ADVIA Centaur CA 19-9 Assay Specifications

The Siemens Healthcare Diagnostics ADVIA Centaur® CA 19-9 Assay is a two-step sandwich immunoassay employing direct chemiluminescence technology using a single MAb, 1116-NS-19-9 for both the solid phase and LITE reagent.

Outstanding Assay Performance

- Broad dynamic assay range (1.2-700 U/mL)
- No high-dose hook effect

Clinical Utility

- FDA cleared for serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas—greater than 15 percent increase in patient CA 19-9 has an 88 percent predictive value for disease progression
- 97.5 percent of normal samples had values below 35 U/mL

ADVIA Centaur—Maximizing Satisfaction

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

Per-Patient Analysis

	Change in Disease State		
Change in CA 19-9	**Progression**	**No Progression**	**Total**
>15% increase	30	17	47
≤15% increase	4	8	12
Total	34	25	59

Concordance = (30+8)/59 = 64.4%
Predictive Value (No Progression) = 8/25 = 32.0%
Predictive Value (Progression) = 30/34 = 88.2%

Monitoring of Pancreatic Cancer Patients for Changes in Disease Status: Correspondence of Serial CA 19-9 Changes and Clinical Status

Visit-to-Visit Analysis

	Change in Disease State		
Change in CA 19-9	**Progression**	**No Progression**	**Total**
>15% increase	39	27	66
≤15% increase	18	47	65
Total	57	74	131

Concordance = (39+47)/131 = 65.7%
Predictive Value (No Progression) = 47/74 = 63.5%
Predictive Value (Progression) = 39/57 = 68.4%

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Answers for life.

SIEMENS

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CA 19-9 Performance Summary

	Sample Type	Sample Volume	Assay Range	Analytical Sensitivity	Calibration Interval	Onboard Stability
ADVIA Centaur	Serum	75 µL	1.2-700 U/mL	1.2 U/mL	28 days	28 days
ADVIA Centaur CP	Serum	75 µL	1.2-700 U/mL	1.2 U/mL	42 days	42 days

Ordering Information

Catalog No.	Description	Contents
10491244	• 5 ReadyPack® primary reagent packs of ADVIA Centaur CA 19-9 LITE reagent and solid phase ADVIA Centaur CA 19-9 Master Curve Card • Calibrator CA 19-9	250 tests • 2 vials low cal • 2 vials high cal
10491379	• 1 ReadyPack primary reagent pack of ADVIA Centaur CA 19-9 LITE reagent and solid phase ADVIA Centaur CA 19-9 Master Curve Card • Calibrator CA 19-9	50 tests • 1 vial low cal • 1 vial high cal
10491972	• ADVIA Centaur CA 19-9 diluent	2 x 5 mL/pack
10491974	• ADVIA Centaur CA 19-9 diluent	25 mL/vial

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.

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