RESPONSE BIOMEDICAL

RAMP® Troponin I

Method Comparison Study
vs. Abbott i-STAT® cTnI, the Quidel Triage® Troponin I Test and the Abbott ARCHITECT® Laboratory System

Troponin I and Myocardial Infarction (MI)

Myocardial infarction (MI) is cardiac cell death due to prolonged ischemia, and is a leading cause of morbidity and mortality worldwide. Chest pain radiating to the arms, back, jaw and upper body is the most common presentation of MI in the emergency department; however, one-third of MI patients do not present with chest pain, but instead with non-specific symptoms such as shortness of breath, fatigue, anxiety, dizziness, heartburn/indigestion, vomiting/nausea or heart palipitations.[1,2] Further, electrocardiogram (ECG) findings may be absent or inconclusive.[3]

The cardiac isoforms of troponin I (cTnI) and T (cTnT) are tissue-specific for the myocardium and are the excellent biomarkers for the detection of myocardial injury/cell death.[5] Because cTn levels a can be associated with non-ischaemic myocardial injury – this is especially true of cTnT which can also be elevated with other conditions such as skeletal muscle damage or chronic kidney disease – detection of a rise and/or fall of cTn values is essential to establish the diagnosis of acute MI.[6]

Method Comparison Study

A method comparison was conducted at Minneapolis Medical Research Foundation - Hennepin County Medical Center (MMRF-HCMC) by Dr. Fred Apple's laboratory (Cardiac Biomarkers Trials Lab (CBTL)) evaluating the performance of the RAMP Troponin I test on the RAMP 200 versus the Abbott i-STAT cardiac troponin (cTnI) Immunoassay, the Quidel Triage Troponin I test and the Abbott ARCHITECT laboratory system.

Frozen (-80°C) plasma (EDTA) clinical specimens from the IRB-approved CBTL ACS specimen bank at MMRF-HCMC were obtained and tested across all four methods over 2 days in May 2014. Samples were tested within 2 hours of sample thaw; results from 79 specimens were included in the analysis. No information on patient presentation, other clinical findings, or final diagnosis was included the analysis, therefore it cannot be inferred that the cause of the elevation in Troponin levels observed was due to acute myocardial infarction (AMI).

Concordance between the four tests was determined using the 99th percentile of each test as the cut-off value (Tables 1 and 2). Further data analysis was performed using the Passing and Bablok regression analysis method described in CLSI guideline EP09-A3 – *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition*. 34 results were excluded from the Triage analysis as the results were non-numerical (i.e. "<0.05"); Spearman correlation coefficients (r_s) were also determined (Figure 1).

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Table 1. Analysis of Concordance vs. the Abbott ARCHITECT

	Concordance to Abbott ARCHITECT Cut-off 0.03 ng/mL
RAMP Troponin I Cut-off 0.10 ng/mL	**67%**
Abbott i-STAT cTnI Cut-off 0.08 ng/mL	62%
Quidel Triage Troponin I Cut-off 0.05 ng/mL	65%

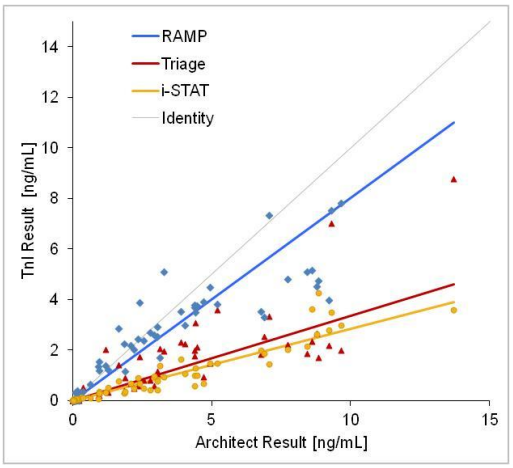
Table 2. Analysis of Concordance of RAMP Troponin I vs. i-STAT cTnI and Triage Troponin I

	Concordance to RAMP Troponin I Cut-off 0.10 ng/mL
Abbott i-STAT cTnI Cut-off 0.08 ng/mL	92%
Quidel Triage Troponin I Cut-off 0.05 ng/mL	97%

2 samples that were negative by Triage Troponin I and 5 samples that were negative by i-STAT were positive by RAMP Troponin I, in agreement with the ARCHITECT.

In these cases, RAMP was able to detect increases above the 99th percentile that were undetected by the other systems.

Figure 1. Passing and Bablok Regression and Correlation Analyses of RAMP Troponin I, Quidel Triage Troponin I and Abbott i-STAT cTnI vs. the Abbott ARCHITECT System



	Regression	Correlation, r_s
RAMP Troponin I	**0.80x – 0.02**	**0.95**
Quidel Triage Troponin I	0.33x + 0.01	0.95
Abbott i-STAT cTnI	0.28x + 0.01	0.83

Conclusion

RAMP Troponin I shows similar performance to both the Abbott i-STAT cTnI and Quidel Triage Troponin I tests. When compared to the Abbott ARCHITECT laboratory system, RAMP Troponin I shows superior concordance, slope and correlation than the other two tests.

1 Thygesen et al. Circulation 2007, **116(22)**:2634-53.
2 Canto et al. *JAMA* 2000. **283**(24):3223-9.
3 Amsterdam et al. 2014 AHA/ACC NSTE-ACS Guideline. *Circulation*, 2014
4 Thygesen et al. *Circulation* 2012, **126**(16):220-35.
5 Cummins et al. *Am Heart J* 1987. **113**:1333-1344.
6 Thygesen et al. *Circulation* 2018, **138**:w618-e651.

For more information about this study or RAMP Acute Care Diagnostics products, please contact Response Biomedical Corp. Technical Support.

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