Rely on Its Proven Performance

The Stratus CS Acute Care Diagnostic System is Designed to Best Fulfill Your Near-patient Setting Needs
Near-patient Settings with Lab-quality Results

Without exception, acute care depends on timeliness, safety, and effectiveness[1,2]. With this in mind, we at Siemens Healthcare Point of Care Diagnostics offer you our solution for the near-patient settings.

The Stratus® CS Acute Care™ Diagnostic System is the perfect fit for your near-patient testing. Intelligent design guarantees ease of use together with gold-standard quality results. The system provides the necessary biomarkers to cover the spectrum of acute cardiac care.

The Benefits of Near-patient Testing[2,3]

In a study evaluating the impact of point-of-care testing with cTnI on the Stratus CS Acute Care Diagnostic System versus routine testing, several benefits were documented. With the Stratus CS Acute Care Diagnostic System, turnaround time for near-patient testing was reduced from 76 to 20 minutes. And, total costs associated with point-of-care cTnI testing decreased by 25 percent.

Caring for Patients Comes before Handling Specimens

Confidence in near-patient cardiac marker results
• Results in as little as 14 minutes versus 60–120 minutes from the central lab
• Less hands-on manipulation than hand-held devices reduces the opportunity for error
• Choose from a robust diagnostic and risk stratification menu

Laboratory Practices Must Be Perfectly Fulfilled

The Stratus CS Acute Care Diagnostic System is designed in compliance with laboratory accrediting agencies (CAP, JCAHO, CLSI), allowing the use of daily system check (Electronic QC) in lieu of daily testing of liquid controls.

• Daily system check with a programmable time lock-out includes:
  – optical detection system
  – mechanical alignments
  – fluid handling system
  – temperature

• If required by your institution or local regulations, liquid control check is also available and includes programmable time/range lock-outs.

Easy to Use by Personnel of All Skill Levels[4,5,6,7]

• Closed whole blood sample processing using on-board centrifugation
• Reduced risk of biohazard
• Capability of integration into your institution’s information system
• No need for daily maintenance

Turnaround time was reduced:

<table>
<thead>
<tr>
<th>Routine Testing</th>
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<td>76 minutes</td>
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Total costs associated with point-of-care cTnI testing decreased 25%.[4,5,6]

Cost in Per Patient Admission

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From "vein to brain" in less than 20 minutes.

Collect whole blood sample and enter patient ID (barcode or keyboard)
Load sample and test cartridge(s)
Press start
14 minutes later report the first result

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Markers You Need That Cover the Spectrum of Acute Cardiac Care

Guideline Acceptable Troponin I
The preferred biomarker for myocardial necrosis\(^8\)
- Meets internationally accepted guidelines (ESC/ACC/AHA/NACB/IFCC)\(^8,9,11\)
- Excellent sensitivity and cardiac specificity\(^9,13\)
- 99th percentile of normal: 0.07 ng/mL\(^11,13\)
- 10% CV at 0.06 ng/mL

NT-proBNP\(^15,16\)
The aid in evaluating and managing heart failure (HF) and acute coronary syndromes (ACS)
- Early and accurate diagnosis
- Additional risk factor for poor outcomes in ACS patients

Myoglobin\(^8\)
For patients in need of early diagnosis
- Excellent negative predictive value rapidly appears in the blood after injury
- Usable for reperfusion monitoring and re-infarction

CardioPhase\(^*\) CRP
Add to the prediction value of other markers used to assess the risk of cardiovascular and peripheral vascular disease
- Inflammation contributing to plaque instability/rupture

CKMB mass\(^8,9\)
The alternative to Troponin I
- Usable for re-infarction detection\(^17\)
- Estimation of infarct-size\(^18\)

Additional Assays Available on the Stratus CS Analyzer

D-Dimer\(^6,19\)
An important test performed in patients suspected of thrombotic disorders
- High negative predictive value for venous thromboembolism (VTE)
- Excludes pulmonary embolism (PE)\(^*\)
- Excellent sensitivity
- High precision at the cut-off level

β-hCG\(^20\)
For answering the question of pregnancy quickly and quantitatively to ensure the safest treatment possible

HeartMark – Cardiac Troponin I – 20 Day Imprecision Study
Siemens Healthcare Diagnostics Inc.

