

Multi Parameter Performance Qualification of the New InnovaStar® POCT Clinical Chemistry Analyzer

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Introduction

POCT systems offer clear advantages such as immediate availability of results and reduction of potential errors from sample transportation or storage. Many established POCT systems are hampered by a limited test portfolio. The new multifunctional InnovaStar® POCT system was designed to overcome these drawbacks and allows the adaptation of a variety of clinical chemistry and immunoturbidimetric assays.

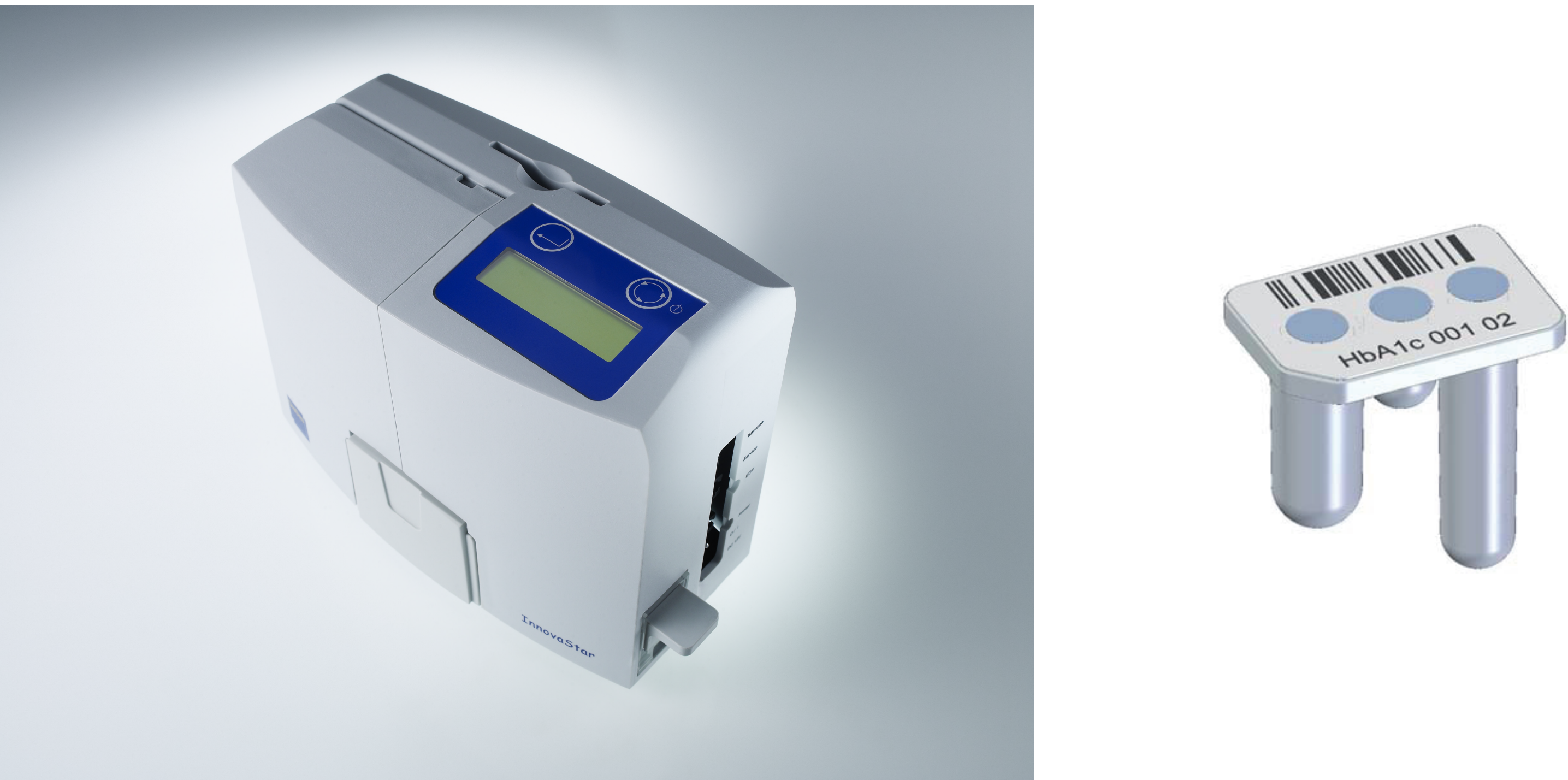


Figure 1: InnovaStar® and reagent cartridge.
(Instrument: 200 mm x 150 mm x 170 mm (w x h x d))

The performance of the InnovaStar® POCT flow-through photometric system is comparable to laboratory based automated clinical analyzers. Reagents are ready to use, pre-calibrated and supplied in barcoded unit-dose cartridges. In a single run up to 3 parameters are determined from one specimen. The photometric unit has a wavelength range from 400 to 700 nm. The micro diode array measures this spectrum simultaneously with a resolution of 3.5 nm. Photometer linearity is given up to 2.2 absorbance units. The performance of the system is demonstrated with four assays: HbA1c, Glucose, Hemoglobin and CRP.

