Dimension TPSA/FPSA Assay Specifications

The Siemens Healthcare Diagnostics Dimension® TPSA and FPSA assays are one-step enzyme immunoassays based on the sandwich principle.

Outstanding Assay Performance

- Free PSA and complexed PSA recognized on an equimolar basis
- Excellent precision to ensure accurate monitoring TPSA: 1.4 – 13.8% within run %CV FPSA: 1.5 – 9.6% within run %CV
- Fast turnaround time (20 minutes)

Clinical Utility of TPSA

- Used as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older
- Used as an aid in the management (monitoring) of prostate cancer patients
- PSA testing, when combined with DRE, is more effective in detecting prostate cancer than DRE alone

Clinical Utility of FPSA

- Percent Free PSA is used as an aid in distinguishing prostate cancer from benign prostate conditions when TPSA is in the "gray zone" range of 4 – 10 ng/mL
- Percent Free PSA 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
- A cutoff of 19% results in the detection of 91.2% of prostate cancers and avoids unnecessary biopsy in 27.9% of men without prostate cancer

Dimension Systems—Proven portfolio of innovative, integrated systems that streamline laboratory workflow

- The Dimension EXL™ with LOCI® module is the next level of proven, best-in-class chemistry and immunoassay integration on a single platform
- The Dimension RxL Max® integrated chemistry system* is engineered to meet the evolving needs of any laboratory
- Combine chemistry, STAT, and specialty testing on a single, compact, easy-to-use system with the Dimension Xpand® Plus system*

*The Dimension RxL Max and Xpand Plus systems are available with Heterogenous Modules.

PSA 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	48.0	41.7 – 54.0
PSA > 4.0 only	39.0	35.9 – 42.1
PSA > 4.0 or DRE+	37.8	34.8 – 40.7
PSA > 4.0 and DRE+	60.6	50.9 – 80.0
PSA > 4.0 and DRE-	34.6	29.2 – 40.0

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

Probability (%) of Detecting Prostate Cancer on Biopsy

	% Free PSA	Age 50 – 59 years	Age 60 – 69 years	Age 70+ years
Total PSA Range 4.0 – 10.0 ng/mL	≤ 10%	40.2	47.1	66.0
	11% – 19%	14.7	24.1	31.6
	≥ 20%	7.1	14.3	12.5
Prostate Cancer Prevalence (%)		25.9	29.5	32.7

Performance Summary

	Sample Type	Sample Volume	Assay Range	Limit of Detection	Cutoff	Calibration Interval	Onboard Stability
Total PSA	Serum and Plasma	40 µL	0.13 – 100 ng/mL	0.13 ng/mL	4.0 ng/mL	90 days	30 days
Free PSA	Serum and Plasma	60 µL	0.06 – 45 ng/mL	0.06 ng/mL	19%	90 days	30 days

Ordering Information TPSA/FPSA		
Catalog No.	**Description**	**Contents**
RF451	• TPSA Flex® Reagent Cartridge	• 120 tests
RF452	• FPSA Flex Reagent Cartridge	• 120 tests
RC452	• TPSA/FPSA Calibrator	• 2 x 6 levels

Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen, Germany
Phone: +49 9131 84 - 0
www.siemens.com/healthcare

Global Division

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA
www.siemens.com/diagnostics

www.siemens.com/diagnostics

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