ADVIA Centaur CA 125II Assay Specifications

The Siemens Healthcare Diagnostics ADVIA Centaur® CA 125II™ Assay is a sandwich immunoassay employing direct chemiluminescence technology using the OC 125 Ab for the capture antibody and the M11 Ab for the signal antibody. The CA 125II assay is a second-generation CA 125™, intended to provide greater reliability.

Outstanding Assay Performance

- Low imprecision levels
- Broad assay range (2-600 U/mL)

Clinical Utility

- 99% of normal samples had values below 35 U/mL
- In patients with values above 35 U/mL, an increase or decrease of 30% or more is indicative of clinical disease progression or regression[1]

ADVIA Centaur—Maximizing Satisfaction

- Optimal productivity—up to 240 tests per hour
- Comprehensive menu including Anemia, Cardiovascular, Fertility, Infectious Disease, Oncology, TDM, and Thyroid
- Complete offerng of breast cancer assays - CEA, CA 15-3, BR 27.29, and HER-2/neu

ADVIA Centaur Longitudinal Patient Evaluation Results Ovarian Cancer Patients Only

Correspondence (Parallels Clinical Course)	N	Percentage
Increasing CA 125II with progression	23	52
Decreasing CA 125II with response	6	14
Stable disease or no evidence of disease with no change in CA 125II values	5	11
Total paralleling clinical course	34	77
No correspondence (total) (Does not parallel clinical course)	10	23

The following table shows the correspondence of the ADVIA Centaur CA 125II changes to changes in the clinical status of the patient. The sensitivity of longitudinal measurements using the ADVIA Centaur CA 125II method was 93.5%

Monitoring Ovarian Cancer Patients

	ADVIA Centaur CA 125II		
Clinical Status	Change	No Change	Total
Change	29	8	37
No Change	2	5	7
Total	31	13	44

		95% CI
Sensitivity	93.5%	78.6% to 99.2%
Specificity	38.5%	13.9% to 68.4%

Answers for life.

SIEMENS

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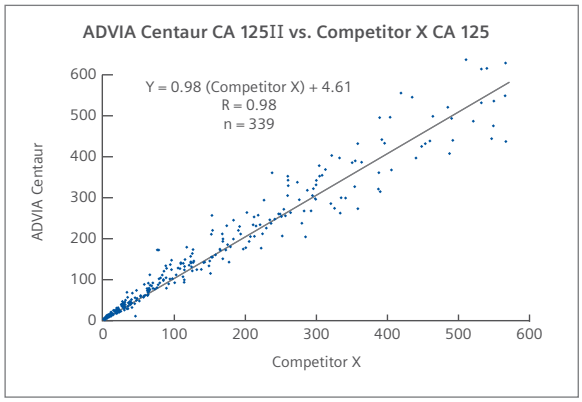
CA 125II Performance Summary

	Sample Type	Sample Volume	Assay Range	Analytical Sensitivity	Cutoff (suggested)	Calibration Interval	Onboard Stability
ADVIA Centaur	Serum	50 µL	2.0-600 U/mL	2.0 U/mL	35 U/mL	28 Days	28 Days
ADVIA Centaur CP	Serum	50 µL	2.0-600 U/mL	2.0 U/mL	35 U/mL	60 Days	60 Days



Ordering Information

Catalog No.	Description	Contents
01678114	• 5 ReadyPack® primary reagent packs of ADVIA Centaur CA 125II LITE reagent and solid phase ADVIA Centaur CA 125II Master Curve Card	500 Tests
09427226	• 1 ReadyPack primary reagent pack of ADVIA Centaur CA 125II LITE reagent and solid phase ADVIA Centaur CA 125II Master Curve Card	100 Tests
02462395	• ADVIA Centaur CA 125II Calibrator (6 pk)	• 6 vials low cal • 6 vials high cal
09750760	• ADVIA Centaur CA 125II Calibrator (2 pk)	• 2 vials low cal • 2 vials high cal

References
[1]Siemens Medical Solutions Diagnostics FDA submissions/CA 125II Method Sheet.

Features and specifications are subject to manufacturer change.

For detailed information on this test, including limitations or interferences that may affect the interpretation of test results, contact your clinical laboratory or Siemens Healthcare Diagnostics.

Please refer to package insert for up-to-date information.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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