Quanterix™
The Science of Precision Health

Simoa™ C-Peptide Advantage Kit
SR-X™ Data Sheet

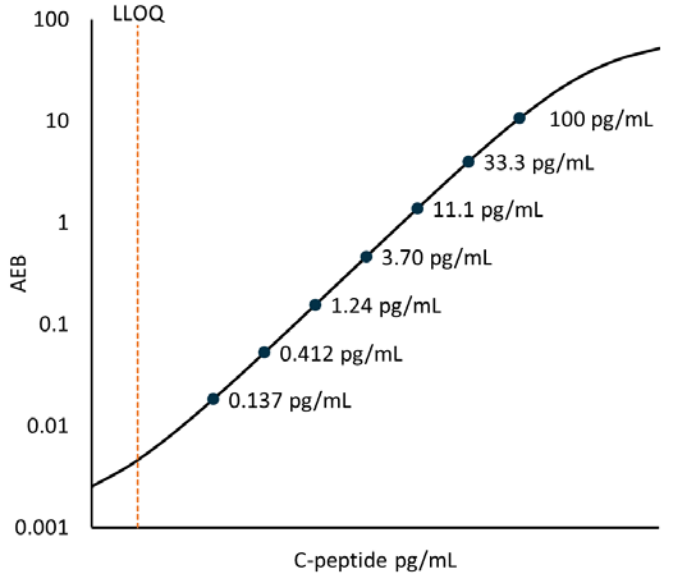
Item 100199

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: Calibrator concentrations and Lower Limit of Quantification depicted.



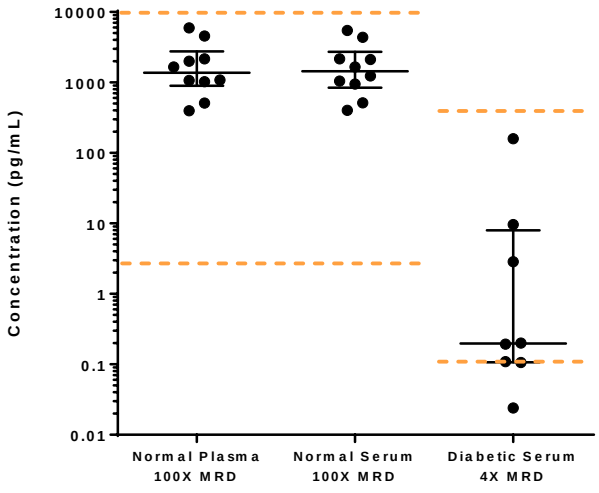
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	**0.027 pg/mL** pooled CV 15.4% mean recovery 106.9%
LOD	**0.008 pg/mL** range 0.002-0.014 pg/mL
Dynamic range (normal serum and plasma)	0-400 pg/mL
Dynamic range (Diabetic serum)	0-10,000 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=10), serum (n=10) and Type I Diabetic serum samples (n=12) were measured. Orange lines represent functional LLOQ and ULOQ. Four of the 12 Type 1 Diabetic samples tested were above the ULOQ (data not shown). Error bars depict median with interquartile range.



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Assay designed by Muriel

Sample Type	Mean C-Peptide pg/mL	Median C-Peptide pg/mL	% Above LOD
Serum	1992.7	1447.3	100%
Plasma	2040.6	1369.1	100%
Type I Diabetic Serum	25	1.53	92%

Precision: Measurements of 3 serum-based panels and 2 calibrator-based controls. Triplicate measurements were made for 6 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control 1	1.8	5.7%	2.3%	1.2%
Control 2	51.3	5.2%	2.9%	2.7%
Panel 1	0.8	9.6%	3.4%	1.8%
Panel 2	1870	4.8%	5.4%	5.3%
Panel 3	2658	4.1%	1.5%	1.5%

Controls and Panel 1- diluted 4X, Panel 2 and 3 diluted 100X

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 SR-X.

Dilution Linearity: 1 endogenous EDTA plasma and 1 endogenous serum sample were diluted 2X serially from MRD (100X) to 128X MRD with Sample Diluent. One Diabetic Serum sample was diluted 2X serially from MRD (4X) to 128X MRD with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**Mean = 106.8%** Range: 100.1-114%
Dilution Linearity Serum and Plasma (128X MRD)	**Mean = 97.3%** Range: 88-117.5%
Dilution Linearity Diabetic Serum (128X MRD)	**Mean = 106.5%** Range: 89.5 –117.1%

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

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