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Stratus CS System Publication Compendium

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This compendium was compiled with the intention of providing one resource for journal publications that have been published for the Stratus® CS Acute Care™ Analyzer and its current commercial assays. Articles that contain claims or cite performance outside of the Information for Use instructions for the Stratus CS Analyzer and associated assays have not been included.

These articles were published in various journals from the year 2003 through 2012 and are provided for informational use only.



High Sensitivity* Troponin I					
Analytical Performance					
Title of Publication	Systems/Assays Cited	Overview/Conclusions	Author	Journal	Year Published
Clinical implications of the change of cardiac troponin I levels in patients with acute chest pain—An evaluation with respect to the Universal Definition of Myocardial Infarction.	<ul style="list-style-type: none"> • Stratus CS Acute Care Diagnostic System • Troponin I assay 	This study sought to evaluate the clinical implications of the relative change of cardiac troponin I (cTnI) levels, and found that a peak cTnI level above the 99th percentile together with a cTnI change of $\geq 20\%$ within 24 hours of admission led to a significantly raised mortality over the study period of 5.8 years. This study concluded that the universal definition of AMI together with a $\geq 20\%$ cTnI change appears to improve the discrimination of acute from chronic causes of cTnI release, and allows a reliable identification of patients at risk.	Eggers KM, et al.	Clin Chim Acta. Jan 2011;412 (1-2):91-7.	2011
Integration between point-of-care cardiac markers in an emergency/cardiology department and the central laboratory: methodological and preliminary clinical evaluation.	<ul style="list-style-type: none"> • Stratus CS Acute Care Diagnostic System • Troponin I assay 	The analytical performance of the troponin I assay on the Stratus CS was evaluated to assess the viability of implementation of POC testing. The preliminary clinical data suggest that the high sensitivity of the Stratus CS Troponin method could play an important role in early identification of patients with acute myocardial infarction. The comparison studies suggest that implementation of POCT requires a high level of integration between cardiologists and pathologists to guarantee appropriate interpretation of the monitoring results for suspected ACS patients.	Di Serio F, et al.	Clin Chem Lab Med. Jan 2005;43 (2):202-9.	2005
†Evaluation of imprecision for cardiac troponin assays at low-range concentrations.	<ul style="list-style-type: none"> • Stratus CS Acute Care Diagnostic System • Abbott AxSYM • Bayer ACS:180 • ADVIA Centaur® • Bayer Immuno 1 • Beckman Access • bioMerieux VIDAS • Byk-Sangtec Diagnostica Liaison • Dimension® RxL • IMMULITE® One • Behring Opus • Ortho Vitros ECI • Roche Elecsys • Roche E170 • Tosoh A1A 21 • Troponin I assay 	Imprecision profiles for commercially available cardiac troponin assays were constructed using AxSYM, ACS:180, Centaur, Immuno 1, Access, VIDAS, Liaison, Dimension, Opus, Stratus CS, IMMULITE, Vitros ECI, and Elecsys analyzers. No assay was able to achieve the 10% CV recommendation at the 99th percentile reference limit defined by the manufacturer.	Panteghini M, et al.	Clin. Chem. Feb 2004; 50:327-32.	2004
Evaluation of point-of-care test systems using the new definition of myocardial infarction.	<ul style="list-style-type: none"> • Stratus CS Acute Care Diagnostic System • Troponin I assay • CK-MB assay 	This study evaluated the clinical utility of the Stratus CS troponin I test. Sensitivity and specificity were 100% and 95.3%, respectively, when 0.2 $\mu\text{g/L}$ was used as the cut-off for myocardial infarction. Stratus CS troponin I appeared to be a reliable method in the low-risk group studied.	Agewall S.	Clin Biochem. Feb 2003; 36(1):27-30.	2003

* Defined as an imprecision level of 10% at the 99th percentile of a normal population by the joint ESC/ACC committee.

† This study was funded partially or fully by Siemens.

