Quanterix™
The Science of Precision Health

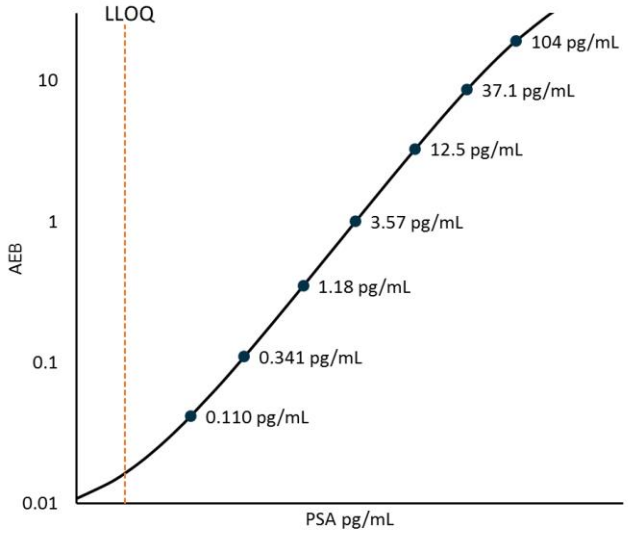
Simoa™ PSA Advantage Kit
SR-X Data Sheet

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: 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	**0.0275 pg/mL** pooled CV 18% mean recovery 92%
LOD	**0.0058 pg/mL** range 0.0029-0.0105 pg/mL
Dynamic range	0 to ~400 pg/mL
Diluted Sample volume (1:4 Dilution)*	100 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

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	3.65	3.6%	12.6%	3.7%
Control 2	88.1	6.1%	9.2%	2.9%
Panel 1	0.633	5.3%	5.6%	7.0%
Panel 2	5.09	3.6%	5.6%	2.2%
Panel 3	60.9	7.7%	7.8%	3.8%

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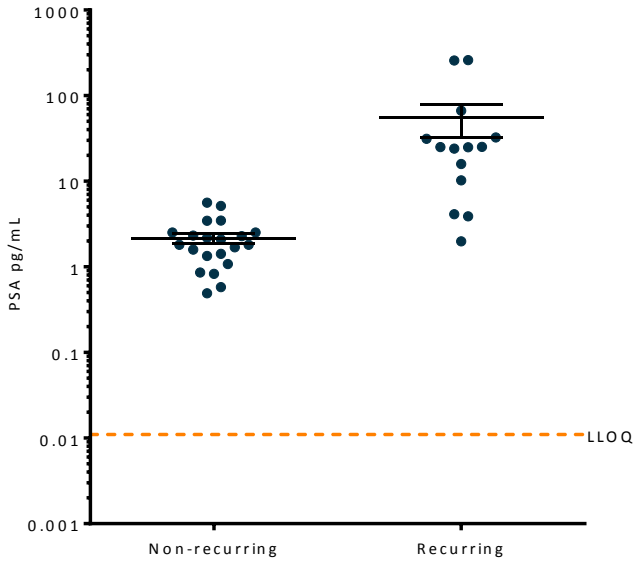
Assay designed by Yao

Dilution Linearity: 1 endogenous EDTA plasma sample and 1 endogenous serum sample were serially diluted 4X (MRD), followed by 2X serial dilution to 128x.

Serum Dilution Linearity (512x)	**Mean = 97%** Range: 93-102%
Plasma Dilution Linearity (512x)	**Mean = 99%** Range: 95-104%

Note: Data in the following sections were obtained using the HD-1 Analyzer.

Endogenous Sample Reading: Nadir [PSA] in serum of 33 subjects was measured on Simoa HD-1 following radical prostatectomy. "Recurring" indicates biochemical recurrence of prostate cancer within 5 years. Error bars depict mean and SEM. Orange line represents functional LLOQ.



Sample Type	Mean PSA pg/mL	Median PSA pg/mL	% Above LOD
Non-Recurring	2.15	1.81	100%
Recurring	55.9	25.0	100%

Spike and Recovery: 4 serum samples were spiked at high and low concentrations within the range of the assay and analyzed on HD-1.

Spike and Recovery	100% Range 81 – 118%

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

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