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Bayer Diagnostics Corporation ADVIA@
Centaur@ BNP 3/28/2003 5 10(k)

Centaur (c) Analytical Comparison and Clinical Agreement A paired comparison was performed at 2 clinical trial sites to assess the relationship of the ADVIA Centaur BNP assay to the predicate device. A total of 167 patients with heart failure (HF; clinical diagnoses of Class I - IV) and 20 individuals without

Bayer Diagnostics ADVIA Centaur BNP Assay

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21) and total (n 26 runs) imprecision

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The [Book] Advia Centaur Assay Manual Bnp ADVIA Centaur® assays on the same samples, which showed BNP within the normal range. We believe that the possibility for false readings for high BNP levels in healthy individuals measured by AxSYM assay should be taken into ...

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The ADVIA Centaur CP System is an immunoassay test instrument for mid-volume labs. Its broad menu lets you both expand and consolidate - by bringing a wide range of assays to one workstation, eliminating redundant systems. The ADVIA Centaur CP System is easy to operate, increases efficiency and streamlines workflow. It offers the excellent sensitivity and specificity expected from direct ...

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BNP Assay for the ADVIA Centaur,ADVIA Centaur delivers a new level of immunodiagnostic productivity. It provides the flexibility to integrate with any laboratory automation system, now and in the future. Most importantly, it offers a comprehensive disease-focused menu of immunoassays - a menu that is under constant expansion.,medicine,medical supply,medical supplies,medical product

BNP Assay for the ADVIA Centaur - Bio-Medicine

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ADVIA Centaur CP system: If any of the affected kit lots have been in use on the system, you must manually track the time that the Multi-Diluent 15 has been

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Advia Centaur Assay Manual Bnp PDF Download - ShukriAkbar In February 2003, Bayer HealthCare LLC, Diagnostics Division (Tarrytown, NY) released the ADVIA Centaur® BNP Assay for ex-U.S. distribution on the ADVIA Centaur Chemiluminescent System. 9 The assay uses the same antibodies as the original ShionoRIA BNP manual assay with one antibody ...

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Actions for ADVIA Centaur XPT system: If you intend to perform onboard dilutions for the ADVIA Centaur BNP and/or TSH3UL assays, you must restart the workstation after scanning the master curve card for the BNP and/or TSH3UL

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assay kit lot, before ordering an onboard dilution for these assays.

Class 2 Device Recall ADVIA Centaur BNP

In February 2003, Bayer HealthCare LLC, Diagnostics Division (Tarrytown, NY) released the ADVIA Centaur® BNP Assay for ex-U.S. distribution on the ADVIA Centaur Chemiluminescent System. 9 The assay uses the same antibodies as the original ShionoRIA BNP manual assay with one antibody coupled to acridinium ester (KYh-BNPII) and one antibody coupled to paramagnetic latex particles (BC-203).

BNP in the Diagnosis of Heart Failure - Elite Learning

The ADVIA Centaur XPT System delivers the results that clinicians depend upon for accurate diagnoses and better patient care—and does so predictably and consistently. Siemens unites innovative workflow solutions with clinical excellence in the ADVIA Centaur

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XPT System, leading to greater laboratory productivity to stay ahead of increasing workload demands.

ADVIA Centaur XPT Immunoassay System - Siemens ...

ADVIA Centaur® High-Sensitivity Troponin I Assay Time is Muscle - Earlier MI Diagnosis with Sensitive Troponin Assays The detection of a rise and/or fall of cardiac troponin (cTn) plays a key role in the earlier diagnosis of myocardial infarction (MI).

ADVIA Centaur® High-Sensitivity Troponin I Assay ...

i ADVIA Centaur XPT System T03013.012
Effective Date: 5/20/20 . Siemens Healthineers • VB12 and Folate releasing agent require manual preparation. • Onboard stability starts when the pack is pierced. ... Change the low and high values for one of the assays. Quality Control ADVIA Centaur XPT System 5-4 . Questions .

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Page 1 ADVIA ® 2400 Chemistry System Operator's Guide 073D0403-01 Rev. A, 2009-06... Page 2 If the system is used in a manner not specified by Siemens, the protection provided by the equipment may be impaired. Observe all warning and hazard statements. The ADVIA Chemistry system is manufactured in Japan for Siemens. Page 3: Table Of Contents

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METHODS: We evaluated the analytical and clinical performance of the Bayer ADVIA Centaur BNP assay. Studies included precision, analytical correlation (against the Shionogi ShionoRIA and Biosite Triage BNP assays), BNP results for blood collected in plastic tubes containing EDTA vs other collection tubes, high-dose hook effect, detection limits, and interferences.

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Analytical and clinical evaluation of the Bayer ADVIA ...

- Fully automated assay on the ADVIA Centaur Immunoassay Systems • Repeatability $\leq 3.5\%$; within-lab precision $\leq 4.3\%$ • No interference to 75 ng/mL biotin • Correlation with the proBNP II assay on the Roche cobas e 411 system A-084 References 1. World Health Organization. Cardiovascular diseases fact sheet N°317.

Performance Evaluation of the NT-proBNP Assay* Using ...

BNP measured on the Bayer Advia Centaur was systematically underestimated in heparin plasma (-47%) and serum (-62%) when compared to K2 EDTA plasma. According to the established 100 ng/L cutoff value, 25% and 37% of the fresh samples collected in heparin plasma or serum were misclassified from the reference K2 EDTA fresh specimen, respectively.

Influence of sample matrix and

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storage on BNP measurement ...

AccessGUDID - ADVIA Centaur®
Systems ACS:180® Systems BNP
Calibrator (00630414472836)- BNP -
CENTAUR - CAL - 2x2x2mL

DEVICE: ADVIA Centaur® Systems ACS:180® Systems BNP ...

Despite these differences, the package inserts for both the Bayer ADVIA Centaur BNP and the Biosite Triage BNP assays recommend the use of a single worldwide BNP cutoff of 100 ng/L for both genders . In the package insert for the US, Roche has recommended two age-specific cutoffs for NT-proBNP: 125 (<75 years) and 450 (\geq 75 years) ng/L (27).

Analytical and Clinical Evaluation of the Bayer ADVIA ...

The Bayer ADVIA Centaur BNP method was calibrated to achieve the same clinical decision threshold for rule-out of HF (100 ng/L) as the Triage BNP assay. The overall clinical specificity (>97%)

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and negative predictive value (>99%) for the ADVIA Centaur BNP assay are equivalent to those reported previously for other methods.

Analytical and clinical evaluation of the Bayer ADVIA ...

ADVIA Centaur BNP assay is a two-site dual-mono-clonal immunochemiluminescent assay. Both antibodies are supplied by Shionogi & Co., Ltd. (Osaka, Japan) and have been widely used in the ShionoRIA BNP assay to demonstrate the clinical efficacy of BNP measurements. The capture biotinylated antibody is directed to the C-

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