Dimension Vista LOCI TPSA/FPSA Assay Specifications

The Siemens Healthcare Diagnostics Dimension Vista® LOCI® TPSA and FPSA assays are homogeneous, sandwich chemiluminescent immunoassays based on LOCI technology.

Outstanding Assay Performance

- Free PSA and complexed PSA recognized on an equimolar basis
- Excellent precision to ensure accurate monitoring—TPSA: 2.31%–5.18% CV; FPSA: 2.32%–3.78% CV
- Rapid assay kinetics (10 minutes)

Dimension Vista System—Intelligence at Work

- Ultra-integration—Four technologies in one smart workstation: Photometry, Nephelometry, LOCI advanced chemiluminescence, and V-LYTE® integrated multi-sensor technology
- LOCI advanced chemiluminescence—the only homogeneous chemiluminescent technology
- Onboard automation—Increased efficiency, simplicity, and convenience for your laboratory

Clinical Utility

LOCI TPSA	LOCI FPSA
Aid for the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older	Percent FPSA is used as an aid in distinguishing prostate cancer from benign prostate conditions when PSA is in the "gray zone" range of 4–10 ng/mL
Aid in the management (monitoring) of prostate cancer patients	Percent FPSA result may be used in two ways: (1) to provide an individual patient risk assessment of prostate cancer or (2) use a single cutoff to indicate the need for additional follow-up
More effective when combined with a DRE in detecting prostate cancer than DRE alone	A cutoff of 19% results in the detection of 90.2% of prostate cancers and avoids unnecessary biopsy in 18.1% of men without prostate cancer

Answers for life.

SIEMENS

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LOCI TPSA as an Aid in the Detection of Prostate Cancer with DRE

The Positive Predictive Value (PPV) was estimated as the probability of having a positive biopsy given a positive result for DRE, PSA, and PSA with DRE. The results are as follows:

Method	PPV%	95% Confidence Interval
DRE+ only	42.6	38.1–47.2
PSA ≥ 4.0 only	42.4	39.6–45.3
PSA ≥ 4.0 or DRE+	39.3	36.7–42.0
PSA ≥ 4.0 and DRE+	57.2	51.3–62.9
PSA ≥ 4.0 and DRE-	37.6	34.4–40.8

PSA concentrations, regardless of value, should not be interpreted as definitive evidence for the presence or absence of prostate cancer. Prostate biopsy is required for the diagnosis of cancer.

Percentage (%) of Patients with Diagnosis of Prostate Cancer on Biopsy: Men with Non-Suspicious DRE Results

	% Free PSA	All Ages
Total PSA Range 4.0 to 10.0 ng/mL	≤ 10%	53.5%
	11–19%	28.4%
	≥ 20%	22.6%
Prostate Cancer Prevalence (%)		35.0%

Performance Summary

	Sample Type	Sample Volume	Assay Range	Limit of Detection	Cutoff	Calibration Interval	Onboard Stability
Dimension Vista LOCI TPSA	Serum/Plasma	3 µL	0.010–100 ng/mL	0.008 ng/mL	4.0 ng/mL	30 days	30 days
Dimension Vista LOCI FPSA	Serum/Plasma	3 µL	0.015–20 ng/mL	0.005 ng/mL	19%	30 days	30 days

Ordering Information

Catalog No.	Description	Contents
K6451	PSA Flex® Reagent Cartridge	120 tests
K6452	FPSA Flex® Reagent Cartridge	80 tests
KC602	PSA Calibrator	2 x 6 levels

*Not available for sale on the Dimension Vista 500 in the U.S.

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