

# Analytical Validation of the Medcaptain Analyser for Cardiac Biomarker Testing in Emergency Settings

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## Objectives:

Concerns exist regarding the accuracy of point-of-care (POC) tests in emergency department (ED) settings compared to laboratory testing. This study aims to validate the Medcaptain Troponin I (hs-TnI), Heart Fatty Acid Binding Protein (HFABP), Suppression of Tumorigenicity 2 (ST2), and N-terminal Prohormone of Brain Natriuretic Peptide (NT-proBNP) assays, and to compare these results with routine laboratory methods.

## Methods:

The Medcaptain chemiluminescent immunoassay analyser was evaluated for HFABP, hs-TnI, ST2, and NT-proBNP quantification in human whole blood, serum, and plasma. Analytical validation included intra- and inter-assay variation, trueness, measurement uncertainty were performed with the internal quality controls, and method comparison using 23 residual samples for hs-TnI and NT-proBNP. The reference method was a microparticle chemiluminescence immunoassay (CMIA) performed on the Alinity i analyser. Passing-Bablok regression, Bland-Altman tests (MedCalc), and validation metrics (Enoval, Arlenda) were applied.



Figure 1: MedCaptain device (Analis)

## Results :

On the Medcaptain device, the maximum intra- and inter-assay CVs were 7% and 8.7% for hs-TnI, 11% and 15.74% for NT-proBNP, 5.5% and 6.7% for ST2, and 3.2% and 6.4% for HFABP (Table 1). The maximum relative bias was 12.8%, 20.4%, 5.8%, and 9.8%, and the maximum relative expanded uncertainty was 18.9%, 34.8%, 14.7%, and 14.3% for hs-TnI, NT-proBNP, ST2, and HFABP, respectively (Figure 2). The regression equation for NT-proBNP was: NT-proBNP Medcaptain = 104.02 + 1.01NT-proBNP Alinity (95% CI intercept: 50.27-280.90; 95% CI slope: 0.90-1.06). A small systematic difference of 2.3% on average was observed between the two methods. For hs-TnI, the regression equation was: hs-TnI Medcaptain = -685.257123 + 1.833114 hs-TnI Alinity (95% CI intercept: -1363.78-215.96; 95% CI slope: 1.66-2.07). A proportional difference of 42.2% was found between the two methods, likely due to different antibodies used in the kits (Figure 3 and 4).