High Sensitivity* Troponin I

Assay Comparison

Title of Publication	Systems/Assays Cited	Overview/Conclusions	Author	Journal	Year Published
†Stratus CS cardiac troponin I method: performance characteristics including imprecision at low concentrations.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Dimension RxL System Troponin I assay 	The performance of the troponin I assay on the Stratus CS was assessed using a Dimension RxL System for comparison. The assay in routine practice has performance characteristics appropriate for clinical use, including good correlation to a central laboratory cTnI method and imprecision of a high sensitivity troponin method with a CV of <10% at the 99th percentile of the reference population.	Christenson RH, et al.	Clin Biochem. Aug 2004;37(8):679-83.	2004
Analytical performance of the i-STAT cardiac troponin I assay.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Abbott I-STAT System Troponin I assay 	The analytical characteristics of the i-STAT cardiac troponin I assay were assessed using the Stratus CS troponin I assay for comparison. Regression analysis for the i-STAT cTnI between whole blood and plasma specimens and for whole blood between the i-STAT and Stratus CS cTnI assays demonstrated slopes of 1.06 and 0.89, respectively.	Apple FS, et al.	Clin Chim Acta. July 2004;345(1-2):123-7.	2004

Hospital Metrics

†Decreased patient charges following implementation of point-of-care cardiac troponin monitoring in acute coronary syndrome patients in a community hospital cardiology unit.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Dimension RxL System Troponin I assay 	This study assessed bedside cTnI testing on the Stratus CS with respect to turnaround times, patient length of stay, financial matrices and patient outcomes compared to central laboratory cTnI testing on a Dimension system. This study demonstrates the cost-effectiveness and clinical effectiveness of implementation of POC whole blood, cTnI testing for assisting clinicians with diagnostic and risk assessment of ACS patients.	Apple FS, et al.	Clin Chim Acta. Aug 2006;370(1-2):191-5.	2006
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Patient Subsets

Gender differences in correlates of troponin assay in diagnosis of myocardial infarction.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Troponin I assay CK-MB assay 	This study assessed the accuracy and correlates of Siemens cardiac troponin I (cTnI) assay on the Stratus CS System in the diagnosis of non-ST-segment elevation MI, to determine how the assay might vary by gender. The study did not observe a significant difference in the assay sensitivity or specificity by gender.	Shoaibi A, et al.	Transl Res. 2009 Nov;154(5):250-6. Epub 2009 Aug 3.	2009
Point-of-care testing: false elevation of cardiac troponin I assayed in the emergency department.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Troponin I assay 	High cTnI levels in an 18-year-old woman with no cardiac history were discordant with the clinical presentation and electrocardiography. Assay interference by heterophilic antibodies (HA) was suspected and subsequently confirmed using a Heterophilic Blocking Tube, a device that contains a blocking reagent composed of specific binders that attach to HA.	Pernet P, et al.	Am J Emerg Med. 2008 Oct;26(8):969.e1-2.	2008
Positive cardiac troponin I and T and chest pain in a patient with iatrogenic hypothyroidism and no coronary artery disease.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Troponin I assay 	A cTnI level above threshold (0.13 µg/L) was measured in a thyroidectomized patient who presented with acute chest pain. The study found that cardiac troponins may be elevated in severe hypothyroidism without coronary artery disease, due to diffuse myocardial injury.	Buschmann IR, et al.	Int J Cardiol. Feb 2007; 115(2): e83-5.	2007

D-Dimer

Title of Publication	Systems/Assays Cited	Overview/Conclusions	Author	Journal	Year Published
†Dendrimers and their applications in immunoassays and clinical diagnostics.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System Dendrimer-coupled antibody reagents 	A review of the synthesis and properties of a unique class of nanoscopic macromolecules exploited in the development of sensitive immunoassays, including dendrimer-coupled antibody reagents utilized in Stratus CS assays.	Singh P.	Biotechnol Appl Biochem. Sep 2007;48(Pt 1):1-9.	2007

NT-proBNP

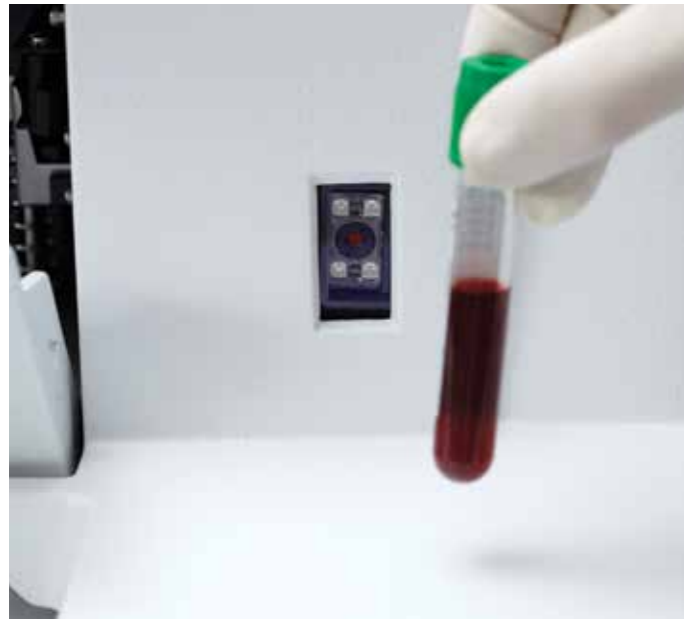
Title of Publication	Systems/Assays Cited	Overview/Conclusions	Author	Journal	Year Published
PATHFAST NT-proBNP (N-terminal-pro B type natriuretic peptide): a multicenter evaluation of a new point-of-care assay.	<ul style="list-style-type: none"> Stratus CS Acute Care Diagnostic System PATHFAST Analyzer NT-proBNP assay 	A multicenter evaluation was performed to assess a new point-of-care testing PATHFAST NT-proBNP assay. The assay was evaluated against Siemens NT-proBNP assay running on the Stratus CS. Satisfactory analytical and clinical performance was observed.	Zaninotto M, et al.	Clin Chem Lab Med. Jul 2010; 48n7: 1029-34.	2010