Materials & Methods

The sytem performance was validated with five InnovaStar® instruments in parallel. Precision data according to CLSI guideline EP 5-A2 were recorded. Method comparison studies were performed to established routine laboratory equipment with commercially available tests.

Results

| Assay | Unit | Coefficients of variation | | | | Measuring range |
|------------|---------|---------------------------|--------|----------|--------|-----------------|
| | | Sample 1 | | Sample 2 | | |
| | | Mean | CV [%] | Mean | CV [%] | |
| HbA1c | %(DCCT) | 4.95 | 2.4 | 11.2 | 1.9 | 3 - 14 |
| Glucose | mg/dL | 88.8 | 2.5 | 286 | 1.8 | 15 - 800 |
| Hemoglobin | g/dL | 6.00 | 1.2 | 13.0 | 1.3 | 0.5 - 30 |
| CRP | mg/L | 5.00 | 3.0 | 20.8 | 1.6 | 1 - 350 |

Table 1: Within run precision according to CLSI EP 5-A2 (CRP precision in series, n=20) and measuring range.

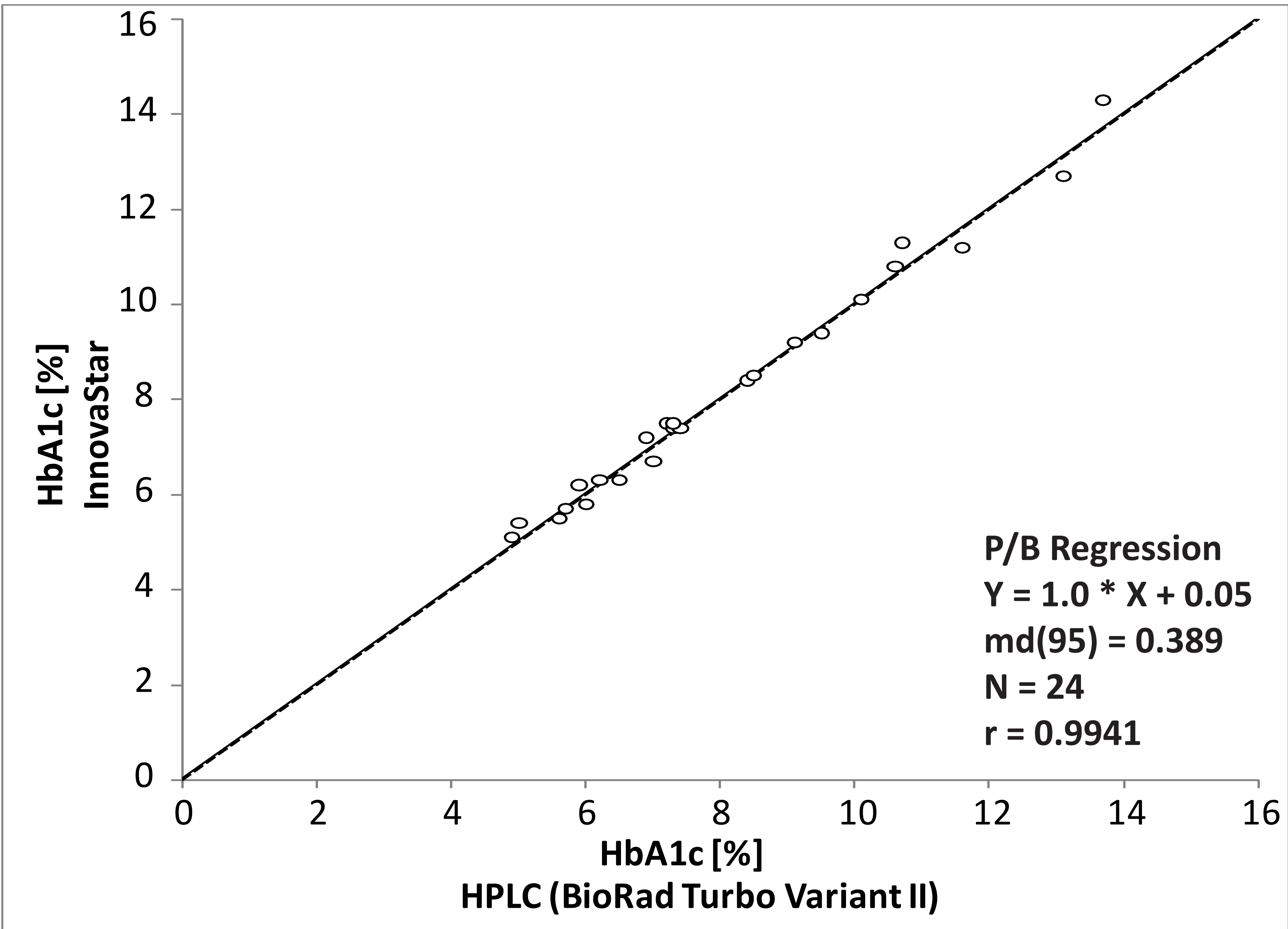


Figure 2: HbA1c method comparison

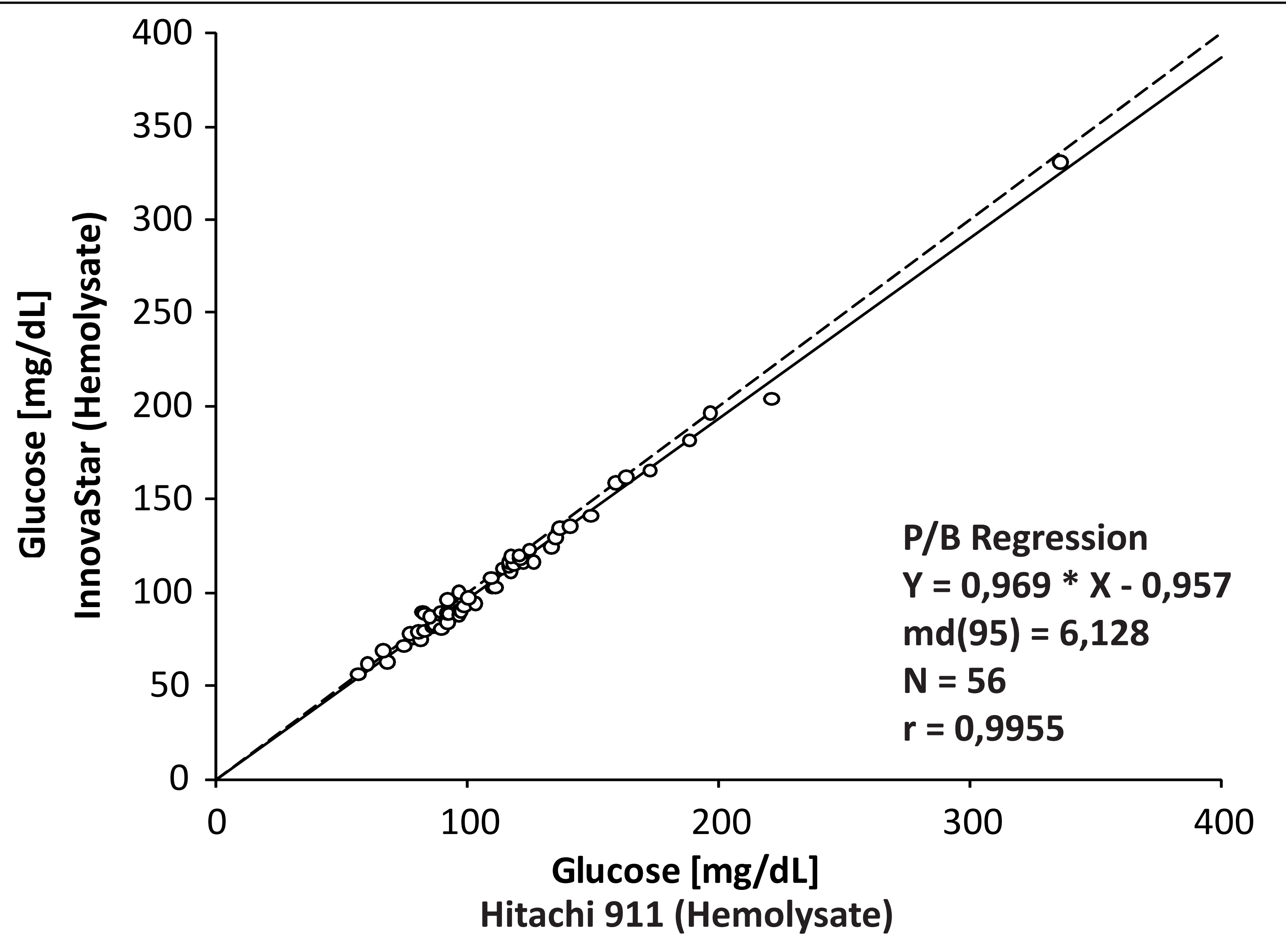


Figure 3: Glucose method comparison

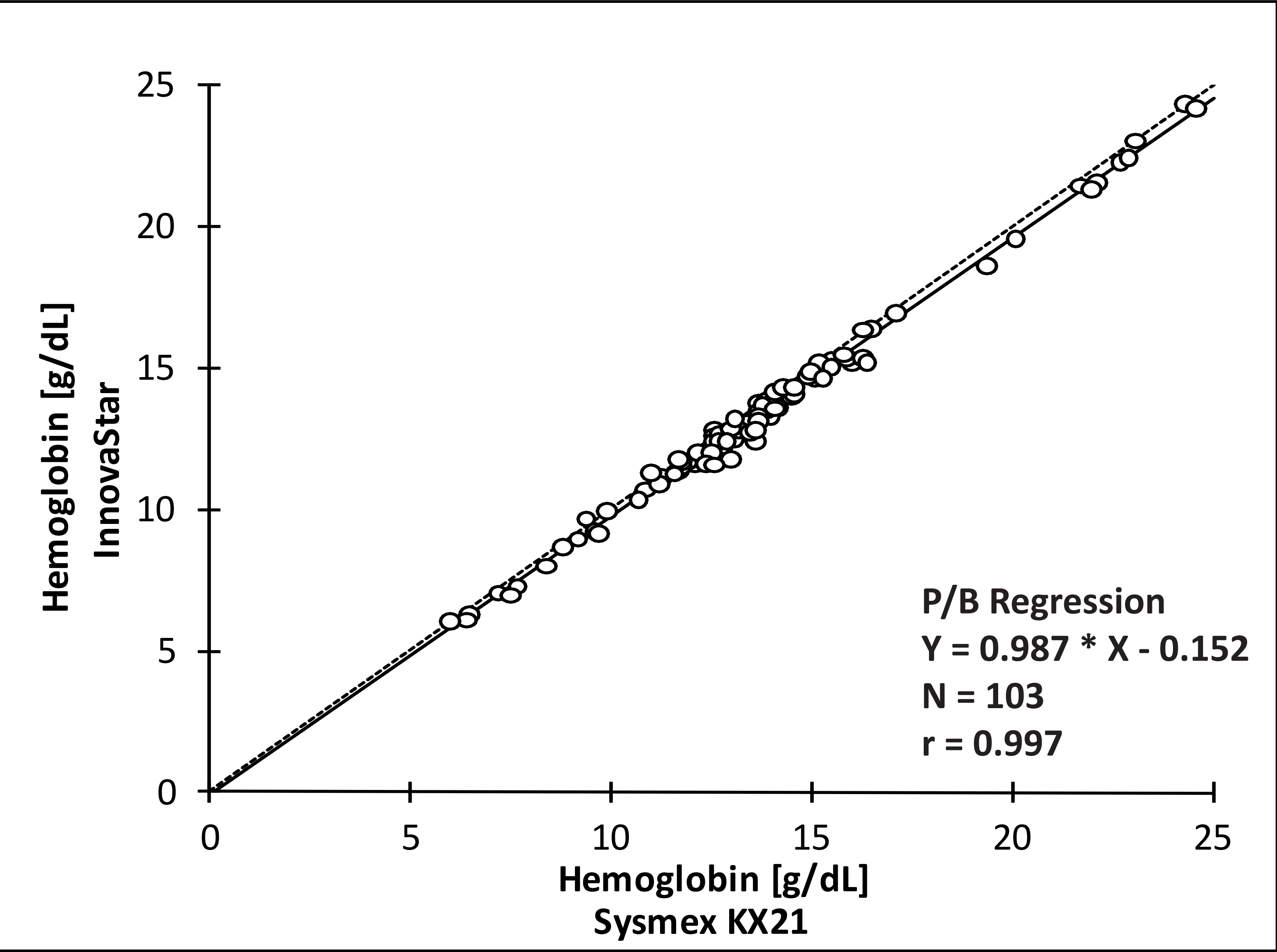


Figure 4: Hemoglobin method comparison