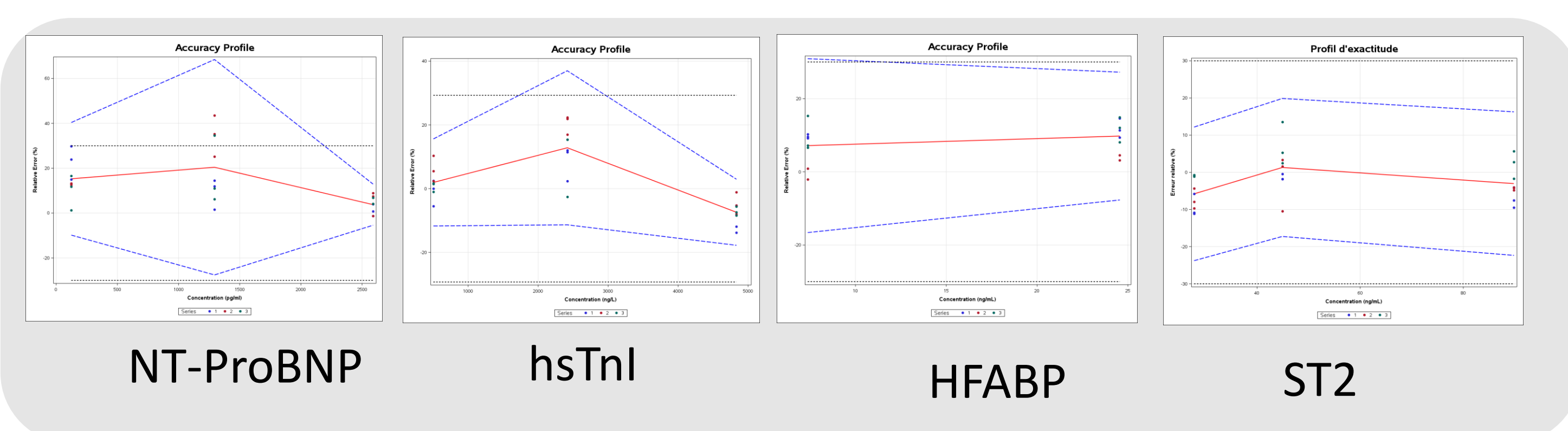


Figure 2: Comparison between routine lab method and POC method-Bland-Altman plot

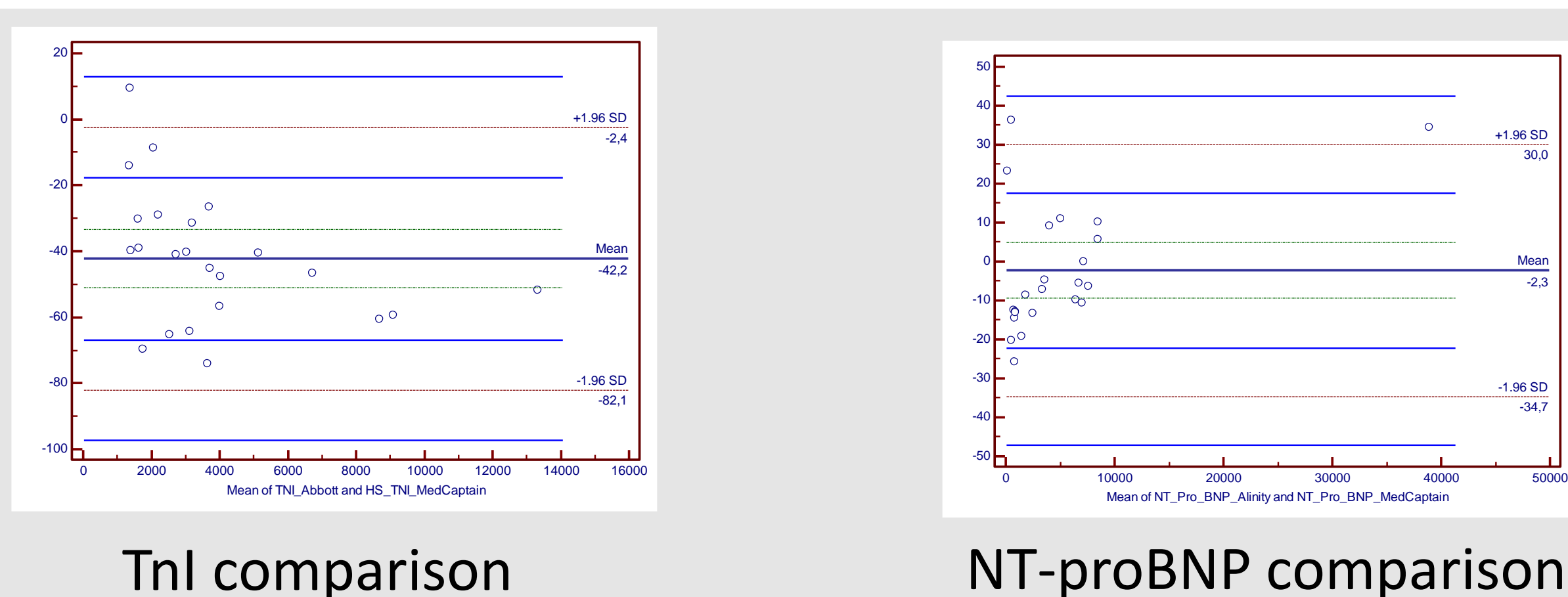


Figure 3: Comparison between routine lab method and POC method-Bland-Altman plot

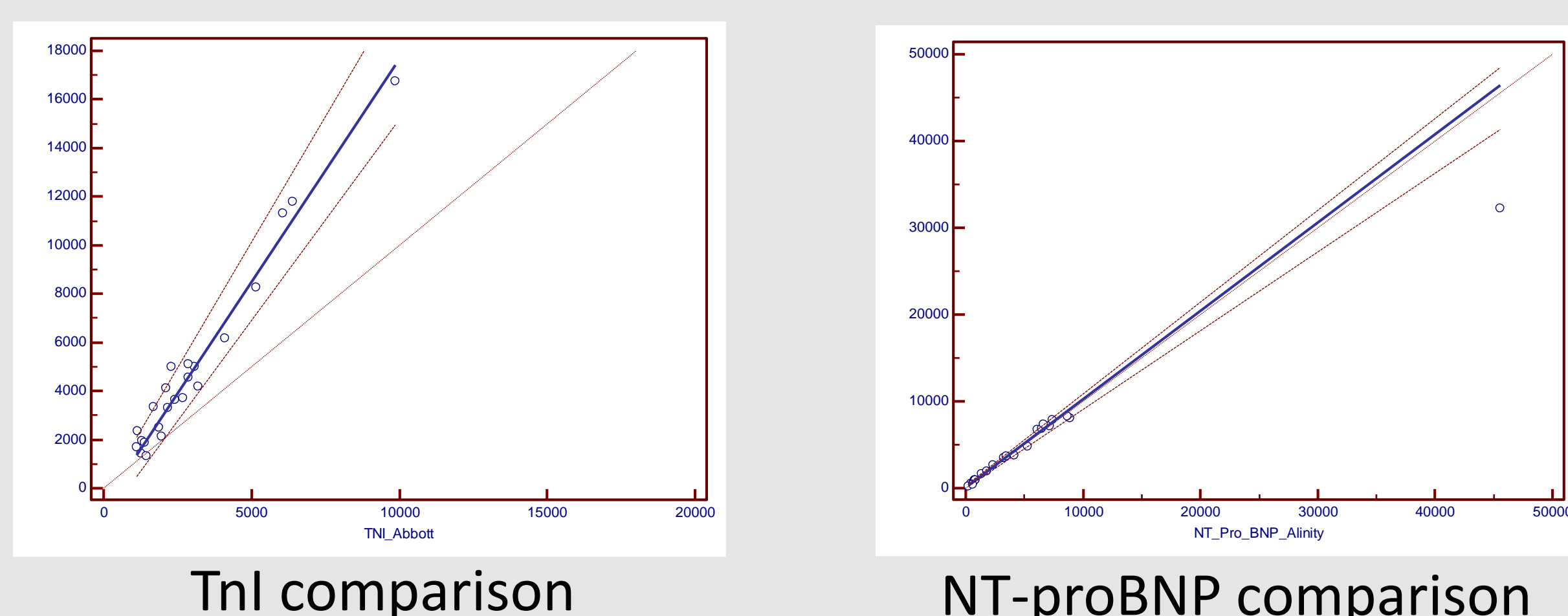


Figure 4: Comparison between routine lab method and POC method Passing-Bablok

Concentration level (ng/L)	Mean introduced concentration (ng/L)	Repeatability (RSD%) <sup>1</sup>	Intermediate precision (RSD%) <sup>1</sup>
1.0	502.8	3.403	4.632
2.0	2416	6.963	8.693
3.0	4832	3.333	3.893

hsTnI

Concentration level (pg/ml)	Mean introduced concentration (pg/ml)	Repeatability (RSD%) <sup>1</sup>	Intermediate precision (RSD%) <sup>1</sup>
1.0	123.8	6.380	8.327
2.0	1294	11.00	15.74
3.0	2509	3.025	3.711

NT-proBNP

Concentration level (ng/mL)	Mean introduced concentration (ng/mL)	Repeatability (RSD%) <sup>1</sup>	Intermediate precision (RSD%) <sup>1</sup>
1.0	7.370	3.248	6.335
2.0	24.55	2.785	4.921

HFABP

Concentration level (ng/mL)	Mean introduced concentration (ng/mL)	Repeatability (RSD%) <sup>1</sup>	Intermediate precision (RSD%) <sup>1</sup>
1.0	27.80	2.359	4.801
2.0	44.90	5.489	6.747
3.0	89.80	2.680	5.254

ST2

Table 1: Intra- and inter-assay CVs

## Conclusions:

POC testing using the Medcaptain analyser is accurate and correlates well with laboratory methods. Although hs-TnI results vary due to standardisation issues, diagnostic consistency remains intact. This device provides ED physicians with rapid, reliable results for cardiac injury detection, enhancing clinical confidence in urgent decision-making.