Quanterix™
The Science of Precision Health

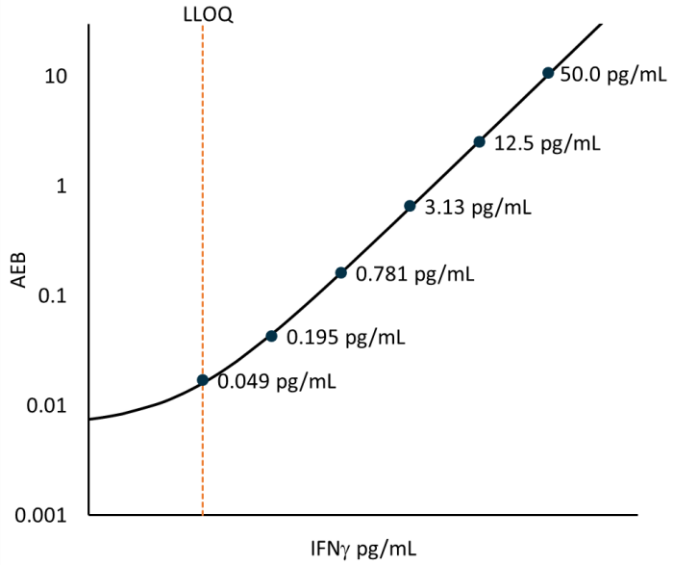
Simoa® IFN-γ Advantage Kit
SR-X® Data Sheet

Item 103337

Description

Human interferon-gamma (IFN-γ) is a dimeric cytokine with subunits of 146 amino acids. Mature human IFN-γ exists as a non-covalently linked homodimer of 20-25 kDa variably glycosylated subunits. IFN-γ does not display significant homology with the other two interferons, IFN-α and IFN-β. Murine and human IFN-γ show approximately 40% sequence homology at the protein level. IFN-γ is expressed by Th1 cells, Tc cells, dendritic cells and natural killer cells, especially under inflammatory conditions. IFN-γ binds to its heterodimeric receptor IFN-γR and related complex for biological function. It plays a key role in host defense by promoting the development and activation of Th1 cells, chemoattraction and activation of monocytes and macrophages, upregulation of antigen presentation molecules, and immunoglobulin class switching in B cells. In addition, IFN-γ functions as an anti-inflammatory mediator by promoting the development of regulatory T cells and inhibiting Th17 cell differentiation. It also exhibits antiviral, antiproliferative, and apoptotic effects. IFN-γ is an attractive drug target for immuno-regulatory diseases.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



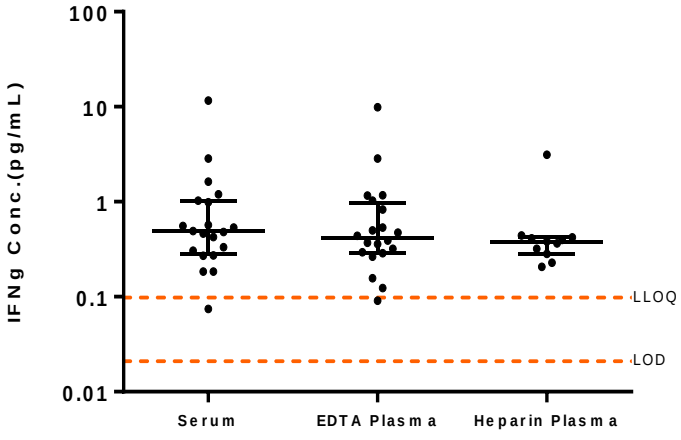
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	**0.0488 pg/mL** pooled CV 16% mean recovery 103%
LOD	**0.0205 pg/mL** range 0.0020-0.0424 pg/mL
Dynamic range	0–100 pg/mL
Diluted Sample volume (1:2 Dilution) *	100 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=20), serum (n=20), and unmatched Heparin plasma (n=10) samples were measured. Bars depict median with interquartile range. Orange lines represent functional LLOQ and LOD.



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Sample Type	Mean IFN-γ pg/mL	Median IFN-γ pg/mL	% Above LLOQ
Serum	1.22	0.487	95%
EDTA plasma	1.08	0.415	95%
Heparin plasma	0.615	0.372	100%

Precision: Measurements of 2 spiked serum panels, 1 spiked plasma panel, and 2 calibrator-based controls. Triplicate measurements were made for 3 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between Inst CV	Between Lot CV
Control 1	11.4	4.0%	6.6%	1.1%	6.5%
Control 2	40.5	3.8%	4.8%	1.7%	14%
Panel 1	4.70	2.7%	9.3%	5.2%	1.2%
Panel 2	7.48	5.5%	7.5%	1.1%	5.6%
Panel 3	60.6	7.8%	13.6%	1.6%	6.9%

Spike and Recovery: 2 serum and 2 plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on HD-1.

Dilution Linearity: One endogenous serum and EDTA plasma sample or one spiked serum and EDTA plasma sample were diluted 2x serially with sample diluent from MRD (2x) to 16x for endogenous samples and from MRD (2x) to 256x for spiked samples.

Spike and Recovery	**Mean = 66.7%** Range 58-81%
Serum/Plasma Endogenous Linearity (16x)	**Mean = 128%** Range: 111-141%
Serum/Plasma Spiked Linearity (256x)	**Mean = 118%** Range: 99-140%

The Simoa IFN-γ assay kit is formulated for use on either the SR-X, HD-1 or HD-X platform. Data in this document was obtained from runs on the SR-X platform unless otherwise noted. Some differences in performance claims between the HD-1/HD-X and SR-X may be observed when comparing datasheets for the two platforms. This may be due to experiments run at different time-points with different reagent lots and different samples or may be due to minor differences in antibody and analyte behavior in the different assay formats.

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