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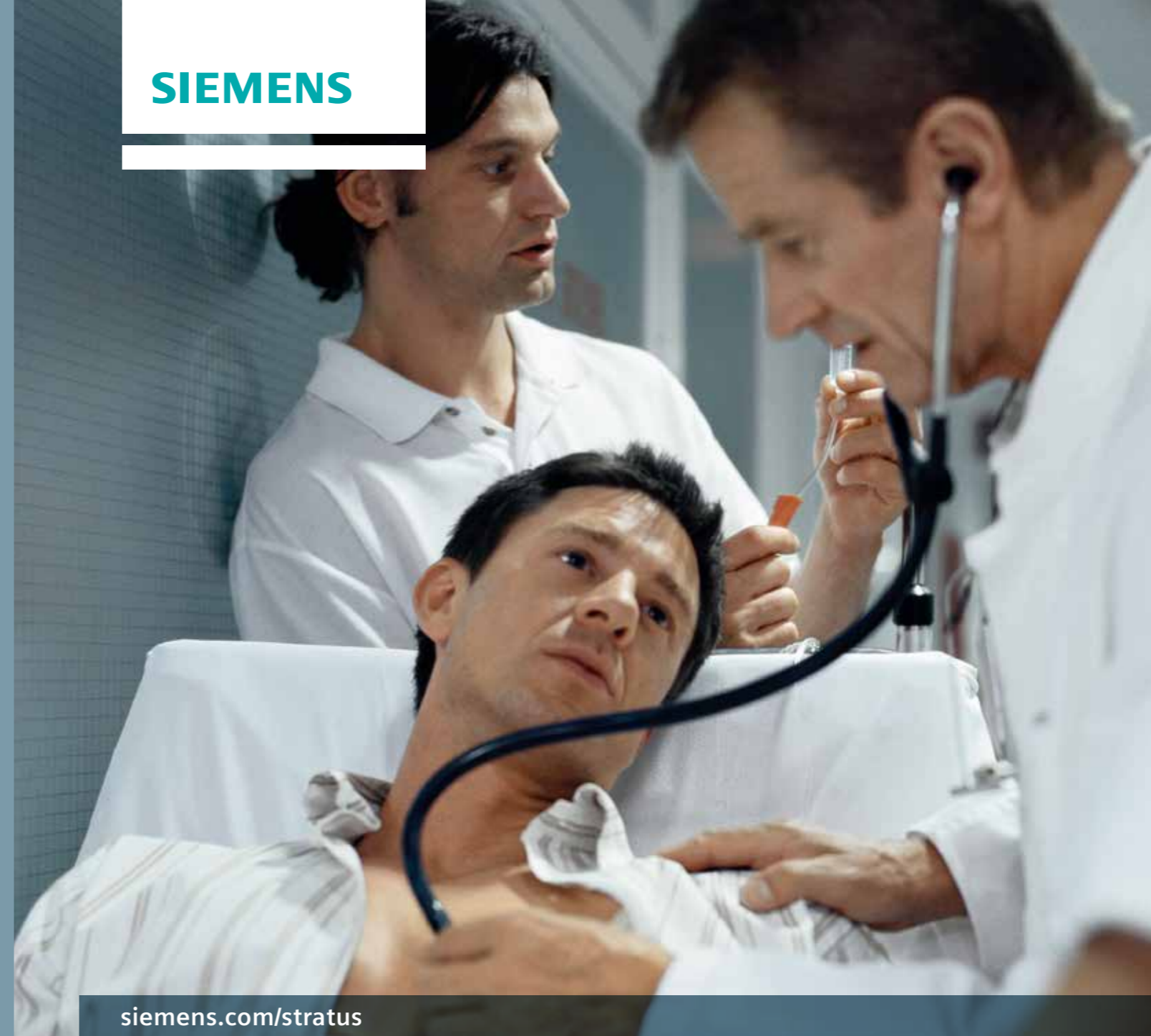
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## Rely on Its Proven Performance

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;<sup>1,2</sup> with this in mind, we at Siemens Healthcare Point of Care Diagnostics offer you our solution for the near-patient settings.

