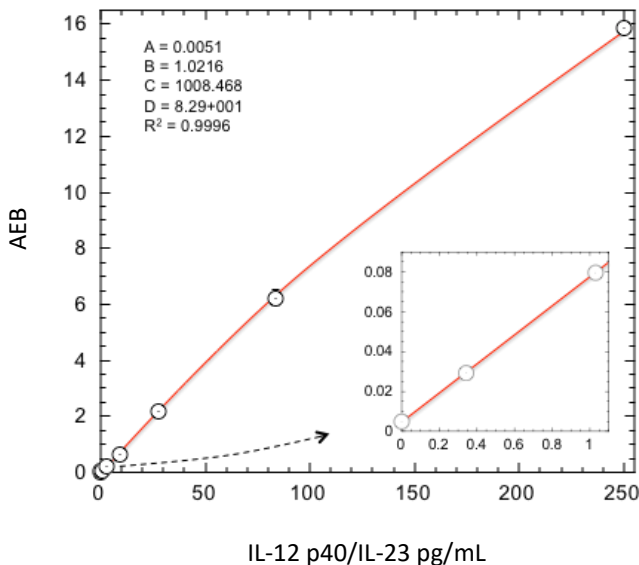


Description

Interleukin-12 (IL-12) is a heterodimeric 70 kDa glycoprotein (IL-12 p70) consisting of a 40 kDa subunit and a 35 kDa subunit linked by disulfide bonds that are essential for the biological activity of IL-12. p40 has been shown to be a subunit of another composite cytokine, designated IL-23. IL-12 is produced by activated hematopoietic phagocytic cells (monocytes, macrophages and neutrophils) and by dendritic cells. IL-12 acts like a growth factor for activated T and NK cells and enhances the lytic activity of NK/lymphokine-activated killer cells. IL-12, in conjunction with the other IL-12 family members IL-23 and IL-27, promotes the development of a CD4+ Th1 immune response. IL-12 has been shown to inhibit the growth of a variety of experimental tumors and to have anti-angiogenic effects *in vivo*.

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



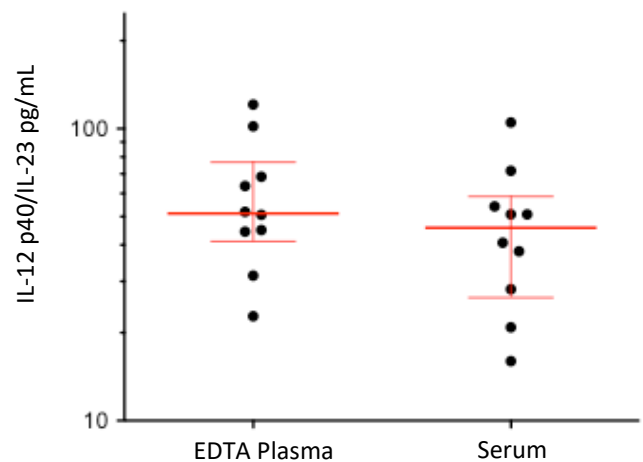
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 2 instruments (5 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 2 instruments (5 runs total).

LLOQ	0.086 pg/mL pooled CV 5.0% mean recovery 100%
LOD	0.020 pg/mL range 0.006–0.036 pg/mL
Dynamic range (serum and plasma)	0–1000 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) were measured. Error bars depict median with interquartile ranges.



Sample Type	Median IL-12 p40/IL-23 pg/mL	% Above LOD
Serum	45.8	100%
Plasma	51.3	100%

Precision: Representative precision was estimated with repeated assay of serum panels using one instrument and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

Sample	Mean (pg/mL)	Within run CV	Between run CV
Panel 1	31.3	4.3%	8.7%
Panel 2	50.6	3.5%	6.8%
Panel 3	108	4.9%	7.4%

Spike and Recovery: IL-12 p40/IL-23 spiked into 2 serum and 2 plasma samples at 2 levels.

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

Spike and Recovery (Serum/Plasma)	Mean = 83.8% Range: 74.4–96.4%
Dilution Linearity (128x)	Mean = 107% Range: 98.3–119%