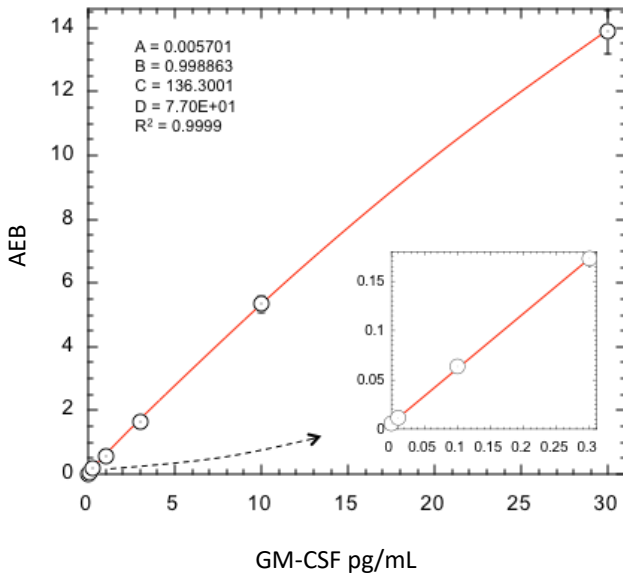


Description

The granulocyte macrophage colony-stimulating factor (GM-CSF) is a homodimeric cytokine composed of 144 amino acid with molecular weight of 22kDa. GM-CSF functions as a white blood cell growth factor which stimulates stem cells to produce granulocytes and monocytes. It is used clinically to treat neutropenia in cancer patients undergoing chemotherapy, in AIDS patients during therapy, and in patients after bone marrow transplantation. GM-CSF is found in high levels in joints with rheumatoid arthritis and blocking GM-CSF may reduce the inflammation or damage.

Calibration Curve: Four-parameter curve fit parameters are depicted.



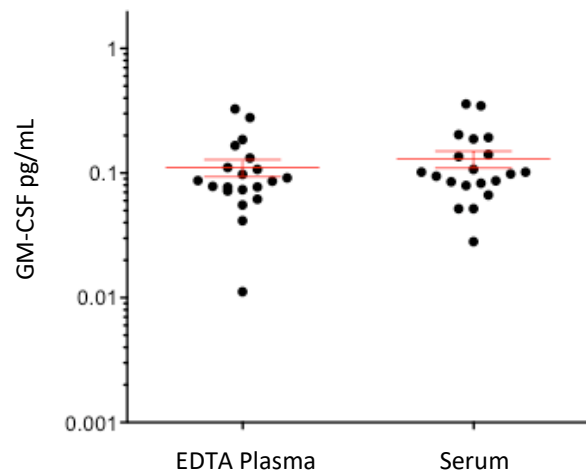
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (10 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 2 reagent lots across 3 instruments (12 runs total).

LLOQ	0.0103 pg/mL pooled CV 12.9% mean recovery 112.5%
LOD	0.0019 pg/mL SD 0.0010 pg/mL
Dynamic range (serum and plasma)	0–120 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

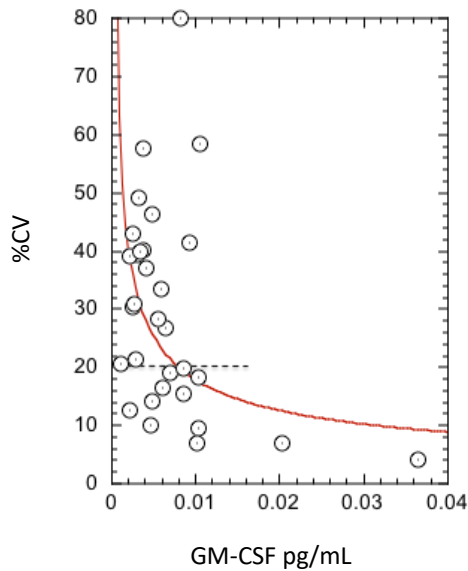
*See Kit Instruction for details

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 GM-CSF pg/mL	% Above LOD
Serum	0.1003	100%
Plasma	0.0865	100%

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (32 measurements).



Precision: Five samples consisting of one plasma-based panel, two serum-based panels, and two GM-CSF controls were assayed in replicates of three at two separate times per day for five days using a single lot of reagents and calibrators. 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	0.198	6.1%	9.6%	9.1%
Control 2	26.2	5.0%	8.8%	0.7%
Panel 1*	0.099	14.2%	0.0%	8.1%
Panel 2	0.261	10.7%	2.7%	0.0%
Panel 3	12.6	7.4%	1.9%	1.6%

*Plasma

Inter Lot CV: Pool of CVs from 6 samples tested with 2 reagent lots across 2 runs x 3 instruments.

Inter Instrument CV: Pool of CVs from 6 samples tested with 3 instruments across 2 runs x 2 reagent lots.

Inter Lot CV	2.6%
Inter Instrument CV	5.1%

Spike and Recovery: GM-CSF spiked into 4 serum samples at 2 levels.

Admixture Linearity: High GM-CSF serum sample admixed with low GM-CSF sample, mean of 10 levels.

Dilution Linearity: Spiked serum diluted 2x serially from MRD (4x) to 128x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	Mean = 87.1% Range: 62–100%
Admixture Linearity	Mean = 102.8%
Dilution Linearity (128x)	Mean = 110.3% Range: 105.0–113.7%