| Dynamic range (serum and plasma) | 0-800 pg/mL | |
| Diluted Sample volume* | 100 μL per measurement | |
| Tests per kit | 96 | |

^{*}See Kit Instruction for details



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Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=20) and serum (n=20) were measured. Error bars depict mean and SEM.



| Sample Type | Median MCP-1 pg/mL |
|-------------|-----------------------|
| EDTA Plasma | 85.3 |
| Serum | 83.6 |

Precision: Five samples consisting of two serum-based panels, one plasma-based panel, and two MCP-1 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 CV |
|-----------|-----------------|------------------|-------------------|-------------------|
| Control 1 | 57.7 | 3.3% | 2.6% | 0.0% |
| Control 2 | 335 | 3.5% | 6.1% | 0.0% |
| Panel 1 | 83.5 | 2.9% | 2.9% | 4.9% |
| Panel 2 | 74.9 | 4.2% | 4.0% | 2.1% |
| Panel 3 | 122 | 3.9% | 4.6% | 0.0% |

Spike and Recovery: MCP-1 spiked into 4 serum samples at 5 and 50 pg/mL.

Dilution Linearity: Plasma sample diluted 2x serially from MRD (4x) to 256x with Sample Diluent.

| Spike and Recovery | Mean = 87.8% |
|---------------------------|------------------|
| (Serum) | Range: 63.2–100% |
| Dilution Linearity | Mean = 112% |
| (256x) | Range: 97.5–125% |