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The Preferred Biochemical Marker for Myocardial Injury

Stratus CS Acute Care Troponin I Assay
Lab-quality cardiac testing at the point of patient care

Stratus CS Acute Care Troponin I Assay – Clinical Utility

The Stratus® CS Acute Care™ Troponin I (cTnI) Assay is an in vitro diagnostic test that can be used as an aid in detection of acute myocardial infarction, meeting ESC/ACC Joint Committee recommendations of ≤10% CV at the 99th percentile of a reference population.

Siemens' cTnI two-site sandwich assay is offered in a convenient TestPak format, and runs on the Stratus CS Acute Care Diagnostic System to measure cardiac troponin I levels in whole blood or plasma. Cardiac troponin I measurements determined by high-sensitivity assays may be used as an aid in the diagnosis of acute myocardial infarction (AMI), and in the risk stratification of patients with acute coronary syndromes.

Diagnosis of AMI

Given impressive levels of myocardial specificity and sensitivity, the European Society of Cardiology (ESC)/American College of Cardiology (ACC) Joint Committee has recognized troponin as the preferred biochemical marker for myocardial damage, and has redefined acute myocardial infarction, in part, as a rise and gradual fall of troponin levels.[1]

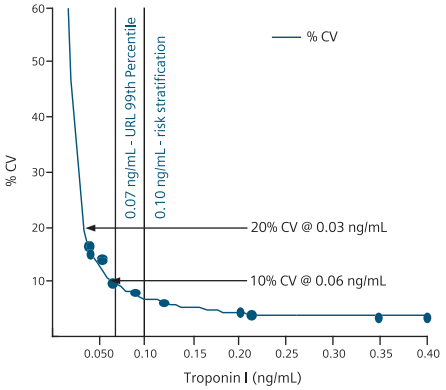
The committee further defines an increased troponin level as a measurement exceeding the 99th percentile of the reference interval, with an acceptable imprecision for measurements at the 99th percentile being ≤10% CV.[2]

Stratus CS Acute Care Troponin I Assay Siemens Healthcare Diagnostics 20 Day Imprecision Study*

The imprecision profile demonstrates a CV of 10% at a troponin I concentration of 0.06 ng/mL, indicative of a high sensitivity assay.

Risk Stratification

In patients with acute coronary syndromes such as unstable angina or non-Q-wave MI, troponin I levels provide useful prognostic information and aid in early detection of such patients with an increased risk of mortality. Any elevation in cardiac troponin should be viewed as useful prognostic information.



*All specific performance characteristics tests were run after normal recommended equipment quality control checks were performed (refer to the Stratus CS Operator Guide).

Answers for life.

Stratus CS Acute Care Troponin I Assay

Specifications

Sample Type	Test Volume	Analytical Measurement Range	Functional Sensitivity	Analytical Sensitivity	Assay Time
Whole blood* in lithium/sodium minutes heparin, or heparinized plasma**	90 µL	0.03 – 50 ng/mL	0.03 ng/mL	< 0.03 ng/mL	14

*Whole blood sample must be collected in a tube qualified for use on the Stratus CS Acute Care Diagnostic System. Minimum volume requirements will vary depending on the qualified collection tube used.
**Dispensed in a sample cup.

Precision

Material	Mean (ng/mL)	Standard Deviation (% CV) Within Run	Total
Human Plasma Pools[a]			
Plasma Pool 1	0.344	0.009 (2.7)	0.014 (4.0)
POC cTnI			
Plasma Pool 2	0.122	0.007 (5.8)	0.007 (5.9)
Plasma Pool 3	0.067	0.005 (8.2)	0.005 (8.2)
Liquichek™ Cardiac Markers Control[a]			
Level 1	0.64	0.03 (4.3)	0.03 (5.1)
Level 2	3.29	0.09 (2.7)	0.12 (3.5)
Level 3	6.48	0.22 (3.4)	0.22 (3.4)

This is a summary of precision information. For more detailed precision data see package insert (IFU).

a. Specimens at each level were analyzed in duplicate for 20 runs. Within Run and Total standard deviations were calculated by analysis of variance.

Liquichek™ Cardiac Markers Control – Bio-Rad Laboratories ECS Division, Irvine, CA.

*Samples with cTnI concentrations between 50.0 – 250 ng/mL can be run using a cTnI DilPak along with a cTnI TestPak. The instrument will automatically perform a 1:5 dilution of the sample. The result obtained is corrected for the dilution factor. Samples with cTnI concentrations > 250 ng/mL can be tested after manually diluting the sample using normal human plasma (cTnI negative) as the diluent.

Ordering Information

Catalog No.	Contents	No. of Tests
CCTNI	• Stratus CS Acute Care cTnI TestPak	100

Materials required but not provided

Catalog No.	Description	Calibration Frequency
CCTNI-CR	• Stratus CS Acute Care cTnI CalPak	Every new TestPak lot Every 60 days per lot
CCTNI-D	• Stratus CS Acute Care cTnI DilPak* • Quality Control Materials	Every new TestPak lot

References
1. Alpert JS, et al. J Am Coll Cardiol. 2000; 36(3): 959-969.
2. Myocardial Infarction Redefined – A Consensus Document of The Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction.

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