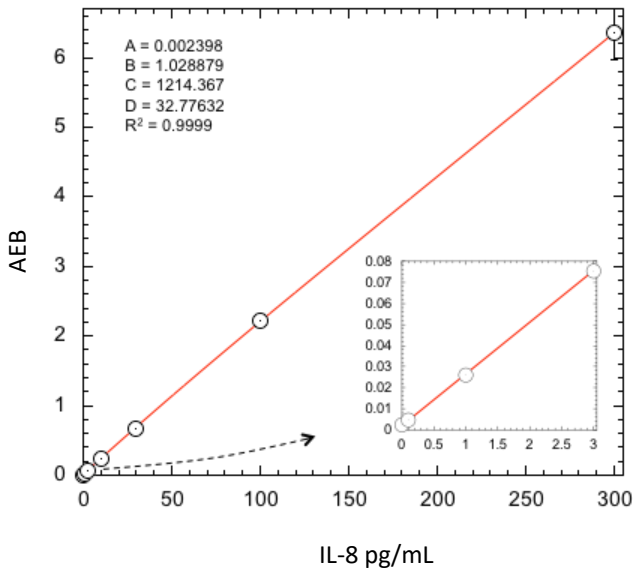


Description

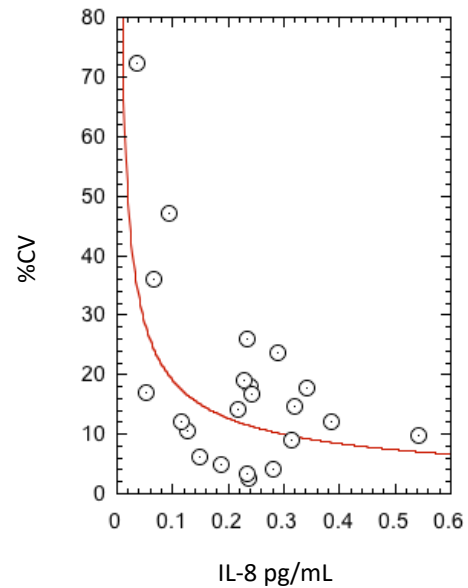
Interleukin 8 (IL-8) is a cytokine of 72 amino acids (molecular weight 8 kDa) whose primary role is induction of chemotaxis in neutrophils, basophils, and T-cells, causing them to migrate to the site of infection. IL-8 also induces phagocytosis by the target cells. IL-8 is secreted by cells involved in the immune response to antigens, typically starting with macrophages, which release IL-8 to recruit other cells. Secretion of IL-8 is increased by oxidant stress, which thereby cause the recruitment of inflammatory cells, inducing a further increase in oxidant stress mediators, making it a key parameter in localized inflammation. IL-8 elevation has been associated with a range of clinical conditions, including psoriasis, chronic hepatitis C, and thyroid disease. IL-8 has recently been identified as a potential therapeutic target in inflammatory diseases.

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.

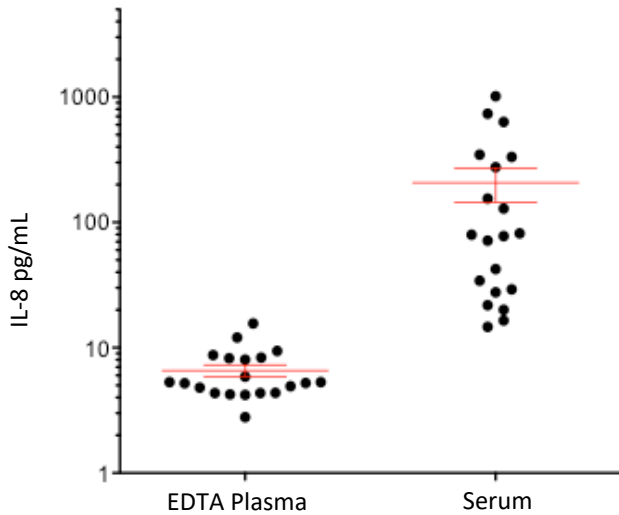
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (22 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



| | |
|-------------------------------|--|
| LLOQ | 0.0921 pg/mL |
| LOD | 0.0560 pg/mL SD 0.0474 pg/mL |
| Diluted Sample volume* | 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) were measured. Error bars depict mean and SEM.



| Sample Type | Median IL-8 pg/mL | % Above LOD |
|-------------|-------------------|-------------|
| EDTA Plasma | 5.31 | 100% |
| Serum | 78.7 | 100% |

Precision: Five samples consisting of three serum-based panels and two IL-8 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 | 14.5 | 3.8% | 5.3% | 0.0% |
| Control 2 | 232 | 4.7% | 5.2% | 4.1% |
| Panel 1 | 29.3 | 7.1% | 3.6% | 1.3% |
| Panel 2 | 87.2 | 7.0% | 4.0% | 0.0% |
| Panel 3 | 328 | 7.8% | 3.5% | 4.0% |

Spike and Recovery: IL-8 spiked into 4 serum samples at 2 levels.

Admixture Linearity: High IL-8 serum sample admixed with low IL-8 sample, mean of 10 levels

Dilution Linearity: 1 spiked serum sample diluted 2x serially from MRD (4x) to 128x with Sample Diluent.

| | |
|-----------------------------------|---|
| Spike and Recovery (Serum) | Mean = 108.3% Range: 97.8–136.6% |
| Admixture Linearity | Mean = 107.9% |
| Dilution Linearity (128x) | Mean = 118.0% Range: 106.4–136.4% |

The Simoa IL-8 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.