Quanterix™
The Science of Precision Health

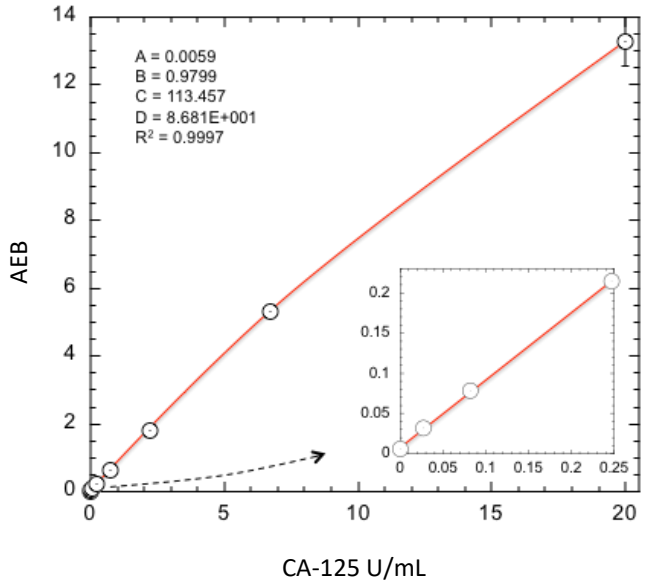
Simoa® CA-125 Discovery Kit
HD-1/HD-X Data Sheet

Item 102136

Description

Mucin 16 (MUC16) is a 3-5 million Da membrane spanning mucin with a 284 aa C-terminal domain, a 12,068 aa N-terminal domain, and a tandem repeat domain sandwiched in between. CA-125 is the 156 aa repeating peptide epitope of MUC16. The tandem repeat domain is composed of up to 60 repeats. The antibodies OC125 and M11 recognize the tandem repeat sequence. CA-125 is expressed in two forms, as a membrane bound protein at surface of cells that undergo metaplasia into a Mullerian–type epithelium or in soluble form in bodily fluids. Normal bronchial, endometrial, ovarian and corneal epithelial cells express MUC16 released from the surface by proteolytic cleavage. Glycosylation around cleavage site regulates cleavage of the ectodomain. CA125 is used widely for the diagnosis and monitoring of ovarian cancer patients and progression of epithelial ovarian cancers. CA125 levels of greater than 35 U/mL are considered an indication of potential malignancies. Recent studies suggest that a ROMA (Risk of Ovarian malignancy Algorithm) using levels of CA125 and HE4 in serum is likely to give a test that is very sensitive and specific in identifying ovarian cancer patients. CA-125 is being investigated as a target for immunotherapy in the treatment of epithelial ovarian cancers. Oregovomab behaves as an active immunotherapeutic agent and forms immune complexes with serum soluble CA-125 and triggers CA125-specific immune responses. Anti-CA-125 antibodies conjugated to cytotoxic drugs are also currently being studied in animal models. Elevated CA-125 levels are also seen in other cancers including endometrial, breast, lung, liver, stomach bladder and non-Hodgkin lymphoma. Elevated CA125 levels have also been found in benign conditions like endometriosis, pregnancy, liver disease, congestive heart failure and infectious disease like tuberculosis.

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 on 1 instrument (5 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 on 1 instrument (5 runs total).

LLOQ	**0.010 U/mL** pooled CV 9% mean recovery 121%
LOD	**0.003 U/mL** range 0.001–0.004 U/mL
Dynamic range (serum and plasma)	0–200 U/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

***See Kit Instruction for details**

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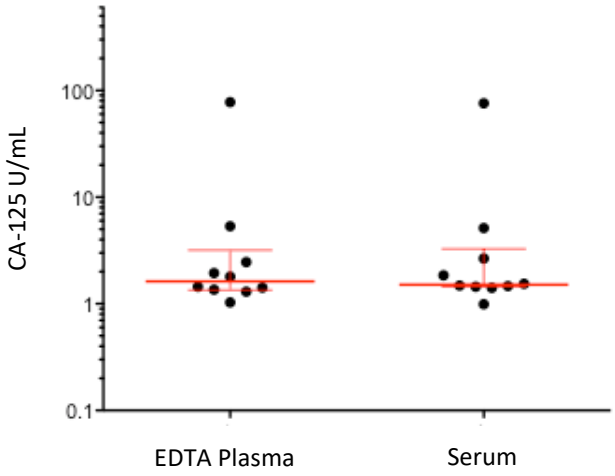
Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) were measured. Error bars depict median with interquartile range.



Sample Type	Median CA-125 U/mL	% Above LOD
Serum	1.51	100%
Plasma	1.62	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 (U/mL)	Within run CV	Between run CV
Serum Panel 1	2.41	4.7%	4.5%
Plasma Panel 2	1.59	4.4%	10.1%
Plasma Panel 3	2.54	4.9%	12.1%

Spike and Recovery: CA-125 spiked into 4 serum samples at 2 levels.

Dilution Linearity: Plasma sample diluted 2x serially from MRD (10x) to 320x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**Mean = 79.8%** Range: 73.6–88.0%
Dilution Linearity (320x)	**Mean = 118%** Range: 108–125%

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