Siemens Healthcare Diagnostics, the leading clinical diagnostics company, is committed to providing clinicians with the vital information they need for the accurate diagnosis, treatment and monitoring of patients. Our comprehensive portfolio of performance-driven systems, unmatched menu offering and IT solutions, in conjunction with highly responsive service, is designed to streamline workflow, enhance operational efficiency and support improved patient care.

Acute Care, CardioPhase, Dimension RxL Max, Dimension Xpand, Stratus, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.
Near-Patient Settings With Lab-Quality Results

Without exception, acute care depends on timeliness, safety and effectiveness;1,3 with this in mind, we at Siemens Healthcare Diagnostics offer you our solution for the near patient-settings.

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

Easy to Use by Personnel of All Skill Levels3,8,9,10
• 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

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.

The Benefits of Near-Patient Testing1,3
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.

Total costs associated with point-of-care cTnI testing decreased 25%.1,3

Stratus CS Acute Care Diagnostic System
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.

Turnaround time was reduced from 76 minutes to fewer than 20 minutes.

Total costs associated with point-of-care cTnI testing decreased 25%.1,3

Cost in Per Patient Admission

$17,163
$12,882

Routine Testing Stratus CS Acute Care diagnostic system

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
Markers You Need That Cover the Spectrum of Acute Cardiac Care

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.”

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.

The Stratus CS Acute Care Troponin I 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 cTnI harmony.

This also makes Stratus CS Acute Care diagnostic system a perfect fit as a back up solution in central laboratories and satellite sites.

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

NT-proBNP
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
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

D-Dimer
The valuable marker for the dyspnea patient
- High negative predictive value for venous thromboembolism (VTE)
- Excellent sensitivity
- High precision at the cut-off level

CKMB mass
The alternative to Troponin I
- Usable for re-infarction detection
- Estimation of infarct-size

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

First High Sensitivity Cardiac Troponin I Method
A high sensitive Troponin I method is defined by the joint ESC/ASCC committee as having an imprecision level of ≤ 10% at the 99th percentile of a normal population. 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).

Siemens Healthcare Diagnostics 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.”

M.S. Sabatine et al., Circulation 2002

R. Christenson et al., Clin Biochem 2004

IFCC Study validates the SCS cTnI precision profile. Pools fell directly on the line. Study lacked sufficient pools between 0.05 - 0.20 to accurately identify the 10% CV concentration. The SCS cTnl precision profile more accurately identifies the 10% CV concentration as 0.06 ng/mL.

0.07 ng/mL - URL 99th Percentile

10% CV @ 0.06 ng/mL

IFCC Study
Validates the SCS cTnI precision profile.
Stratus CS Acute Care System
Designed for Acute Care Diagnostics
System, Sample, and Reagent 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>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>FEU</td>
<td>0.1–50 ng/mL</td>
</tr>
</tbody>
</table>

| Sensitivity | 0.03 ng/mL | 0.3 ng/mL | 15.0 pg/mL | 6.0 ng/mL | 0.1 mg/mL | 1.0 ng/mL | 0.5 mIU/mL |

| Reproducibility (CV) | 5.1% at 0.64 ng/mL | 10% at 0.06 ng/mL | 4.0% at 3.7 ng/mL | 4.4% at 96.6 pg/mL | 4.1% at 412 ng/mL | 6.8% at 1.16 mg/mL | 3.4% at 56 ng/mL | 2.6% at 5.1 mIU/mL |

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 bar code 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 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 reviewed 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 (Storage: -10 to -20°C)

Calibration Stability
- 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

References
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