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. 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

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.

Turnaround time was reduced:

<table>
<thead>
<tr>
<th>Routine Testing</th>
<th>Stratus CS Acute Care Diagnostic System</th>
</tr>
</thead>
<tbody>
<tr>
<td>76 minutes</td>
<td>to fewer than 20 minutes</td>
</tr>
</tbody>
</table>

Total costs associated with point-of-care cTnI testing decreased 25%.

The Benefits of Near-patient Testing

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<tr>
<td>$17,163</td>
<td>$12,882</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Collect whole blood sample and enter patient ID (barcode or keyboard)</th>
<th>Load sample and test cartridge(s)</th>
<th>Press start</th>
<th>14 minutes later report the first result</th>
</tr>
</thead>
</table>
Markers You Need That Cover the Spectrum of Acute Cardiac Care

**First Guideline Acceptable Troponin I Method**

A guideline acceptable Troponin I method is defined by the joint ESC/AACC committee as having an imprecision level of ≤10% at the 99th percentile of a normal population. 8,9,11,21 The assay can be used for the measurement of cardiac Troponin I to aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with acute coronary syndrome (ACS). 13

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

We found that a cTnl value of 0.07 ng/mL corresponded to the 99th percentile of a reference control population. A cTnl 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 cTnl 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

<table>
<thead>
<tr>
<th>Troponin I (ng/mL)</th>
<th>0.07</th>
<th>0.06</th>
</tr>
</thead>
<tbody>
<tr>
<td>%CV</td>
<td>0.35</td>
<td>0.40</td>
</tr>
</tbody>
</table>

**Guideline Acceptable Troponin I**

The preferred biomarker for myocardial necrosis 8,9

- Meets internationally accepted guidelines (ESC/AACC/AHA/NACLBIFCC)* 8,9,11
- Excellent sensitivity and cardiac specificity 8,9,11
- 99th percentile of normal: 0.07 ng/mL 8,9,11
- 10% CV at 0.06 ng/mL

**NT-proBNP** 8,9,11

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** 8,9

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 8,9
- Estimation of infarct-size 8,9

**Additional Assays Available on the Stratus CS Analyzer**

**D-Dimer** 8,9

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

**βhCG** 20

For answering the question of pregnancy quickly and quantitatively to ensure the safest treatment possible

*In conjunction with a non-high clinical pretest probability (PTP) assessment model
**European Society of Cardiology American College of Cardiology

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 cTnl and NT-proBNP is an increasingly important issue for laboratory medicine. 8,9,11

The Stratus CS Acute Care cTnl assay has been shown to demonstrate good agreement across the measurement range with the Siemens central laboratory platforms, the Dimension® Rxl Max®, and Xpand® Plus integrated chemistry systems as well as the Dimension Vista® Intelligent Lab System. Siemens offers the only point-of-care/central-lab pair of instruments that demonstrates real cTnl harmony. 8,9,11

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

“...”

M.S. Sabatine et al., Circulation 2002
## Stratus CS Acute Care System
**Designed for Acute Care Diagnostics**

### System Specifications

<table>
<thead>
<tr>
<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>Assay Range</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.03–50 ng/mL</td>
<td>0.1–150 ng/mL</td>
<td>15–20,000 pg/mL</td>
<td>6–5000 ng/mL (mg/L)</td>
<td>0.1–50 ng/mL</td>
<td>1–900 ng/mL (mg/L)</td>
<td>0.5–1250 mIU/mL (SUL)</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 ng/mL</td>
<td>1.0 ng/mL</td>
</tr>
<tr>
<td>Reproducibility (CV)</td>
<td>5.1% at 0.64 ng/mL</td>
<td>10.0% 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/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%
- All hazardous materials are contained within a disposable waste liner

### 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 Storage Requirements)
- NT-proBNP CalPak: −10 to −20°C
- TestPaks, CalPaks, and DilPaks: 2 to 8°C
- Up to 3 separate TestPak lots per assay can be stored

### Calibration
- 30 days for NT-proBNP

### References:
11. Collins P, Global Perspective: Managing Cardiovascular Disease (Educational Video/CD-ROM)
14. Stratus CS cTnI TestPak (product insert)