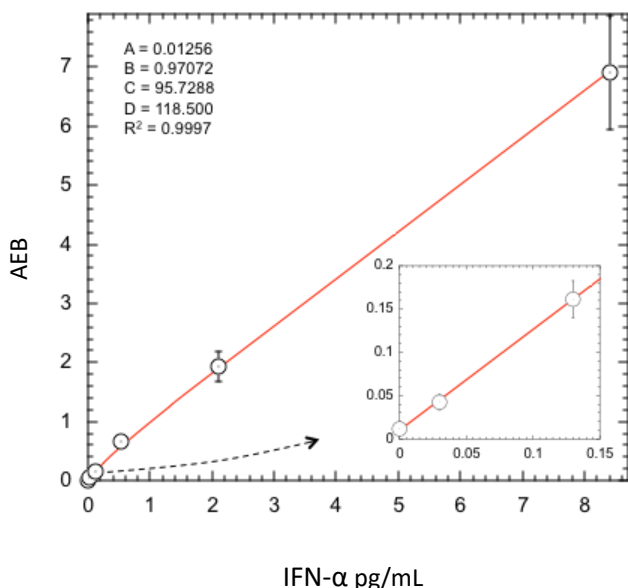


Description

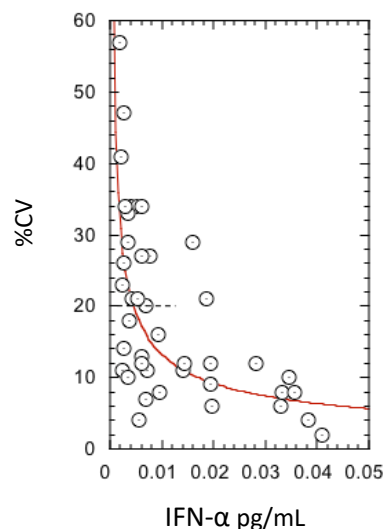
Interferon-alpha (IFN-α) is a cytokine of 188 amino acids (molecular weight 21.5 kDa) mainly involved in an innate immune response against viral infection. IFN-α, produced by leukocytes, is a type I interferon which binds to a specific cell surface receptor complex known as the IFN-α receptor (IFNAR) 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.



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.

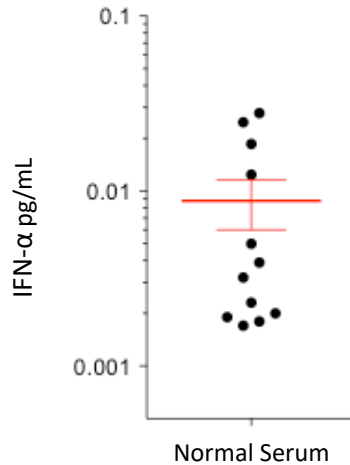
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (41 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



LLOQ	0.0047 pg/mL
LOD	0.0025 pg/mL SD 0.0021 pg/mL
Dynamic range (serum and plasma)	0–60 pg/mL
Diluted Sample volume*	170 μL per measurement
Tests per kit	96

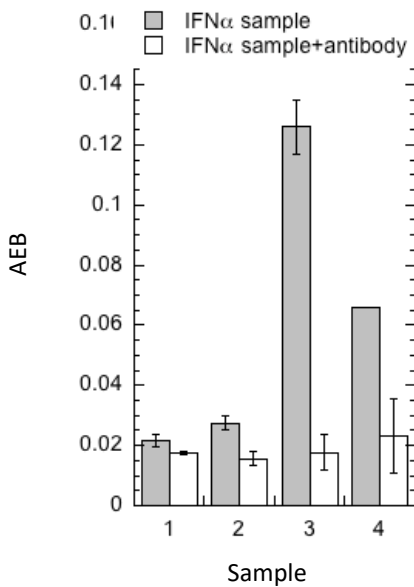
*See Kit Instruction for details

Endogenous Sample Reading: IFN-α in 12 serum samples. IFN-α was undetectable in 9/20 samples. Error bars depict mean and SEM.



Sample Type	Median IFN-α pg/mL
Serum	0.0036

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	0.104	13.5%	1.9%	0.0%
Panel 1	1.94	9.8%	7.3%	7.0%
Panel 2	10.43	14.0%	8.2%	0.0%

Spike and Recovery: IFN-α spiked into 4 serum samples at 1 and 10 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 512x with Sample Diluent.

Spike and Recovery (Serum)	Mean = 118.1% Range: 95.1–134.3%
Admixture Linearity	Mean = 110.8% Range: 104.2–117.2%
Dilution Linearity (512x)	Mean = 92.1% Range: 75.9–99.5%