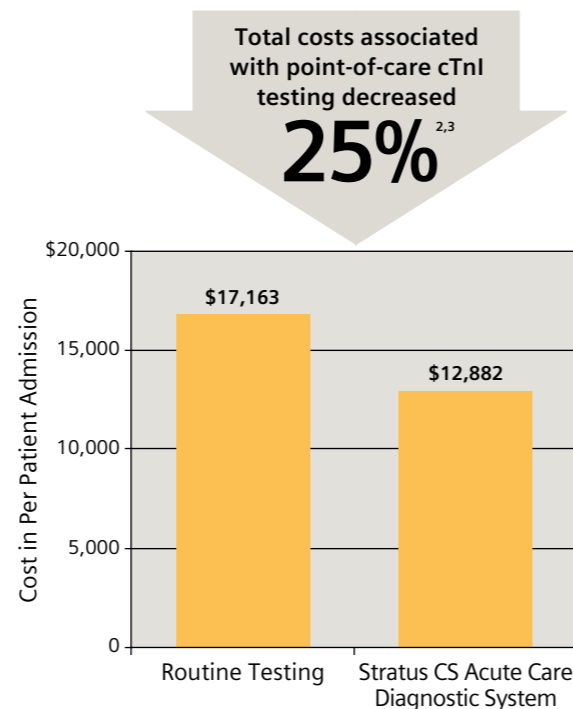
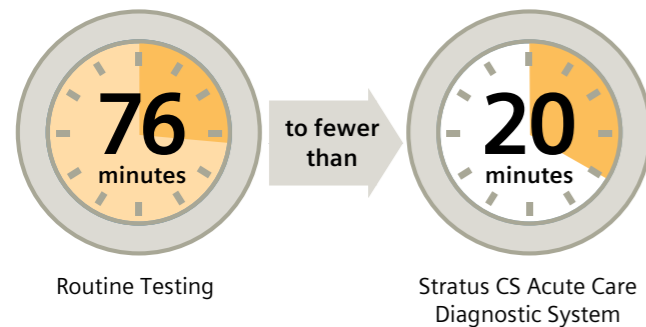


**The Stratus® CS Acute Care™ Diagnostic System is the perfect fit for your near-patient testing. Intelligent design guarantees ease of use together with gold-standard quality results. The system provides the necessary biomarkers to cover the spectrum of acute cardiac care.**

### The Benefits of Near-patient Testing<sup>2,3</sup>

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:



### 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 Levels<sup>4,5,6,7</sup>

- 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.

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



# Markers You Need That Cover the Spectrum of Acute Cardiac Care

"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."<sup>2</sup>

M.S. Sabatine et al., Circulation 2002

## 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."<sup>8</sup>

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.<sup>8,9,10</sup>

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® 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.<sup>6,11,12</sup>

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

### Guideline Acceptable Troponin I

The preferred biomarker for myocardial necrosis<sup>8,9</sup>

- Meets internationally accepted guidelines (ESC/ACC/AHA/NACB/IFCC)<sup>8,9,11</sup>
- Excellent sensitivity and cardiac specificity<sup>13,14</sup>
- 99th percentile of normal: 0.07 ng/mL<sup>11,13</sup>
- 10% CV at 0.06 ng/mL

### NT-proBNP<sup>15,16</sup>

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<sup>8,9</sup>

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<sup>8,9</sup>

The alternative to Troponin I

- Usable for re-infarction detection<sup>17</sup>
- Estimation of infarct-size<sup>14</sup>

