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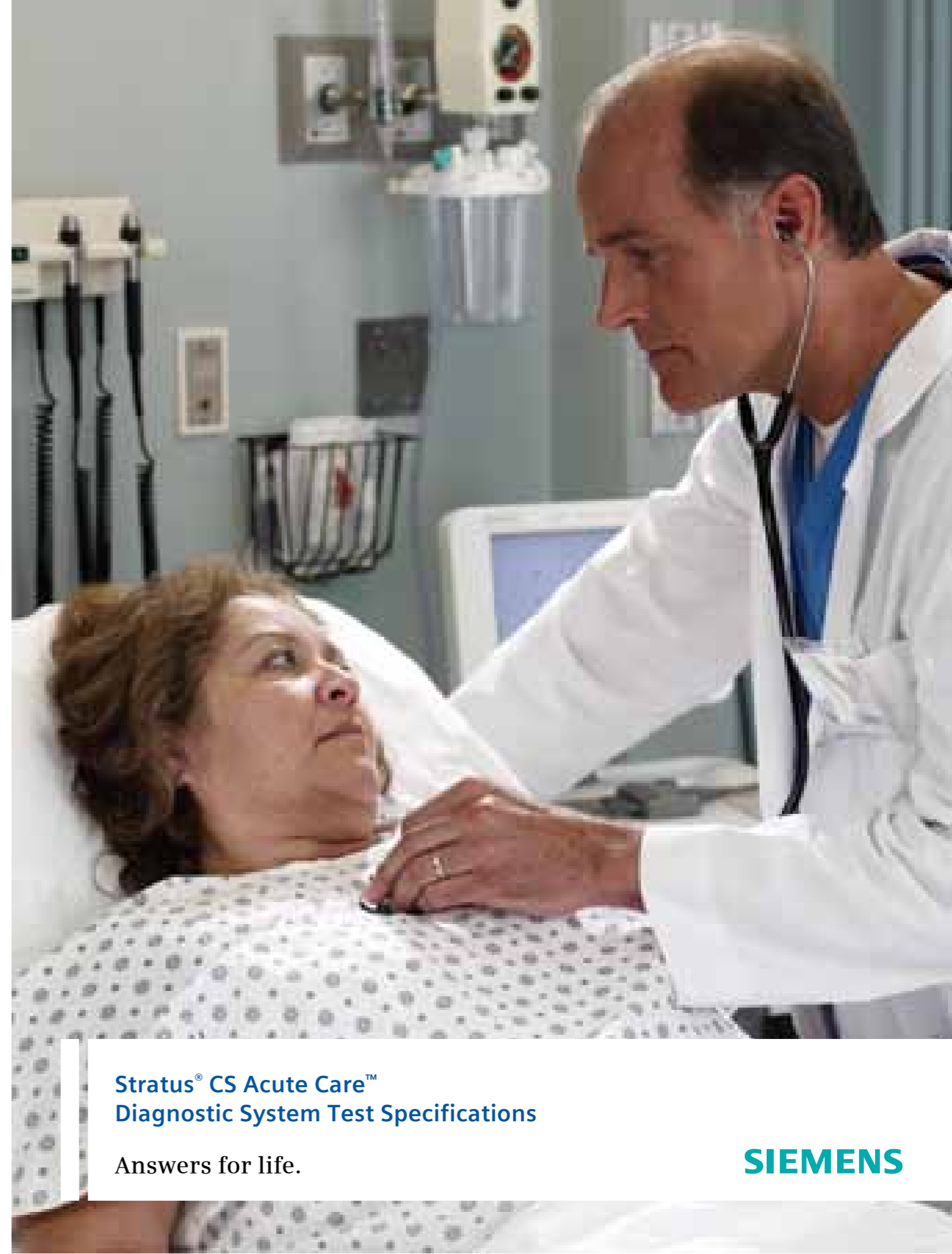
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**Stratus® CS Acute Care™
Diagnostic System Test Specifications**

Answers for life.

