Evaluation of RAMP Whole Blood Analyzer for Point of Care Troponin I and NT-proBNP Testing

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Introduction

- Accurate and rapid measurement of bio-markers aid in the diagnosis of cardiovascular disease[1].
- This study evaluates the performance of the RAMP Point of Care whole blood tests for Troponin I (TnI), and N-terminal pro-brain natriuretic peptide (NT-proBNP).
- TnI testing methods are not harmonized and normal reference ranges and method comparisons are required to establish clinical cut-offs.
- NT-proBNP assays are harmonized and common clinical cut-offs and ranges have been established[2,3].

Methods and Materials

- EDTA and heparinized blood samples were collected from patients for whom testing was clinically indicated, n=46 (TnI) and n=42 (NT-proBNP).
- EDTA samples were collected from subjects without cardiac symptoms to determine the 99th percentile cut-off for the RAMP TnI test, n=100.
- Method comparisons and clinical concordance analysis were carried out for RAMP versus:
  - Centaur Ultra Sensitive TnI (Siemens Medical Diagnostic Solutions, Germany).
  - Roche Elecsys 2010 proBNP (Roche Diagnostics, Indianapolis, IN).
- EDTA whole blood samples analyzed on RAMP; heparinized plasma samples analyzed on Centaur (TnI) or Elecsys (NT-proBNP).

Results: Clinical Agreement

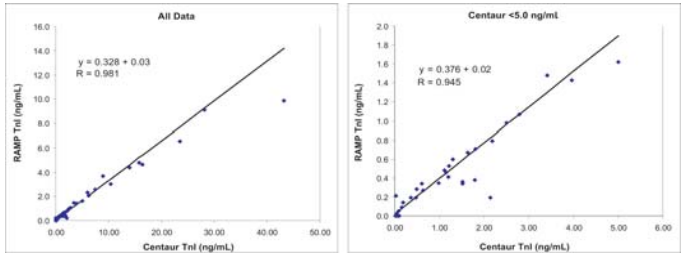
TnI: Normal range (99th percentile) cut-off on RAMP was determined as 0.16 ng/mL (CV = 18%). A 0.06 ng/mL cut-off was used for the Centaur.

NT-proBNP: 300 pg/mL age independent rule out was used on both systems[2].

	TnI	NT-proBNP
Sensitivity	87.2%	97.1%
Specificity	85.7%	100%
Concordance	87.0%	97.6%

Results: Troponin I

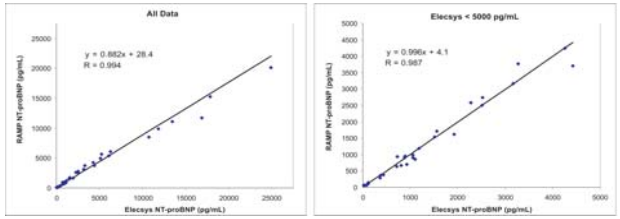
Passing & Bablok analysis of RAMP versus Centaur for TnI



RAMP TnI correlated strongly with the Centaur TnI (Pearson R=0.981, n=45, one outlier excluded). Strong correlation was maintained when the analysis was confined to samples with TnI levels <5.0 ng/mL by Centaur (Pearson R=0.945; n=31).

Results: NT-proBNP

Passing & Bablok analysis of RAMP versus Roche Elecsys



RAMP NT-proBNP correlated strongly with the Elecsys proBNP (Pearson R=0.994, n=41, one out of range value excluded) across a wide range of NT-proBNP values. Strong correlation was maintained when analysis was confined to samples <5000 pg/mL (Pearson R=0.987, n=31).

Conclusions

- The RAMP TnI assay correlates strongly with the Centaur TnI assay and using an appropriately defined cut- off point, provides accurate diagnostic results in less than 20 minutes.
- The RAMP NT-proBNP assay correlates strongly with the Roche Elecsys proBNP assay and provides accurate diagnostic results in 15 minutes.

Bibliography

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3 Januzzi JL, Camargo CA, Anwaruddin S, et al. The N-terminal Pro-BNP investigation of dyspnea in the emergency department (PRIDE) study. Am J Cardiol. 2005;95:948-954.

*RAMP NT-proBNP Assay: CE marked; Currently under FDA / Health Canada review.