### Additional Assays Available on the Stratus CS Analyzer

#### D-Dimer<sup>18,19</sup>

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

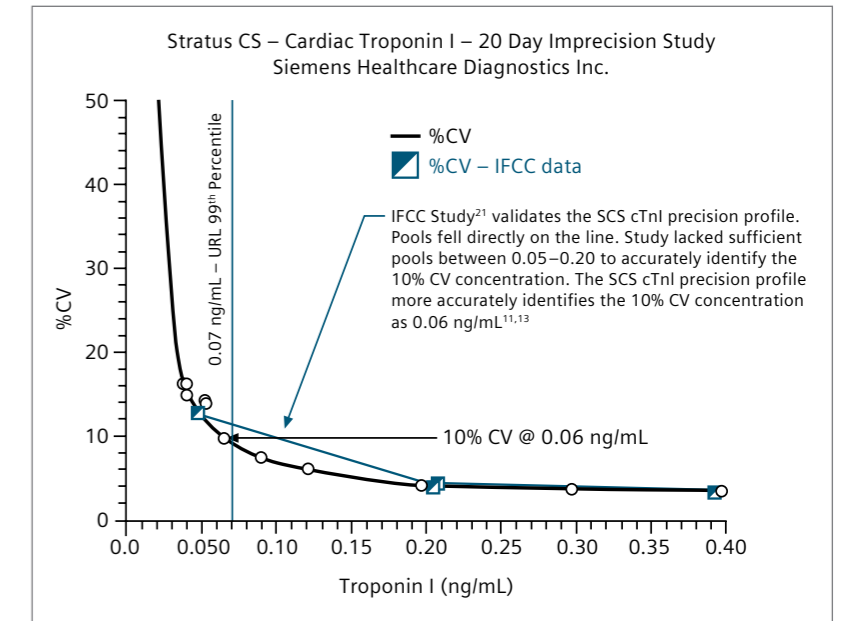
#### βhCG<sup>20</sup>

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

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

"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."<sup>11</sup>

R. Christenson et al., Clin Biochem 2004

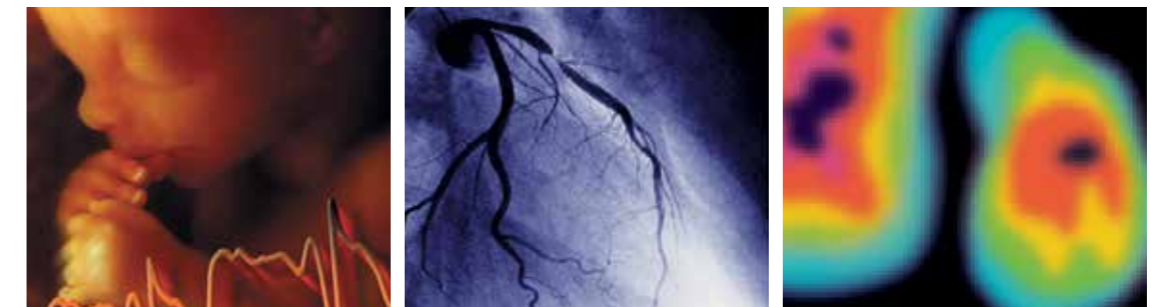


## First Guideline Acceptable Troponin I Method

A guideline acceptable 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.<sup>8,9,11,21</sup> 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).<sup>13</sup>

## Siemens Acute Care Markers

The system's robust and comprehensive cardiac marker panel provides reliable answers to critical questions.



\*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

	Troponin-I	CKMB	NT-proBNP	D-dimer	hsCRP	Myoglobin	βhCG
Assay Range	0.03–50 ng/mL (mg/L)	0.3–150 ng/mL (mg/L)	15–20000 pg/mL	6–5000 ng/mL (mg/L) FEU	0.1–50 mg/L	1–900 ng/mL (mg/L)	0.5–1250 mIU/mL (IU/L)
Sensitivity	0.03 ng/mL	0.3 ng/mL	15.0 pg/mL	6.0 ng/mL	0.1 mg/L	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/L	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 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 and NT-proBNP CalPak: -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

Ordering Information			
Catalog No.	SMN#	Product Description	Quantity
CCTNI	10445071	Stratus CS Acute Care Troponin I TestPak	100
CCTNI-CR	10445072	Stratus CS Acute Care cTnI CalPak	5
CCTNI-D	10445073	Stratus CS Acute Care cTnI DilPak	5
CCKMB	10445068	Stratus CS Acute Care CKMB TestPak	100
CCKMB-C	10445069	Stratus CS Acute Care CKMB CalPak	5
CCKMB-D	10445070	Stratus CS Acute Care CKMB DilPak	5
CPBNPM	10445086	Stratus CS Acute Care pBNP TestPak	100
CPBNPM-C	10445087	Stratus CS Acute Care pBNP CalPak	5
CPBNP-D	10445085	Stratus CS Acute Care pBNP DilPak	5
CDDMRE	10701511	Stratus CS Acute Care D-Dimer TestPak	60
CDDMR-C	10445076	Stratus CS Acute Care DDMR CalPak	5
CDDMR-D	10445077	Stratus CS Acute Care DDMR DilPak	5
CCCRP	10445066	Stratus CS Acute Care CCRP TestPak	60
CCCRP-C	10445067	Stratus CS Acute Care CCRP CalPak	5
CMYO	10445079	Stratus CS Acute Care Myoglobin TestPak	100
CMYO-C	10445080	Stratus CS Acute Care MYO CalPak	5
CMYO-D	10445081	Stratus CS Acute Care MYO DilPak	5
CBHCG	10445060	Stratus CS Acute Care βhCG TestPak	100
CBHCG-C	10445061	Stratus CS Acute Care βhCG CalPak	5
CBHCG-D	10445062	Stratus CS Acute Care βhCG DilPak	5
CROTOR	10445088	Centrifuge Rotor	100
CCANBD	10445063	BD Vacutainer® Cannula Adapter	100
CCANS	10445064	Sarstedt® Cannula Adapter	100
CCUPS	10445074	Sample Cups	100
CPAPER	10445082	Thermal Printer Paper	10
CTIPS	10445089	Pipette Tips	1,920
CLINER	10445078	Waste Container	50

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