**Quanterix™**
The Science of Precision Health

Description

Granulocyte Colony Stimulating Factor (G-CSF) is a 19.6 kDa glycoprotein which stimulates the growth of neutrophil granulocyte precursors at the myeloid progenitor cell level. Functionally, G-CSF is a cytokine and hormone produced by a number of different sources in the body which include monocytes, mesothelial cells, fibroblasts, and endothelial cells. An important clinical application of measuring G-CSF is in the treatment of transient phases of leukopenia following chemotherapy and/or radiotherapy. G-CSF can also act on neuronal cells as a neurotrophic factor. This property is currently under investigation for the development of treatment of neurological diseases such as cerebral ischemia.

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

A = 0.01124
B = 0.99445
C = 15,917,071
D = -7.894+005
R^2 = 0.9995

G-CSF pg/mL
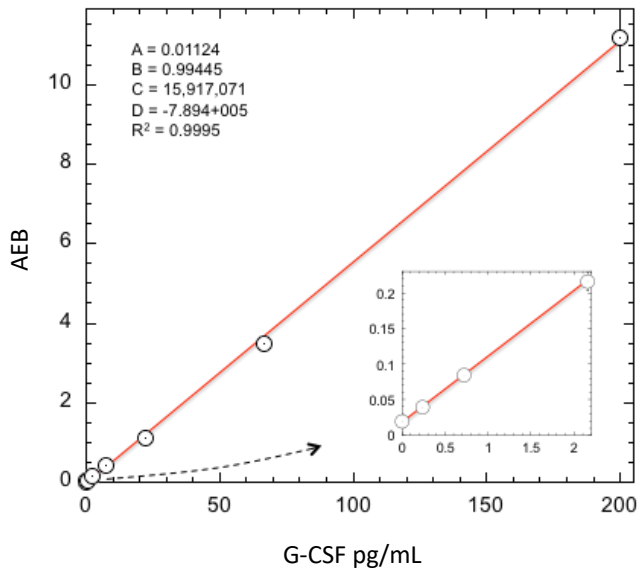
Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 10 runs.
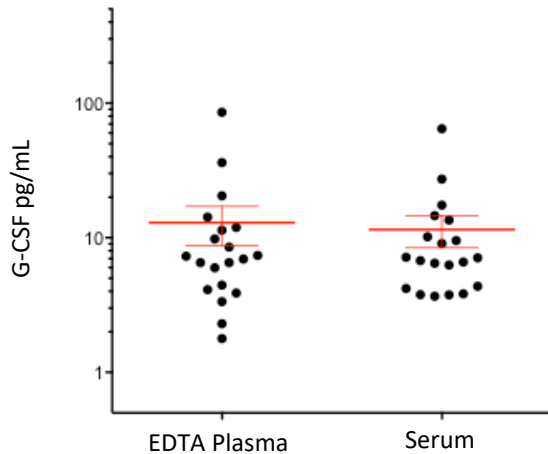
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (62 measurements). LLOQ determined as the concentration below which the %CV exceeds 20% according to the power equation fit to the data.

G-CSF pg/mL
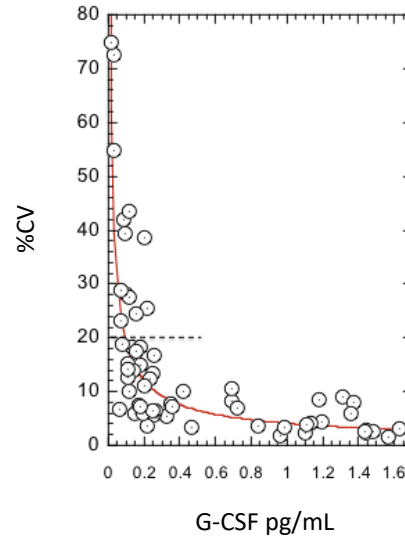
LLOQ	0.095 pg/mL
LOD	0.095 pg/mL SD 0.0572 pg/mL
Dynamic range (serum and plasma)	0–800 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

*See Kit Instruction for details

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 G-CSF pg/mL	% Above LOD
Serum	6.94	100%
Plasma	7.12	100%

Precision: Five samples consisting of two serum-based panels, one plasma-based panel and two G-CSF 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	2.77	6.3%	4.2%	0.0%
Control 2	41.5	5.2%	2.5%	1.8%
Panel 1*	5.90	5.8%	0.0%	5.7%
Panel 2	8.57	4.6%	1.4%	1.9%
Panel 3	131	5.6%	4.1%	9.4%

*Plasma

Spike and Recovery: G-CSF spiked into 4 serum samples at 2 and 20 pg/mL.

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

Spike and Recovery (Serum/Plasma)	Mean = 67.4% Range: 46.9–84.8%
Admixture Linearity	Mean = 98.1% Range: 87.8–106.3%