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Insert Sheet Summary

Precision					Correlation				Recommended Specimens
Method	Units SI	Mean	Within Run SD (%Cv)	Total SD (%Cv)	Slope	Intercept	Coefficient	N	WB, P ¹
βhCG	mIU/mL [IU/L]	13.4	0.26 (1.9)	0.31 (2.3)	Correlation to Dimension® Clinical Chemistry System				WB, P ¹
		111.0	2.7 (2.4)	2.4 (2.2)	0.94	-1.5	0.996	122	WB, P ¹
		456.7	11.3 (2.5)	11.9 (2.6)					
		1055.8	29.9 (2.8)	27.2 (2.6)					
CKMB	ng/mL [ug/mL]	3.7	0.14 (3.9)	0.15 (4.0)	Correlation to Stratus® II Immunoassay System				WB, P ¹
		18.3	0.65 (3.5)	0.75 (4.1)	0.97	0.65	0.988	215	WB, P ¹
		39.3	1.15 (2.9)	1.27 (3.2)					
cTnl	ng/mL [ug/L]	0.344	0.009 (2.7)	0.014 (4.0)	Correlation to Stratus II Immunoassay System				WB, P ¹
		0.122	0.007 (5.8)	0.007 (5.9)	0.90	0.12	0.988	211	
		0.067	0.005 (8.2)	0.005 (8.2)	Correlation to Dimension Clinical Chemistry System				
					0.93	0.0	0.99	163	
DDMR	ng/mL [ug/L] FEU	412	11.4 (2.8)	17.1 (4.1)	Correlation to Vidas® D-DIMER				WB, P ⁵
		1311	51.2 (3.9)	74.5 (5.7)	0.995	159.2	0.923	123	
		3679	99.1 (2.7)	99.1 (2.7)					
cCRP	mg/L	3.52	0.30(8.5)	0.33(9.5)	Correlation to Siemens CardioPhase® hsCRP				WB, P ¹
		20.81	0.88(4.2)	1.00(4.8)	0.952	0.098	0.999	154	
MYO	ng/mL [ug/L]	56	1.55 (2.8)	1.87 (3.4)	Correlation to Stratus® II Immunoassay System				WB, P ¹
		142	6.53 (4.6)	6.53 (4.6)	0.97	8	0.987	203	
		308	11.99 (3.9)	12.71 (4.1)					
PBNP	pg/mL	96.6	3.6 (3.7)	4.2 (4.4)	Correlation to Elecsys® proBNP				WB, P ¹
		363.7	11.0 (3.0)	12.4 (3.4)	0.96	39	0.99	78	
		6027.7	253.6 (4.2)	258.6 (4.3)					

Note: This is a summary of the general, overall precision data for each assay. For more detailed information see the individual package insert (IFU) for each method.



Method Specifications								
Method	Sample Volume (mL)	Analytical Measurement Range	Reference Interval	Decimal Places	Recommended Diluent ³	Calibration Frequency ⁶	Calibration Material ⁴	Tests/Pak
βhCG	75	0.5–1250 mIU/mL [IU/L]	0–3 mIU/mL F ⁷ (non-pregnant) 0–0.5 mIU/mL M ⁹	1	βhCG DilPak	90 Days	βhCG CalPak	100
CKMB	70	0.3–150 ng/mL [ug/L]	0.6–3.5 ng/mL	1	CKMB DilPak	60 Days	CKMB CalPak	100
cTnl	90	0.03–50 ng/mL [ug/L]	0.00–0.07 ng/mL 99th percentile ²	2	cTnl DilPak	60 Days	cTnl CalPak	100
DDMR	75	6 - 5000 ng/mL [ug/L] FEU	<552 ng/mL (citratd plasma) <682 ng/mL (lithium heparin plasma)	0	DDMR DilPak	60 Days	DDMR CalPak	60
cCRP	50	0.1–50 mg/L	<1.0 Low Risk 1.0-3.0 Average Risk >3.0 High Risk ⁸	2	N/A	60 days	CCRIP CalPak	60
MYO	70	1–900 ng/mL [mg/L]	21–98 M 19–56 F 20–82 C	0	MYO DilPak	60 Days	MYO CalPak	100
PBNP	50	15–20000 pg/mL	Patients < 75 years: 125 pg/mL Patients ≥ 75 years: 450 pg/mL	0	pBNP DilPak	30 Days	pBNP CalPak	100

1. Only 4 mL B-D Vacutainer tubes with Hemogard closure (sodium and Lithium heparin) and 2.6 mL Lithium heparin Monovette tubes can be used.
2. For other cutpoints, see package insert.
3. Automated 1:5 dilution with DilPak. Higher dilutions require manual dilution. See package insert.
4. Six-point calibration curve set in barcode by manufacturer. Calibration update performed by customer.
5. Only the 4.5 ml B-D Sodium Citrate tube and the 4 mL BD Lithium Heparin tube have been qualified for use on the Stratus CS. Citrate Sarstedt Monovette® tubes can be used. Fill sodium citrated tubes completely.
6. Or every new TestPak lot.
7. See insert for gestational age ranges.
8. Risk Stratification: Patient with CRP >10mg/L experience a high event rate (mortality of MI) than patient with a CRP <10 mg/L
9. This test is not intended for use as a surrogate marker for aiding in the diagnosis or monitoring the treatment of cancer patients.

