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Case
Study

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Troponin I Testing Improves Cardiac Interventions

Community Hospital of the Monterey Peninsula

Troponin I Testing Improves Cardiac Interventions at the Community Hospital of the Monterey Peninsula

Immediate cardiac care is one of the many healthcare specialties provided by Community Hospital of the Monterey Peninsula (CHOMP), a nonprofit hospital founded in 1934. Situated in Monterey, California, CHOMP supports 220 acute-care and 28 skilled-nursing beds and delivers services across 15 sites. The hospital was designed to create a healing environment, incorporating extensive use of natural light and art, and to capitalize on its surroundings in a pine forest with views of the Pacific Ocean.

CHOMP is accredited as a chest pain center by the Society of Cardiovascular Patient Care (SCPC), a status that recognizes the hospital's expertise in responding to, treating, and caring for patients who arrive with symptoms of a heart attack. Hospitals that receive SCPC accreditation carry out standardized diagnostic and treatment programs that provide more efficient and effective evaluation as well as more appropriate and rapid treatment of patients presenting with chest pain and other acute cardiac symptoms.

Critical diagnostics in place at CHOMP supporting cardiac-care excellence include the Siemens Healthcare Troponin I (cTnI) test running on the Stratus® CS Acute Care™ Diagnostic System.

Elevated cardiac troponin is an indicator of myocardial damage

Cardiac troponin proteins are released into the blood within hours of the onset of symptoms of myocardial infarction, and they remain for several days post-myocardial infarction.¹ Measurement of cardiac troponin I levels provides a sensitive and specific determination of myocardial injury over a wide diagnostic time frame. Given troponin's high specificity and sensitivity, the Joint European Society of Cardiology/American College of Cardiology Committee recognizes troponin as the preferred biochemical marker for myocardial damage. The results of cardiac troponin testing serve as guidance for intervention in instances of suspected heart attack. Cardiac troponin I measurements can be used as an aid in the diagnosis of acute myocardial infarction (AMI) and in risk stratification of patients with acute coronary syndrome (ACS).

cTnI test on the Stratus CS system

The Siemens Stratus CS system's cTnI method is an in vitro diagnostic assay for the measurement of cardiac troponin I protein in heparinized plasma. The test is approved as guideline acceptable, meeting the Joint European Society of

Cardiology/American College of Cardiology Committee's recommended assay imprecision level for troponin I of $\leq 10\%$ at the 99th percentile of a normal population.

The Stratus CS system is easy to use in point-of-care environments such as the emergency department and the coronary-care unit. First results in as little 14 minutes (and results in 4-minute intervals thereafter) support the fast and accurate evaluation of patients presenting with symptoms of an acute cardiac condition.

The Stratus CS system provides a panel of other biomarkers (including NT-proBNP, myoglobin, *CardioPhase*® CRP, and CKMB mass) to cover the spectrum of cardiac conditions.

Comparative evaluation of troponin I testing at CHOMP

Community Hospital of the Monterey Peninsula installed two Stratus CS systems in January 2015. Familiarization runs were conducted in the main laboratory. "Our plan was to get comfortable with protocols and procedures and then move the instruments to the emergency department," says Jay Wilkerson, director of Laboratory Services.



"We intended to use the Stratus CS system to support more effective cardiac interventions in near-patient situations. We were surprised when we found that the system was reporting far fewer false-positive troponin I results than the primary analyzer we were relying on in the main lab."

Jay Wilkerson
Director of Laboratory Services
Community Hospital of the Monterey Peninsula

Study conclusions

The study demonstrated a significantly higher rate of false-positive troponin I results on CHOMP's in-place laboratory instrument and indicated that the Stratus CS system had higher positive predictive specificity and utility for AMI, potentially eliminating the need for additional (and costly) follow-up assessment and extended patient stays. Higher test specificity did not appear to come at the cost of lower test sensitivity.

Summary

The comparative evaluation of troponin I testing at CHOMP demonstrated that the Siemens Stratus CS Acute Care Diagnostic System—an analyzer originally chosen for its point-of-care utility—delivered results that were a better indicator of a patient's cardiac status than results generated on a platform routinely used in many central laboratories.

As a result, the Stratus CS Acute Care system is now the analyzer of choice for all laboratory cardiac troponin I testing at the Community Hospital of the Monterey Peninsula.

Summary of discrepant samples that were followed with chart review.

Sample ID	Ortho (ng/mL)	Stratus CS System (ng/mL)	MI
S00002	0.054	0.015	No
S00003	0.048	0.04	No
S00005	0.049	0.035	No
S00007	0.07	0.03	No
S00016	0.034	0	No
S00024	0.041	0.01	No
S00025	0.045	0.01	No
S00027	0.052	0.02	No
S00029	0.047	0.01	No
S00033	0.051	0	No
S00048	0.034	0.01	No
S00050	0.065	0.03	No
S00051	0.051	0.025	No
S00053	0.034	0	No
S00060	0.042	0	No
S00061	0.041	0.005	No

The outcomes obtained by the Siemens customer described here were realized in the customer's unique setting. Since there is no typical laboratory, and many variables exist, there can be no guarantee that others will achieve the same results.

References:

- Cummins B, Auckland MS, Cummins P. Cardiac-specific troponin-I radioimmunoassay in the diagnosis of acute myocardial infarction. *American Heart Journal*. 1987;113(6):1333-44.
- Myocardial Infarction Redefined – A Consensus Document of The Joint European Society of Cardiology/ American College of Cardiology Committee for the Redefinition of Myocardial Infarction.

"We concluded that the Stratus CS system cTnI test was a superior predictor of acute myocardial infarction. It's no surprise that we are now using Stratus CS analyzers for all troponin I tests."

Jay Wilkerson
Director of Laboratory Services
Community Hospital of the Monterey Peninsula

"We considered other suppliers' near-patient troponin I test instruments, but concluded that the Stratus CS system would best meet our needs. We expected good performance but we didn't expect results that were dramatically better than those generated by a primary analyzer in the main laboratory."

Jay Wilkerson and his team conducted a study to compare the clinical specificity of the Stratus CS cTnI test against troponin I test specificity on an integrated laboratory platform, Ortho Clinical Diagnostics Vitros® 5600 Integrated System. 89% of results falling within the clinical decision window were discrepant. 71% of random specimens tested were positive on the primary analyzer, but when these same specimens were tested on the Stratus CS system, only 8% reported positive. A positive result was defined as one above the manufacturer's 99th percentile upper reference limit.

16 discrepant result pairs were chosen at random for review against patient charts; the findings were surprising. Chart review showed further work-up and prolonged patient hospital stays but no evidence of AMI in any of the cases.

"In other words, the Stratus CS troponin I measurement correctly determined the clinical condition of the patient in all of these 16 cases," Jay Wilkerson explains. "Our primary analyzer gave false-positive results that did not accurately represent the patient state."



Stratus CS Acute Care Diagnostic System