Quanterix™
The Science of Precision Health

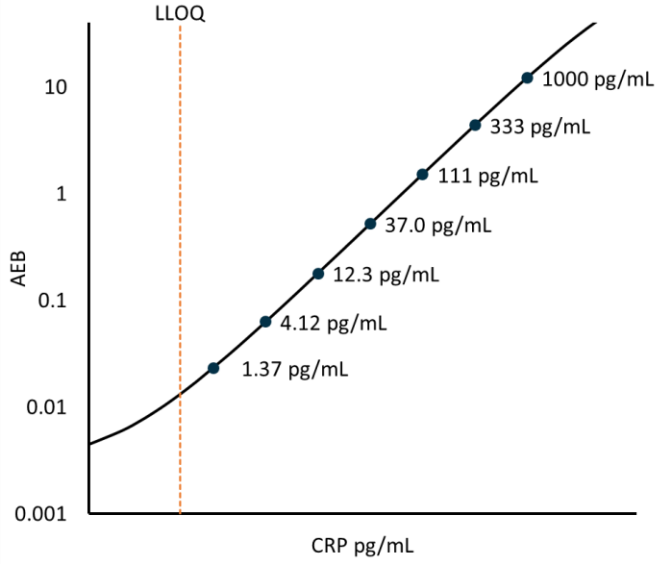
# Simoa® CRP Discovery Kit
## HD-1/HD-X Data Sheet

Item 102583

### Description

C-reactive protein (CRP) is an annular, homopentameric protein found in blood serum and plasma. It is an acute-phase protein of hepatic origin whose levels rise in response to tissue injury, infection or other inflammatory stimuli. After a single stimulus, CRP concentrations rise within 2 hours, peaking at 48 hours. With a constant half-life of 19 hours, CRP concentrations are solely determined by the rate of production and hence the severity of the precipitating cause. The physiological function of CRP is to bind to phosphocholine expressed on cells undergoing apoptosis. Upon binding to the damaged plasma membranes of dying cells, CRP activates the complement system via the C1q complex. As a sensitive inflammation marker, high CRP concentrations at baseline have been associated with early death after a cancer diagnosis. Additionally, elevated CRP levels are associated with increased risk of cancer of any type, along with many other diseases such as cardiovascular disease, diabetes, and rheumatoid arthritis.

**Calibration Curve:** Four-parameter curve fit parameters are depicted.



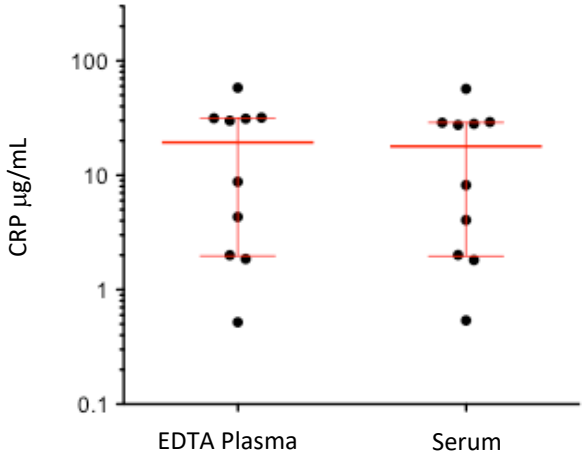

**Lower Limit of Quantification (LLOQ):** Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 2 instruments (7 runs total).

**Limit of Detection (LOD):** Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 2 instruments (7 runs total).

| | |
|---|---|
| **LLOQ** | **0.686 pg/mL**<br>pooled CV 8.9%<br>mean recovery 122% |
| **LOD** | **0.048 pg/mL**<br>range 0.020–0.083 pg/mL |
| **Dynamic range (serum and plasma)** | 0–48 µg/mL |
| **Diluted Sample volume*** | 100 µL<br>per measurement |
| **Tests per kit** | 192 |

***See Kit Instruction for details**

**Endogenous Sample Reading:** Healthy donor matched EDTA plasma (n=10) and serum (n=10) were measured. Error bars depict median with interquartile range.




| Sample Type | Median CRP µg/mL | % Above LOD |
|---|---|---|
| Serum | 17.86 | 100% |
| Plasma | 19.37 | 100% |

**Precision:** Representative precision was estimated with repeated assay of serum and plasma panels using one instrument and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

| Sample | Mean (pg/mL) | Within run CV | Between run CV |
|---|---|---|---|
| Serum Panel 1 | 5.1 | 4.3% | 6.6% |
| Plasma Panel 2 | 18.0 | 5.0% | 7.9% |
| Plasma Panel 3 | 24.7 | 4.4% | 4.4% |

**Spike and Recovery:** CRP spiked into 4 serum samples at 2 levels.

**Dilution Linearity:** Serum diluted 2x serially from MRD (48,000x) to 3,072,000x with Sample Diluent.

| | |
|---|---|
| **Spike and Recovery (Serum)** | **Mean = 104.5%** Range: 93.7–114.1% |
| **Dilution Linearity (3,072,000x)** | **Mean = 98.0%** Range: 93.9–101.9% |