Quanterix™
The Science of Precision Health

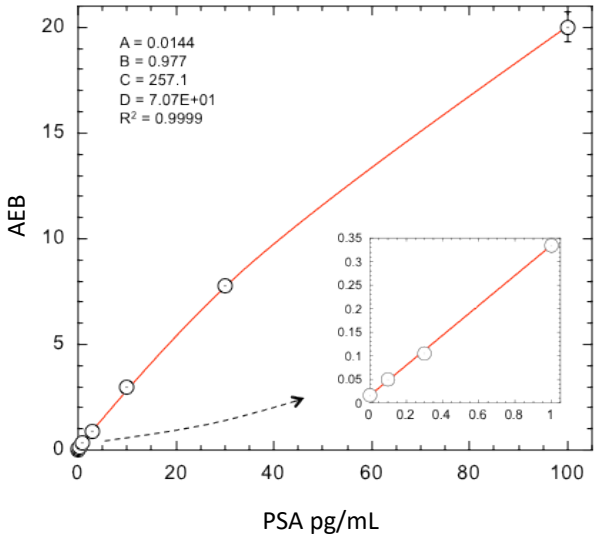
Simoa® PSA Advantage Kit
HD-1/HD-X Data Sheet

Item 101478

Description

Prostate specific antigen (PSA) is a serine protease with chymotrypsin-like activity. It is a member of the kallikrein-related peptidase gene family. PSA is a single-chain glycoprotein of 237 amino acids with a molecular weight of approximately 30,000 daltons. The major site of PSA production is the glandular epithelium of the prostate, but it has also been found in breast cancers, salivary gland neoplasms, breast milk, and other sources. PSA occurs in two major immunodetectable forms in blood. The major form is PSA complexed with the serine protease inhibitor, α-1-antichymotrypsin (PSA-ACT). Uncomplexed, or free, PSA is the other detectable form of PSA in serum. The Simoa™ Total PSA assay uses reagents that recognize both forms equally. Measurement of PSA following radical prostatectomy (RP) has become standard practice for prostate cancer recurrence monitoring. PSA is typically undetectable by conventional assay methods following surgery. However, low-abundance PSA could be rising while remaining undetected. Early adjuvant and salvage radiation therapies following surgery significantly improve patient outcomes, and recent clinical data with extreme sensitivity, non-conventional immunoassay (immunoPCR and digital immunoassay) indicate potential utility from low-abundance PSA measurement following RP for risk stratification and early cancer recurrence monitoring.

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



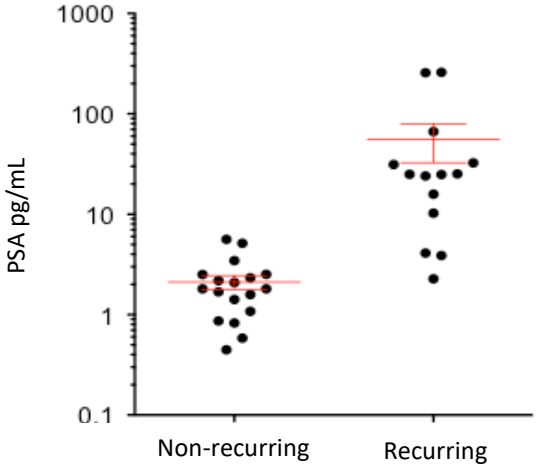
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (10 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 2 reagent lots across 3 instruments (12 runs total).

LLOQ	**0.024 pg/mL** pooled CV 15.1% mean recovery 108%
LOD	**0.015 pg/mL** range 0.0004–0.173 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**

Endogenous Sample Reading: Nadir [PSA] in serum of 32 subjects following radical prostatectomy. "Recurring" indicates biochemical recurrence of prostate cancer within 5 years[1]. Error bars depict mean and SEM.



Sample Type	Median PSA pg/mL
Non-recurring	1.81
Recurring	24.97

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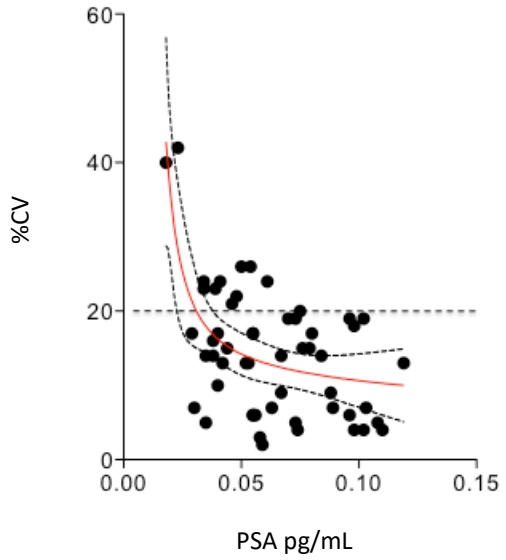
Sample Dose CV Profile: Triplicate measurements of diluted female serum samples assayed over multiple runs (54 measurements). 95% confidence intervals are depicted.



Precision: Five samples consisting of three serum-based panels and two PSA 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	3.04	6.6%	8.8%	0.0%
Control 2	60.2	5.0%	4.1%	6.9%
Panel 1	0.934	10.0%	8.6%	0.0%
Panel 2	16.3	6.3%	7.3%	0.0%
Panel 3	39.2	5.1%	8.3%	6.6%

Inter Lot CV: Pool of CVs from 4 samples (range: 2.65–60.2 pg/mL) tested with 2 reagent lots across 2 runs x 3 instruments.

Spike and Recovery: PSA spiked into 4 serum samples at 3 levels.

Admixture Linearity: High PSA sample admixed with low PSA sample, mean of 12 levels.

Dilution Linearity: 2 to 16-fold serial dilution of serum and plasma with Sample Diluent following initial 25x dilution, mean of 3 experiments.

Endogenous Interferences: High bilirubin, hemoglobin, and protein, mean of 6 samples.

Inter Lot CV	**3.2%**
Spike and Recovery (Serum/Plasma)	**Mean = 99.7%** Range: 81.3–118%
Admixture Linearity	**Mean = 93.5%**
Dilution Linearity (16x)	**Mean = 113.6%** Range: 88.2–130.4%
Endogenous Interferences*	**Mean = <10%**

*% interference from 20 mg/dL bilirubin, 500 mg/dL hemoglobin, 12 g/dL protein

The Simoa Total PSA 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.

References

1. Wilson DH, Hanlon DW, Provuncher GK, Chang L, Song L, Patel PP et al. Fifth-generation digital immunoassay for prostate-specific antigen by single molecule array technology. Clin Chem 2011; 57:1712–21.

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