

Clinical Utility of the RAMP Whole Blood NT-proBNP Assay for the Exclusion of Acute Heart Failure

G Arthur¹, E Winckel², A Jung², T Lamy³, ML Zucker¹, and M Offner²

¹Response Biomedical Corporation, Burnaby, BC, Canada, ²Laboratoire de Biochimie Générale et Spécialisée, Hôpital Civil, Strasbourg, France, ³All.DIAG.SA, Strasbourg, France

Introduction

- Current methods for diagnosis and assessment of Heart Failure (HF) are often not conclusive.
- Accurate evaluation and management of acute dyspnea remains a significant clinical challenge^{1,2}.
- Blood levels of NT-proBNP:
 - are indicative of the degree of heart failure
 - augment diagnosis and clinical judgment^{3,4}.
 - have been used for risk stratification of patients with acute coronary syndrome and congestive HF^{5,6}.

Chronic HF	
HF Unlikely	Possible HF
< 125 pg/mL < 75 yrs	> 125 pg/mL < 75 yrs
< 450 pg/mL ≥ 75 yrs	> 450 pg/mL ≥ 75 yrs
+ additional investigations	

Acute HF		
Unlikely	Possible	Probable
< 300 pg/mL	300 pg/mL to probable cut-off	> 450 pg/mL < 50 yrs
		> 900 pg/mL 50-75 yrs
		> 1800 pg/mL > 75 yrs
+ additional investigations		

- Compared with centralized lab testing, Point of Care testing (POC) allows clinical decisions to be made rapidly by reducing the time to receive test results.

Aims

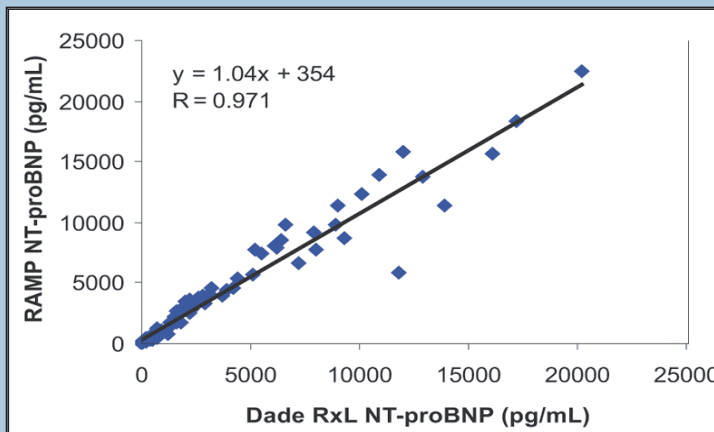
This study was conducted to compare the RAMP POC and lab based Dade Dimension RxL systems for measurement of NT-proBNP levels in patients suspected of having HF.

Methods and Materials

- Patients (n=91) suspected of HF enrolled (no age data available).
- EDTA and heparin anticoagulated blood samples were obtained.
- NT-proBNP determined on:
 - Dade Dimension RxL analyzer (Dade-Behring, Deerfield, IL)
Heparinized plasma in hospital laboratory
 - RAMP Reader (Response Biomedical Corporation, Burnaby, BC)
EDTA whole blood samples in near patient setting

Results: Method Comparison

86 of 91 patient samples measured had NT-proBNP levels within the reportable ranges of both test systems (5-35,000 pg/mL).



Linear regression analysis showed excellent correlation ($R=0.971$) between the two systems and a slope of 1.04

Results: Clinical Concordance

Clinical Concordance between RAMP and Dade Dimension RxL	
Cut-off	300 pg/mL
Sensitivity %	100
Specificity %	76.2
Positive Predictive Value %	93.3
Negative Predictive Value %	100
Concordance %	94.5

Clinical concordance analysis showed excellent clinical agreement between the RAMP and the Dimension.

Conclusions

- The RAMP NT-proBNP whole blood assay is an accurate indicator that can be used to rule-out acute HF in this patient population, with results comparable to the Dimension RxL laboratory analyzer.
- With results available in 15 minutes, the RAMP NT-proBNP Assay allows for rapid initiation of appropriate patient treatment.

Bibliography

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