Quanterix™
The Science of Precision Health

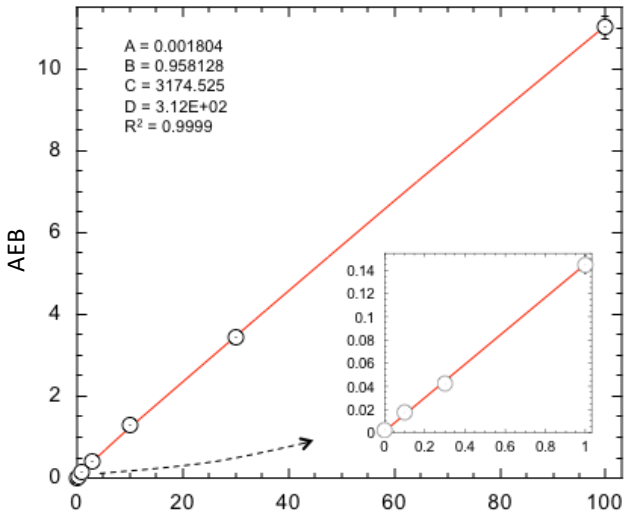
Simoa® C-Peptide Advantage Kit
HD-1/HD-X Data Sheet

Item 100199

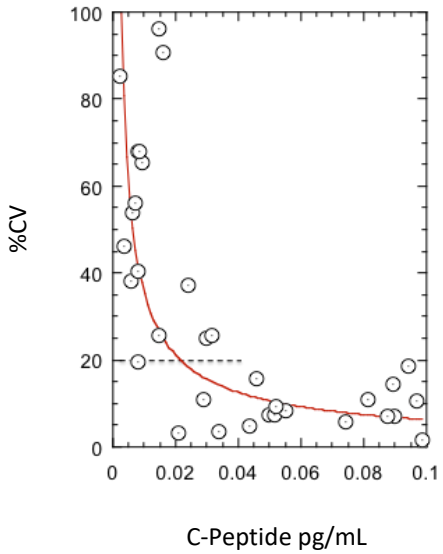
Description

The connecting Peptide, or C-Peptide, is a short 31-amino-acid protein that connects insulin's A-chain to its B-chain in the proinsulin molecule. Patients with diabetes may have their C-Peptide levels measured as a means of distinguishing Type 1 diabetes from Type 2 diabetes or Maturity Onset Diabetes of the Young (MODY). Serum C-Peptide levels correlate with endogenous insulin production and surviving β-cells and are present in equimolar amounts. Ultrasensitive assays reveal C-Peptide production persists for decades after Type 1 disease onset and remains functionally responsive in patients with advanced disease, whose β-cells function was thought to have ceased. C-Peptide levels are measured instead of insulin levels because C-Peptide can assess a person's own insulin secretion even if they receive insulin injections, and because the liver metabolizes a larger and variable amount of insulin secreted into the portal vein but does not metabolize C-Peptide, which means that blood C-Peptide may be a better measure of portal insulin secretion than insulin itself.

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



Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (33 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



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.

LLOQ	**0.021 pg/mL**
LOD	**0.013 pg/mL** SD 0.0125 pg/mL
Dynamic range (serum and plasma)	0–400 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

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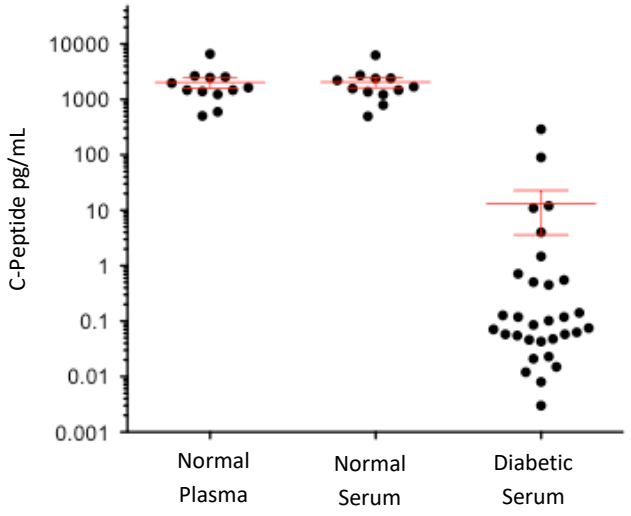
Endogenous Sample Reading: Healthy donor EDTA plasma (n=12) and serum (n=12) were measured. Serum from Type 1 diabetes patients (n=31) was measured. Of 38 Type I samples tested, 5 were unreadable and 4 were >400 pg/mL. Error bars depict mean and SEM.



Sample Type	Median C-Peptide pg/mL
Normal Serum	1,628
Normal Plasma	1,559
Diabetic Serum	0.0860

Precision: Five samples consisting of three serum-based panels, and two C-Peptide 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	1.80	8.2%	0.0%	2.9%
Control 2	57.2	5.4%	6.0%	0.0%
Panel 1[1]	51.6	9.1%	2.8%	7.1%
Panel 1[2]	49.8	3.1%	2.6%	1.1%
Panel 2[2]	1830	4.4%	2.5%	4.3%

[1]Auto-diluted 4x [2]Pre-diluted 25x, followed by auto-dilution 4x (total 100x pre-dilution)

Spike and Recovery: C-Peptide spiked into 3 serum samples at 2 levels.

Admixture Linearity: High C-Peptide serum sample admixed with low C-Peptide sample, mean of 10 levels.

Dilution Linearity: 1 endogenous serum sample was diluted 2x serially from MRD (100x) to 3200x with Sample Diluent.

Spike and Recovery (Serum)	**Mean = 103.0%** Range: 94.1–111.7%
Admixture Linearity	**Mean = 96.7%**
Dilution Linearity (3200x)	**Mean = 91.0%** Range: 86.1–93.6%

The Simoa C-Peptide 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.