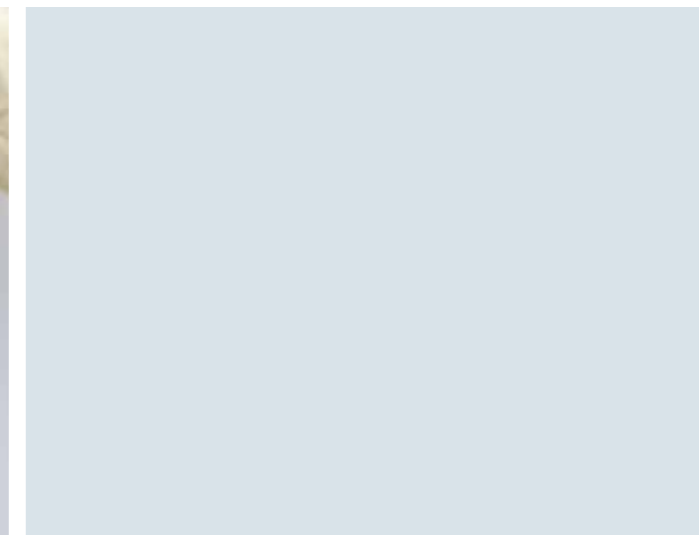
* Defined as an imprecision level of 10% at the 99th percentile of a normal population by the joint ESC/ACC committee.

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† This study was funded partially or fully by Siemens.



βhCG					
Title of Publication	Systems/Assays Cited	Overview/Conclusions	Author	Journal	Year Published
†Two-center clinical evaluation of a new automated fluorometric immunoassay for the quantitative analysis of total beta-human chorionic gonadotropin.	<ul style="list-style-type: none"> • Stratus CS Acute Care Diagnostic System • BhCG assay 	This study evaluated the quantitative total beta hCG assay on the Stratus CS System. The test offers the advantage of quantitative measurement of total beta hCG in whole blood at the point of care and is suitable for clinical use.	Azzazy HM, et al.	Clin Biochem. Oct 2003; 36(7):523-8.	2003
Myoglobin					
Title of Publication	Systems/Assays Cited	Overview/Conclusions	Author	Journal	Year Published
†Evaluation of the Stratus CS fluorometer for the determination of plasma myoglobin.	<ul style="list-style-type: none"> • Stratus CS Acute Care Diagnostic System • Cobas Integra 400 System • Myoglobin assay 	The analytical performance of the myoglobin assay on the Stratus CS was evaluated using a Cobas Integra 400 for comparison. Method comparison and recovery experiments indicated that despite good between-method correlations, the Stratus CS method overestimated myoglobin concentrations in comparison with values obtained on Cobas Integra 400. However, since the manufacturers' cut-off for elevated plasma myoglobin levels was higher for Stratus CS than for other techniques, few discrepant results were observed between methods.	Couck P, et al.	Acta Clin Belg. Mar 2005;60(2):75-8.	2005



The Stratus CS Analyzer for acute care diagnostics provides quantitative cardiac assays for fast, cost-effective evaluation of patients presenting with suspected myocardial ischemia. Its menu, efficiency, and ease of use make it ideal for both point-of-care testing and laboratory applications.

- This list of publications was compiled using the online service PubMed. PubMed is a service of the U.S. National Library of Medicine that includes over 19 million citations from MEDLINE and other life science journals. The service can be found at: www.ncbi.nlm.nih.gov/pubmed. The following search terms were used: Stratus CS Analyzer.
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