

ADVIA Centaur Free PSA Assay Specifications



The Siemens Healthcare Diagnostics ADVIA Centaur® free PSA (fPSA) assay is a fully automated, single-step sandwich immunoassay employing direct chemiluminescence technology using two monoclonal assays.

Outstanding Assay Performance

- Excellent within run precision across the assay range to ensure accurate monitoring (2.0%–5.3%)
- Fast turnaround time:
ADVIA Centaur XP: 18 min
- Traceable to WHO 96/668 Free Prostate-Specific Antigen standard for consistent results

Intended Use

The ADVIA Centaur free PSA (fPSA) assay is for the *in vitro* quantitative measurement of free prostate specific-antigen in human serum using the ADVIA Centaur and ADVIA Centaur XP systems. The ADVIA Centaur fPSA assay is intended to be used in conjunction with the ADVIA Centaur PSA assay in men aged 50 years or older with total PSA values between 4 and 10 ng/mL and digital rectal exam (DRE) non-suspicious for cancer to determine the percent free PSA value. The percent free PSA value can be used as an aid in discriminating between prostate cancer and benign prostatic disease. Prostate biopsy is required for the diagnosis of prostate cancer.

Clinical Utility

- 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
- Percent fPSA result may be used in two ways: (1) to provide an individual patient risk assessment of prostate cancer or (2) to use a single cutoff to indicate the need for additional follow up
- A single cutoff of 27% results in the detection of 90% of prostate cancers and avoids unnecessary biopsy in 15.5% of men without prostate cancer

ADVIA Centaur System – Maximizing Satisfaction

- Optimal productivity:
ADVIA Centaur XP System – up to 240 tests per hour
- Comprehensive menu including Anemia, Cardiovascular, Fertility, Infectious Disease, Oncology, TDM and Thyroid
- Complete offering of prostate cancer assays – PSA, free PSA (fPSA), complexed PSA (cPSA)

ADVIA Centaur fPSA Assay Specifications

Answers for life.

SIEMENS

ADVIA Centaur Free PSA Assay Specifications

Probability of Detecting Prostate Cancer on Biopsy

	% fPSA	All Ages
Total PSA Range 4.0–10.0 ng/mL	≤ 10%	69.5%
	11%–18%	35.1%
	19%–27%	26.0%
	> 27%	27.4%
Prostate Cancer Prevalence (%)		36.8%

Free PSA Performance Summary

	Sample Type	Sample Volume	Assay Range	Limit of Detection	Cutoff	Calibration Interval	Onboard Stability
ADVIA Centaur XP	Serum	30 µL	0.01–25 ng/mL	0.01 ng/mL	27%	28 days	60 days

Ordering Information

Catalog No.	Description	Contents
06862518	• 1 ReadyPack® primary reagent pack of ADVIA Centaur fPSA	• 50 tests
04846115	• ADVIA Centaur fPSA Calibrator	• 2 x 2

ADVIA Centaur, ReadyPack and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners. Product availability may vary from country to country and is subject to varying regulatory requirements. This assay is currently not available in the US. Please contact your local representative for availability.

Siemens Global Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen, Germany
Telephone: +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