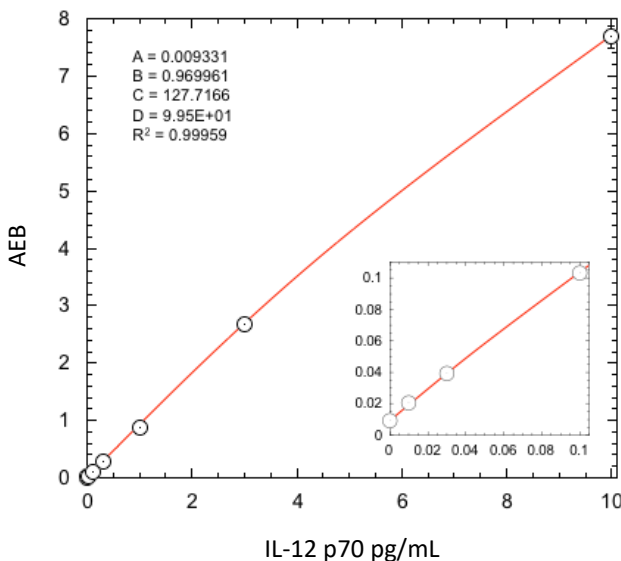


Description

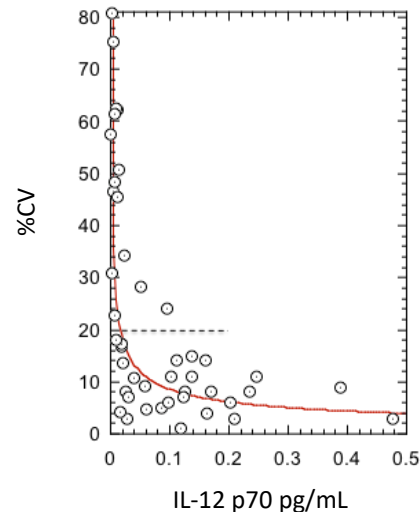
Interleukin-12, p70 (IL-12 p70) is a disulfide-linked heterodimeric 70-kDa cytokine composed of a 197 amino acid 35-kDa (p35) subunit and a 306 amino acid 40-kDa (p40) subunit. It is naturally produced by dendritic cells, macrophages and human B-lymphoblastoid cells in response to antigenic stimulation. IL-12 stimulates growth and function of T cells, production of interferon-gamma (IFN-γ) and tumor necrosis factor-alpha (TNF-α) from T cells and natural killer (NK) cells, and reduces IL-4-mediated suppression of IFN-γ. IL-12 has been reported to be associated with autoimmune and inflammatory conditions. Increased IL-12 plasma levels may also be detected in patients with neurological disorders such as multiple sclerosis.

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



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.

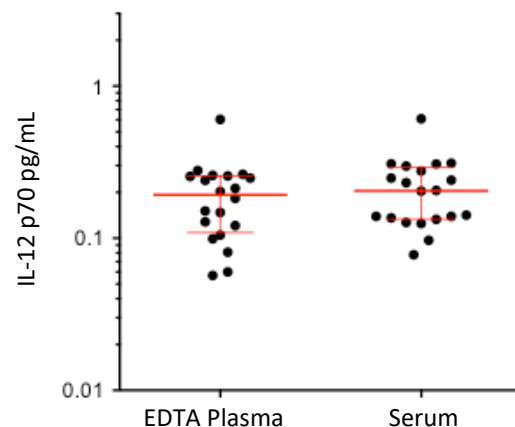
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (45 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



LLOQ	0.0170 pg/mL
LOD	0.0048 pg/mL SD 0.00332 pg/mL
Dynamic range (serum and plasma)	0–40 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 median with interquartile range.



Sample Type	Median IL-12 p70 pg/mL	% Above LOD
Serum	0.205	100%
Plasma	0.193	100%

Precision: Five samples consisting of one plasma panel, two serum panels, and two IL-12 p70 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	0.0947	7.4%	0.0%	8.4%
Control 2	8.19	5.3%	12.5%	0.0%
Panel 1*	0.126	7.1%	9.5%	0.0%
Panel 2	0.299	10.0%	5.0%	0.0%
Panel 3	22.2	5.9%	13.3%	0.0%

*Plasma

Spike and Recovery: IL-12 p70 spiked into 4 serum samples at 5 and 20 pg/mL.

Admixture Linearity: Spiked serum sample admixed with low IL-12 p70 sample, mean of 10 levels.

Dilution Linearity (Serum): Spiked serum was diluted 2x serially from MRD (4x) to 1,024x with Sample Diluent.

Dilution Linearity (Plasma): Spiked EDTA plasma was diluted 2x serially from MRD (4x) to 1,024x with Sample Diluent.

Spike and Recovery (Serum)	Mean = 77.1% Range: 70.2–81.8%
Admixture Linearity	Mean = 95.1% Range: 80.4–105%
Dilution Linearity (Serum – 1,024x)	Mean = 114.7% Range: 108.4–122.7%
Dilution Linearity (Plasma – 1,024x)	Mean = 86.5% Range: 56.1–114%