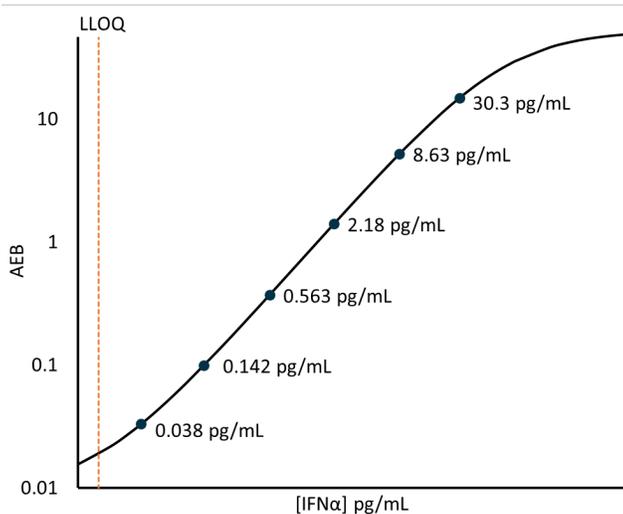


Description

Interferon-alpha (IFN-α) is a cytokine of 188 amino acids (molecular weight 21.5 kDa) mainly involved in an innate immune response against viral infection. IFN-α, produced by leukocytes, is a type I interferon which binds to a specific cell surface receptor complex known as the IFN-α receptor (IFNAR) that consists of IFNAR1 and IFNAR2. IFN-α is mainly employed as a standard therapy for a number of tumors and viral infections. Both hepatitis B and hepatitis C are treated with IFN-α, often in combination with other antiviral drugs.

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



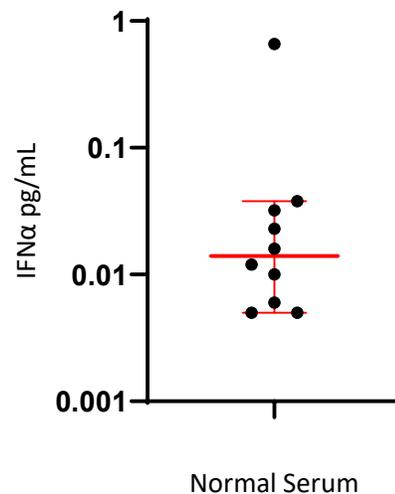
Lower Limit of Quantification (LLOQ): Calculated with the four-parameter logistic curve tool over 9 runs. Functional LLOQ is the Analytical LLOQ multiplied by Minimal Required Dilution.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 9 runs.

LLOQ	0.016 pg/mL
LOD	0.003 pg/mL SD 0.0015 pg/mL
Dynamic range (serum)	0–60 pg/mL
Diluted Sample volume*	170 μL per measurement
Tests per kit	96

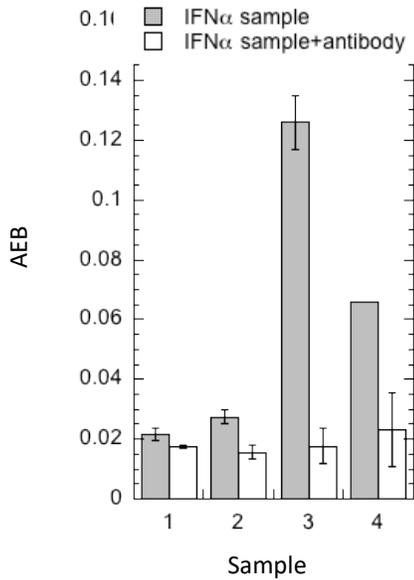
*See Kit Instruction for details

Endogenous Sample Reading: IFN-α in 10 serum samples. Error bars depict median and SEM.



Sample Type	Median IFN-α pg/mL
Serum	0.014

Specificity Verification: Assay signal from 4 serum samples before and after addition of 2 µg/mL anti-IFN-α antibody. Error bars: standard deviation of 3 reps.



Precision: Four samples consisting of two serum-based panels and two IFN-α 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	3.39	4.2%	1.1%	4.9%
Control 2	0.106	8.5%	4.7%	0.0%
Panel 1	1.94	9.8%	7.3%	7.9%
Panel 2	10.6	8.1%	7.3%	0.0%

Spike and Recovery: IFN-α spiked into 2 serum samples at 1 and 20 pg/mL.

Admixture Linearity: Spiked IFN-α serum sample admixed with low IFN-α sample, mean of 10 levels.

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

Spike and Recovery (Serum)	Mean = 238% Range: 228–253%
Admixture Linearity	Mean = 112% Range: 104–117%
Dilution Linearity (128x)	Mean = 89.8% Range: 72.8–93.9%