RESPONSE BIOMEDICAL

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# RAMP® NT-proBNP

## Method Comparison Study vs the Roche Elecsys® proBNP II

### Introduction

RAMP NT-proBNP is a quantitative test that measures NT-proBNP levels in EDTA whole blood, providing lab quality results in 15 minutes. The purpose of this study was to compare the RAMP NT-proBNP assay and the Roche Elecsys® proBNP II assay.

### NT-proBNP and Heart Failure

Heart failure (HF) is the inability of the heart to pump well enough to meet the body's needs for blood and oxygen.[1] Symptoms of HF are non-specific (e.g. shortness of breath (dyspnoea), fatigue, weight changes) making it difficult to differentiate between HF and other diagnoses.[2] Natriuretic peptides such as NT-proBNP and BNP are commonly used as diagnostics biomarkers for HF as they have high diagnostic accuracy in distinguishing HF from other causes of dyspnoea.[3] They should be assessed in all patients presenting with symptoms indicative of HF as their use facilitates the early diagnosis and risk stratification of HF.[3] The biomarker of choice is NT-proBNP for patients suspected of HF as it has greater sensitivity and is stable over time.[4]

The National Institute for Health and Care Excellence (NICE) has updated its diagnosis and management of chronic heart failure guidelines in 2018.[4] The classical triad of symptoms displayed in patients with HF are breathlessness, ankle swelling, and/or fatigue. Clinical assessments should include a history of symptom onset, change in exercise tolerance, cardiovascular disease risk factors, and any history of cardiovascular disease. In addition, the patient's pulse, blood pressure, oxygen saturation, auscultation of the heart and lungs with assessment of fluid retention should be examined. In patients suspected of HF, a blood test for NT-proBNP or BNP is required to guide referral decisions.[4] For NT-proBNP levels above 400 pg/mL, the NICE recommends referral for transthoracic echocardiography and assessment with a specialist.[4]

### Methods and Materials

A method comparison study between RAMP NT-proBNP test on the RAMP 200 instrument versus the Roche Elecsys proBNP II immunoassay on the Cobas 6000 instrument was conducted in November 2023 at one community hospital in Virginia, United States. 101 paired serum and whole blood (EDTA) clinical waste samples were used for the evaluation. No information on patient presentation, other clinical findings, or final diagnosis could be gathered for the analysis.

### Results

As per the NICE guidelines, NT-proBNP threshold of 400 pg/mL (ng/L) was the optimal cut-off for referral for specialist assessment.[4] For the purpose of this analysis, the cut-off of 400 ng/L was used for the RAMP and Roche results.

The RAMP NT-proBNP test showed 98% concordance vs the Roche Elecsys proBNP II (Table 1). Patient diagnosis could not be obtained to confirm the discrepant results.

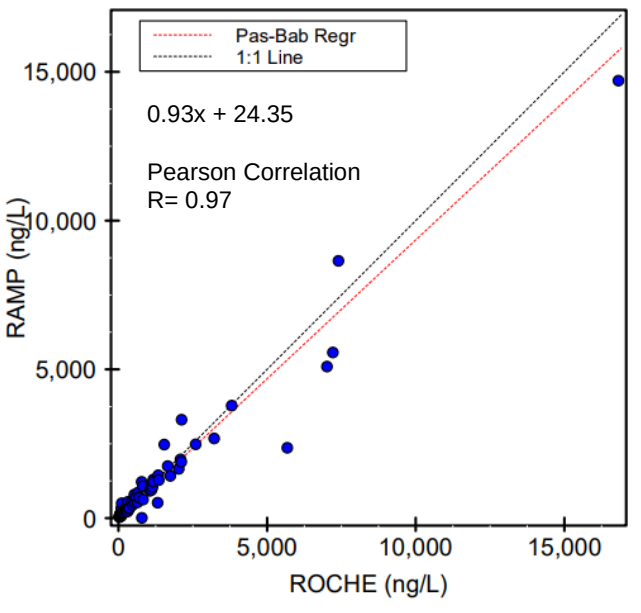
Table 1. Concordance Analysis of RAMP NT-proBNP vs Roche Elecsys proBNP II

| | | Roche Elecsys proBNP II | |
|---|---|---|---|
| | | **POS** | **NEG** |
| **RAMP NT-proBNP** | ***POS*** | 42 | 2 |
| | ***NEG*** | 0 | 57 |
| ***Concordance*** | | 98% | |

42 patients tested positive on both RAMP and Roche NT-proBNP II assay. 57 patients tested negative on both RAMP and Roche proBNP II assay. 2 patients tested negative on the Roche assay but tested positive on the RAMP assay. Information on final patient diagnosis was not available for the discrepant results.

Further data analysis was performed using the Passing and Bablok regression analysis method described in CLSI guidelines EP09-A3-Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition. 36 samples with a result of <36 ng/L or >22000 ng/L could not be included in the analysis due to the non-numerical result (Figure 1).

Figure 1. Passing and Bablock Regression and Correlation Analyses of RAMP NT-proBNP vs. Roche Elecsys proBNP II




## Conclusion

In this study, RAMP® NT-proBNP showed excellent performance with 98% concordance and R value of 0.97 when compared to the Roche Elecsys® proBNP II assay on Cobas.

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


[1] Peacock et al. JACC. 2010. 56(5): 343-351.
[2] Ponikowski et al. *European Heart Journal* 2016. 37(27): 2129–2200.
[3] Mueller et al. European Journal of Heart Failure 2019, 21(6): 715–731.
[4] Taylor et al. The British Journal of General Practice 2018. 69(682), 265–266



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