First Guideline Acceptable Troponin I Method
A guideline acceptable Troponin I method is defined by the joint ESC/ACC committee as having an imprecision level of ≤10% at the 99th percentile of a reference control population. A cTnI concentration of 0.06 ng/mL corresponded to a total imprecision of 10% CV for two independent Stratus CS analyzers in routine use. Thus, the 10% CV for the Stratus CS cTnI assay is below the 99th percentile of a reference control population, and in compliance with specifications of the ESC/ACC\(^*\) redefinition of MI.\(^11\)

R. Christenson et al., Clin Biochem 2004

Stratus CS Acute Care Guideline Acceptable Troponin I Assay Fulfills International Recommendations

Harmonizing the Central Lab and Near-patient Testing
"As more assay systems are devised for point-of-care (POC) testing, identical criteria must apply to both central laboratory methodologies and POC testing systems."\(^8\)
Siemens has been proactive in taking steps to ensure the alignment of cardiac Troponin I assays in the central laboratory and near-patient setting. Harmonizing cTnI and NT-proBNP is an increasingly important issue for laboratory medicine.\(^9,10\)

The Stratus CS Acute Care cTnI assay has been shown to demonstrate good agreement across the measurement range with the Siemens central laboratory platforms, the Dimension\(^\text{®}\) RxL Max\(^\text{®}\), and Xpand\(^\text{®}\) Plus integrated chemistry systems as well as the Dimension Vista\(^\text{®}\) Intelligent Lab System. Siemens offers the only point-of-care-central-lab pair of instruments that demonstrates real cTnI harmony.\(^9,13\)

This also makes Stratus CS Acute Care Diagnostic System a perfect fit as a backup solution in central laboratories and satellite sites.

CardioPhase\(^*\) CRP
Add to the prediction value of other markers used to assess the risk of cardiovascular and peripheral vascular disease
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CKMB mass\(^8,9\)
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"We found that a cTnI value of 0.07 ng/mL corresponded to the 99th percentile of a reference control population. A cTnI concentration of 0.06 ng/mL corresponded to a total imprecision of 10% CV for two independent Stratus CS analyzers in routine use. Thus, the 10% CV for the Stratus CS cTnI assay is below the 99th percentile of a reference control population, and in compliance with specifications of the ESC/ACC\(^*\) redefinition of MI."\(^11\)

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Troponin I (ng/mL)

%CV – IFCC data

%CV

0.30

0.35

0.40

0.0

0.05

0.10

0.15

0.20

0.25

0.30

0.35

0.40

0.45

0.50

0.0

0.05

0.10

0.15

0.20

0.25

0.30

0.35

0.40

0.45

0.50

Stratus CS Acute Care Markers
The system’s robust and comprehensive cardiac marker panel provides reliable answers to critical questions.

"Troponin, CRP, and BNP each provide unique prognostic information in patients with ACS. A simple multimarker strategy that categorizes patients based on the number of elevated biomarkers at presentation allows risk stratification over a broad range of short- and long-term major cardiac events."\(^7\)

M.S. Sabatine et al., Circulation 2002

*In conjunction with a non-high clinical pretest probability (PTP) assessment model
**European Society of Cardiology
American College of Cardiology
Stratus CS Acute Care System
Designed for Acute Care Diagnostics

System, Sample, and Reagent Specifications

<table>
<thead>
<tr>
<th>Assay Range</th>
<th>Troponin-I</th>
<th>CKMB</th>
<th>NT-proBNP</th>
<th>D-dimer</th>
<th>hsCRP</th>
<th>Myoglobin</th>
<th>βhCG</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.03–50 ng/mL (mg/L)</td>
<td>0.3–150 ng/mL (mg/L)</td>
<td>15–20000 pg/mL</td>
<td>6–5000 ng/mL (mg/L)</td>
<td>0.1–50 mg/L</td>
<td>1–900 ng/mL (mg/L)</td>
<td>0.5–1250 mIU/mL (IU/L)</td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>0.03 ng/mL</td>
<td>0.3 ng/mL</td>
<td>15.0 pg/mL</td>
<td>6.0 ng/mL</td>
<td>0.1 mg/L</td>
<td>1.0 ng/mL</td>
<td>0.5 mIU/mL</td>
</tr>
<tr>
<td>Reproducibility (CV)</td>
<td>5.1% at 0.64 ng/mL</td>
<td>10% at 0.06 ng/mL</td>
<td>4.0% at 3.7 ng/mL</td>
<td>4.4% at 96.6 pg/mL</td>
<td>4.1% at 412 ng/mL</td>
<td>6.8% at 1.16 mg/L</td>
<td>3.4% at 56 ng/mL</td>
</tr>
</tbody>
</table>

