Quanterix™
The Science of Precision Health

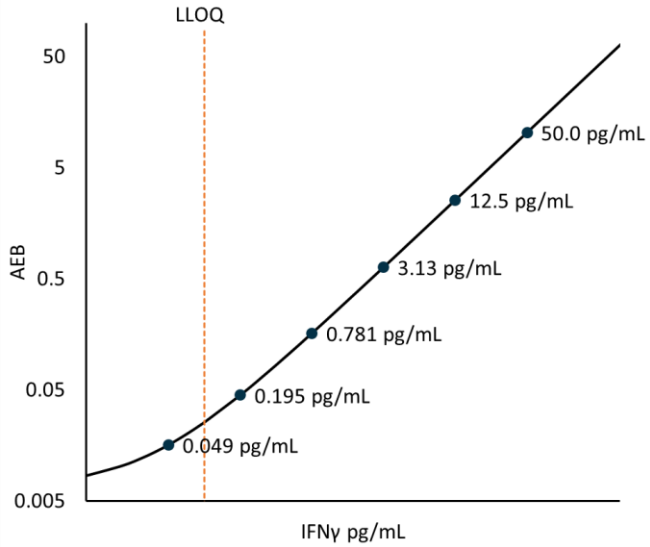
Simoa® IFN-γ Advantage Kit
HD-1/HD-X Data Sheet

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.



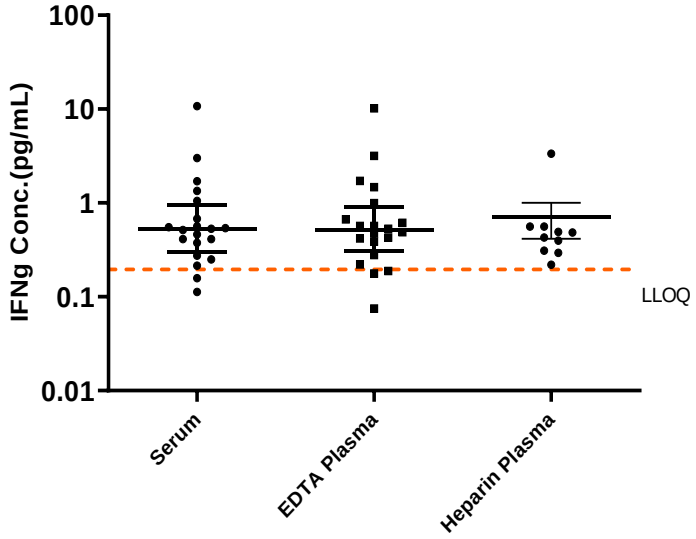
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

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	**0.098 pg/mL** pooled CV 18% mean recovery 95%
LOD	**0.0155 pg/mL** range 0.0080-0.0265 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) and serum (n=20), and unmatched Heparin plasma (n=10) samples were measured. Bars depict median with interquartile range. Orange lines represent functional LLOQ and average assay LOD.



Sample Type	Mean IFN-γ pg/mL	Median IFN-γ pg/mL	% Above LLOQ
EDTA plasma	1.18	0.510	85%
Serum	1.20	0.522	90%
Heparin Plasma	0.709	0.458	100%

Precision: Measurements of 3 spiked serum panels 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)	Intra-run CV	Inter-run CV	Inter-Instrument CV	Inter-Lot CV
Control 1	7.44	2.7%	6.3%	0.4%	19%
Control 2	75.2	7.6%	7.2%	0.4%	14%
Panel 1	1.58	8.0%	5.6%	0.7%	18%
Panel 2	3.40	3.4%	4.0%	0.8%	12%
Panel 3	31.6	5.1%	3.1%	1.4%	9%

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

Dilution Linearity: 3 endogenous serum and 3 endogenous EDTA plasma samples were diluted 2x serially from MRD (2x) to 256x with sample diluent.

Spike and Recovery	**Mean = 59%** Range: 49-65%
Dilution Linearity (256x)	**Mean = 122%** Range: 92.0-142%

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