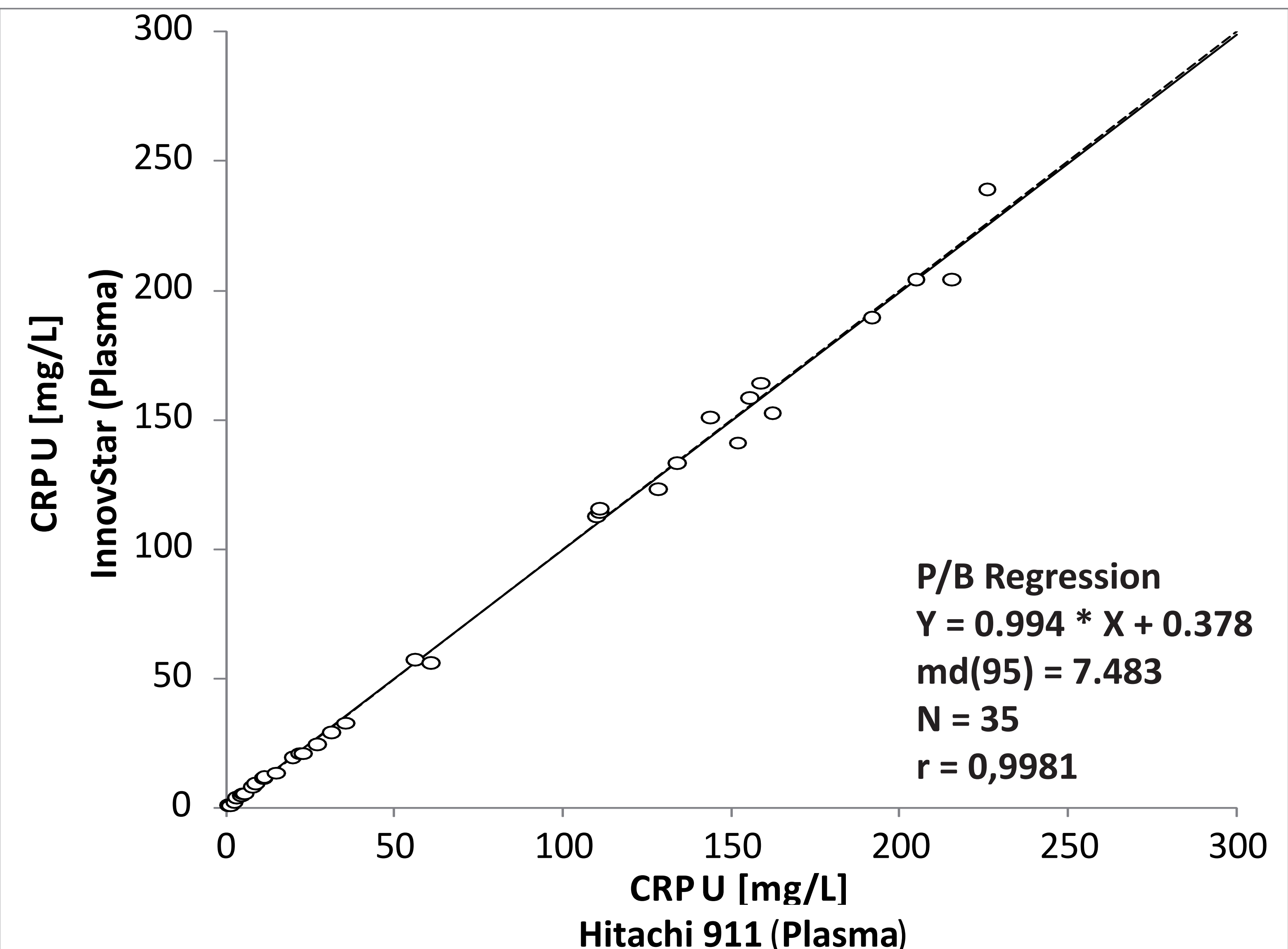


Figure 5: CRP U method comparison

Conclusion

The InnovaStar® is a unique multifunctional POCT clinical chemistry analyzer with a comparable performance to established automated laboratory systems. Almost every parameter which can be adapted to photometric systems can be applied onto the instrument. Further clinical chemistry and immunoturbidimetric assays for the InnovaStar® are in progress.

References

[1] H. Passing and W. Bablok. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods Part 1. *J Clin Chem Clin Biochem* (1983);21(11):709-720.

[2] CLSI. Method Comparison and Bias Estimation Using Patient Samples; approved guideline-second edition. CLSI Document EP9-A2. Wayne (PA): CLSI; 2002.

[3] H. Passing and W. Bablok. Comparison of Several Regression Procedures for Method Comparison Studies and Determination of Sample Sizes Part 2. *J Clin Chem Clin Biochem* (1984);22(6):431-445.

[4] CLSI. Evaluation of Precision Performance of Quantitative Measurement Methods; approved guideline-second edition. CLSI Document EP5-A2. Wayne (PA): CLSI; 2004.