

ADVIA Centaur Serum HER-2/neu Assay Specifications

The Siemens Healthcare Diagnostics ADVIA Centaur® Serum HER-2/neu test is a sandwich immunoassay employing direct chemiluminescence technology using two monoclonal antibodies that are specific for unique epitopes on the extracellular domain of the HER-2/neu oncoprotein. The Serum HER-2/neu test is the only serum test available to monitor Serum HER-2/neu level changes over the course of the disease.

Outstanding Assay Performance

- Broad assay range (0.5-350 ng/mL)
- Excellent reproducibility (Total %CV Range 3.2-5.7%)

Clinical Utility

- HER-2/neu values obtained may be used in the follow-up and monitoring of patients with metastatic breast cancer whose initial Serum HER-2/neu level is greater than 15 ng/mL
- No interference from HER-2/neu-based therapy¹
- 95% of normal patients have Serum HER-2/neu levels below 15.2 ng/mL
- Serial changes in Serum HER-2/neu have been correlated with changes in clinical status for all patients whose pre-treatment Serum HER-2/neu values exceeded 15 ng/mL²

- For each pair of serial measurements, an increase of equal or greater than 15% is considered to indicate progression (predictive value of 67%)²
- For each pair of serial measurements, a change of less than 15% increase is considered to indicate a lack of progression (predictive value 71%)²

ADVIA Centaur Immunoassay Systems—Maximizing Satisfaction

- Optimal productivity – The ADVIA Centaur® and ADVIA Centaur® XP Systems each perform up to 240 tests per hour; The ADVIA Centaur® CP System performs up to 180 tests per hour
- Comprehensive menu including Anemia, Cardiovascular, Fertility, Infectious Disease, Oncology, TDM, and Thyroid
- Complete offering of breast cancer assays – CEA, CA 15-3, BR 27.29, and Serum HER-2/neu



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Answers for life.

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Serum HER-2/neu Performance Summary

| | Sample Type | Sample Volume | Assay Range | Analytical Sensitivity | Calibration Interval | Onboard Stability |
|------------------|-------------|---------------|---------------|------------------------|----------------------|-------------------|
| ADVIA Centaur | Serum | 20 µL | 0.5-350 ng/mL | 0.5 ng/mL | 14 Days | 41 Days |
| ADVIA Centaur CP | Serum | 20 µL | 0.5-350 ng/mL | 0.5 ng/mL | 28 Days | 60 Days |

Ordering Information

| Catalog No. | Description | Contents |
|-------------|--|---|
| 00915031 | <ul style="list-style-type: none"> 1 ReadyPack® primary reagent pack containing ADVIA Centaur HER-2/neu LITE Reagent, Solid Phase and Fluorescein Conjugate Reagent ADVIA Centaur HER-2/neu Master Curve card | <ul style="list-style-type: none"> 50 Tests |
| 00913551 | <ul style="list-style-type: none"> HER-2/neu Calibrator | <ul style="list-style-type: none"> 2 x 2.0 mL Low Calibrator 2 x 2.0 mL High Calibrator |
| 00913276 | <ul style="list-style-type: none"> HER-2/neu Quality Control Material | <ul style="list-style-type: none"> 2 x 2.0 mL Control 1 2 x 2.0 mL Control 2 |
| 131217 | <ul style="list-style-type: none"> HER-2/neu Master Curve Material | <ul style="list-style-type: none"> 7 x 1 mL |

References:

- Payne RC, et al. *Clinical Chemistry* 2000; 46(2):175.
- Siemens Healthcare Diagnostics FDA submission/HER-2/neu Method Sheet.

Assay availability subject to local regulatory requirements. 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.

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

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