Please refer to the assay insert sheets or operator's guide for more detailed information.

Automatic Alignment
Level-sensing capabilities automatically align to each TestPak and module

Computer Interface Specifications
Uni-directional

Environmental Specifications
Room Temperature: 17–30°C
Humidity: 20–80%

Waste Disposal
All hazardous materials are contained within a disposable waste liner

Centrifuge Speed
Microprocessor-verified between 18,000 and 22,000 rpm

Sample and TestPak Identification
Universal barcode reader

Automatic Dilutions
Single-use DilPaks per method

Real-Time Fluid Management
Liquid level sensing capability combined with fluidic dispense monitoring system

Turnaround Time
System provides first result in as little as 14 min and a panel of 4 tests in 26 min from a whole blood sample

Specimen Type
Sodium heparin or lithium heparin for all methods except D-dimer. Please refer to assay product inserts for more detailed information. D-dimer requires lithium heparin or sodium citrate whole blood or plasma.

Quality Control
• Daily system check (electronic QC) with programmable time lockout
• Liquid controls are processed after calibration, upon receipt of a previously calibrated lot of reagents or whenever the site wishes to verify performance, and according to local, state, and/or federal regulations
• On-board “QC Required” alert for a time element and/or range check

Software Features
• The last 20 results are stored and can be reprinted and/or transmitted to LIS
• Patient ID and/or sample ID entry sample collection time entry
• Unauthorized operator lockout capability
• TestPak lot expiration notification password protection of advanced setup functions
• POC interface mode for connectivity

Storage Requirements
TestPaks, CalPaks, and DilPaks: 2 to 8°C (Troponin-I CalPak: -10 to -20°C)

Calibration
• 90 days for βhCG
• 60 days for cTnI, CKMB, Myoglobin, D-dimer, and hsCRP
• 30 days for NT-proBNP

Calibration
Up to 3 separate TestPak lots per assay can be stored

Reagent Capacity
Single-use assay cartridges

Assay Technology
Dendrimer enhanced radial partition immunoassay

Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
<th>Quantity</th>
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<tbody>
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<td>CTTNI</td>
<td>Stratus CS Acute Care Troponin I TestPak</td>
<td>100</td>
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<tr>
<td>CTTNI-CR</td>
<td>Stratus CS Acute Care cTnI CalPak</td>
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<td>CTTNI-D</td>
<td>Stratus CS Acute Care D-dimer TestPak</td>
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<td>CKMK-B-C</td>
<td>Stratus CS Acute Care CKMB DilPak</td>
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<td>CKMK-D</td>
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<td>Stratus CS Acute Care βhCG TestPak</td>
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<td>Stratus CS Acute Care D-Dimer TestPak</td>
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<td>CMMH-D</td>
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<td>CMMH-CR</td>
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<td>CMMH-DR</td>
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<td>Centrifuge Rotor</td>
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<td>CCANBD-BD</td>
<td>BD Vacutainer® Cuvulla Adapter</td>
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<tr>
<td>CCAMS</td>
<td>Sarsted® Cuvulla Adapter</td>
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<tr>
<td>CCLBP</td>
<td>Sample Cups</td>
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<td>Thermal Printer Paper</td>
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<td>CTIPS</td>
<td>Pipette Tips</td>
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<tr>
<td>CLINNER</td>
<td>Waste Container</td>
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References:
10. Collinson P. Global Perspective: Managing Cardiovascular Disease (Educational Video/CD-ROM)
13. Stratus CS cTnI TestPak (product insert)