Simoa® IL-17F Advantage PLUS Kit
HD-X Data Sheet

Item 105588

Description: This data sheet summarizes data from the analytical validation performed at Quanterix to characterize performance of the IL-17F Advantage PLUS kit on the Simoa HD-X Analyzer®.

Matrix Types: Assay performance and a minimum required dilution (MRD) were evaluated in multiple matrices (Table 1). See the Kit Instructions for sample and dead volume requirements.

Table 1. Minimum required dilutions

Matrix Types	EDTA Plasma, Serum
Diluted Sample Volume	100 uL per measurement
Human Serum MRD	4x
Human EDTA Plasma MRD	4x

Calibration Curve: The reconstitution volume, assigned concentrations, Limit of Detection (LOD), analytical Upper Limit of Quantification (ULOQ), analytical Lower Limit of Quantification (LLOQ) described here are representative and may vary from kit lot to kit lot (Figure 1). Refer to the Certificate of Analysis (CoA) for lot-specific calibrator concentrations and reconstitution volumes.

Limit of Quantification (LOQ): The analytical LLOQ was determined as the lowest concentration of the analyte in Sample Diluent with a recovery between 80 – 120% and a CV < ±20%. The analytical ULOQ (ULOQ) is the concentration of the highest calibrator. The analytical LLOQ and the analytical ULOQ multiplied by the MRD yields the functional LLOQ (fLLOQ) and the functional ULOQ (fLLOQ). The LLOQ was experimentally verified for each kit lot. Minor variations in ULOQ between kit lots may be observed where lot matching was performed (Table 2).

Limit of Detection (LOD): The LOD was calculated as 2.5 standard deviations above the mean of the background (Cal A) (Table 2).

Table 2. LLOQ and LOD

	Analytical	Functional
LLOQ	0.0293 pg/mL	Serum: 0.1172 pg/mL EDTA Plasma: 0.1172 pg/mL
ULOQ	60.0 pg/mL	Serum: 240 pg/mL EDTA Plasma: 240 pg/mL
LOD	0.0044 pg/mL	N/A

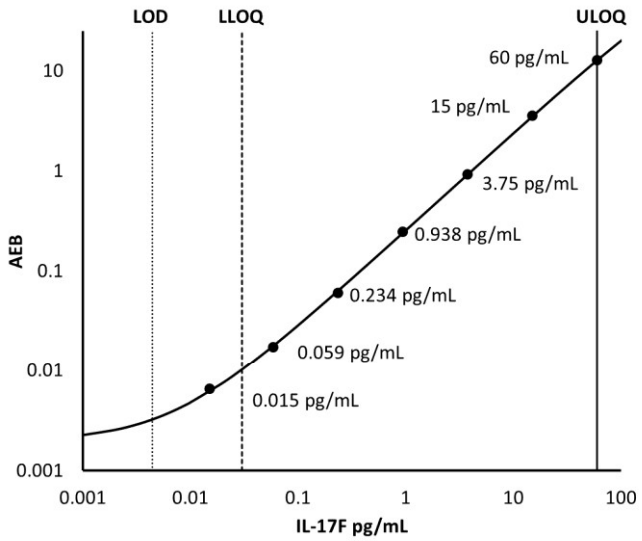

Figure 1. Example calibrator curve

Quanterix Corporation
900 Middlesex Turnpike, Billerica, MA 01821
techsupport@quanterix.com

©2026 Quanterix Corporation | Simoa® and Quanterix® are registered trademarks of Quanterix Corporation. For research use only. Not for use in diagnostic procedures.

Reference Ranges: Range was established using normal matched serum (n=20) and EDTA plasma (n=20). The mean and median analyte concentrations and the percent of samples above fLLOQ and LOD are reported below (Figure 2 and Table 3).

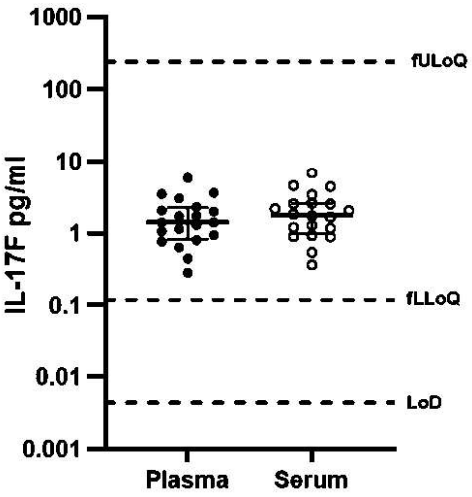

Figure 2. Normal sample readings. Bars depict the median with the interquartile range.

Table 3. Normal sample readings

Sample Type	Mean pg/mL	Median pg/mL	% Above LOD	% Above fLLoQ
Serum	2.1853	1.7715	100%	100%
EDTA Plasma	1.7974	1.4103	100%	100%

Precision: Precision was calculated using commercial pooled plasma, commercial pooled serum, and assay kit controls diluted to the appropriate MRD (Table 4). Triplicate measurements were made across 12 runs. Two reagent lots were each tested 6 times across 2 instruments, providing a mean of 36 individual measurements. Four distinct precision values were calculated from the 36 measurements:

1. **Within Run %CV** describes the variability of the %CV within a run, inclusive of 2 reagent lots and 2 instruments.
2. **Run to Run Conc %CV** describes the variability of the concentration value across all 12 runs, inclusive of 2 reagent lots and 2 instruments.
3. **Instrument %CV** describes instrument-to-instrument variability.
4. **Lot %CV** describes lot-to-lot variability.

Table 4. Precision

Sample	Mean (pg/mL)	Within Run %CV	Run to Run Conc %CV	Instrument %CV	Lot %CV
Control 1	1.9200	6.2%	7.9%	2.0%	3.6%
Control 2	47.9580	5.7%	5.2%	0.1%	0.1%
Plasma 1	0.7230	6.3%	7.6%	2.0%	0.1%
Plasma 2	3.7632	4.7%	7.1%	1.1%	1.0%
Plasma 3	51.1523	5.5%	7.6%	6.0%	0.6%
Serum 1	0.7734	6.5%	8.9%	2.2%	1.2%
Serum 2	5.1934	5.6%	8.4%	4.9%	0.1%
Serum 3	29.1392	5.8%	10.0%	6.6%	1.9%

Quanterix Corporation
900 Middlesex Turnpike, Billerica, MA 01821
techsupport@quanterix.com

©2026 Quanterix Corporation | Simoa® and Quanterix® are registered trademarks of Quanterix Corporation. For research use only. Not for use in diagnostic procedures.

Spike Recovery: Percent recovery was calculated as the difference between the spiked (with antigen) sample and the un-spiked sample, relative to the spiked (with antigen) Sample Diluent (Table 5).

Linearity: Normal Human Serum and EDTA Plasma samples (spiked with antigen as necessary) were diluted 2x serially with Sample Diluent. Linearity refers to the assay's ability to produce proportional and accurate results across a defined dilution range. Linearity was assessed by performing serial dilutions of samples diluted with Sample Diluent (Table 5).

Table 5. Spike Recovery and Linearity

Spike Recovery (Serum)	**Mean 68.3%** Range 60.8 – 73.3%
Spike Recovery (EDTA Plasma)	**Mean 76.0%** Range 66.7 – 88.8%
Linearity Mean * (Serum, Range 4x – 16x)	**Mean 114.8%** Range 106.7 – 128.9%
Linearity Mean * (EDTA Plasma, Range 4x – 16x)	**Mean 113.0%** Range 103.6 – 122.5 %

* Linearity is within 80-120% between 4X-16X for EDTA plasma and serum.

- **Cross-Reactivity:**
  The Simoa® IL-17F Advantage PLUS assay was evaluated for cross-reactivity with other IL-17 family members. No cross-reactivity was observed with IL-17A, IL-17B, IL-17C, IL-17D, or IL-17E across the concentrations tested. The assay specifically detects IL-17F homodimer and does not detect the IL-17A/F heterodimer. Measured signals for non-target IL-17 family members were at or near background levels, demonstrating assay specificity for IL-17F.

The Simoa® IL-17F Advantage PLUS assay kit is formulated for use on the Simoa HD-X Analyzer®. Validation results for the Simoa HD-X Analyzer® are summarized in this data sheet.

Quanterix Corporation
900 Middlesex Turnpike, Billerica, MA 01821
techsupport@quanterix.com

©2026 Quanterix Corporation | Simoa® and Quanterix® are registered trademarks of Quanterix Corporation. For research use only. Not for use in diagnostic procedures.