An All-Purpose Particle Enhanced Immunoturbidimetric Assay for the Comparable, Instrument-Independent Monitoring of Procalcitonin in the Management of Sepsis

T. Masetto[1], I. Wieland[1], M. Grimmler[1,2]

[1]DiaSys Diagnostic Systems GmbH, Alte Strasse 9, 65558 Holzheim, Germany

[2]Fresenius University of Applied Science, Limburger Strasse 2, 65510 Idstein, Germany

BACKGROUND

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host immune response to infection. It is a global health concern and a leading cause of death worldwide, affecting an estimate of 48.9 million people every year. Procalcitonin (PCT) revealed to be an indispensable parameter for the management of sepsis. However, recent analysis of EQA survey results suggested crucial deviations of PCT measurements in Germany and studies by the IFCC Working Group on standardization of PCT stated the need for a higher-order reference measurement procedure. Here we present the evaluation of the all-purpose particle enhanced immunoturbidimetric assay (PETIA) of DiaSys, which can be easily applied to every high-throughput clinical chemistry analyzer. The high diversity of applications and datasets match current diagnostic and regulatory needs (IVDR). *Procalcitonin FS* enables the equivalent and instrument-independent monitoring of PCT in the management of sepsis.

METHODOLOGY

Evaluation of *Procalcitonin FS* was performed on seven clinical chemistry analyzer platforms (Jeol BioMajesty® JCA-BM6010/C, DiaSys respons®920 and respons®940, Roche cobas c501, Abbott Architect c8000 and Alinity c, Beckman Olympus AU680). Measurements were performed according to Clinical and Laboratory Standards Institute (CLSI) protocols.

RESULTS

The following interferents were measured at clinically relevant concentrations and had no significant impact (acceptance criteria ± 15%): α-CGRP, azithromycin, β-CGRP, bilirubin (conjugated and unconjugated), calcitonin, cefotaxime, cromolyn, dobutamine, dopamine, doxycyclin, ethanol, furosemide, hemolysis, heparin, ibuprofen, imipenem, katacalcin, noradrenaline, pantoprazole, rheumatoid factors, salmeterol, scopolamine, triglyceride, and vancomycin.

Tab. 1: Excerpt of performance data of *Procalcitonin FS* on seven clinical chemistry analyzers.

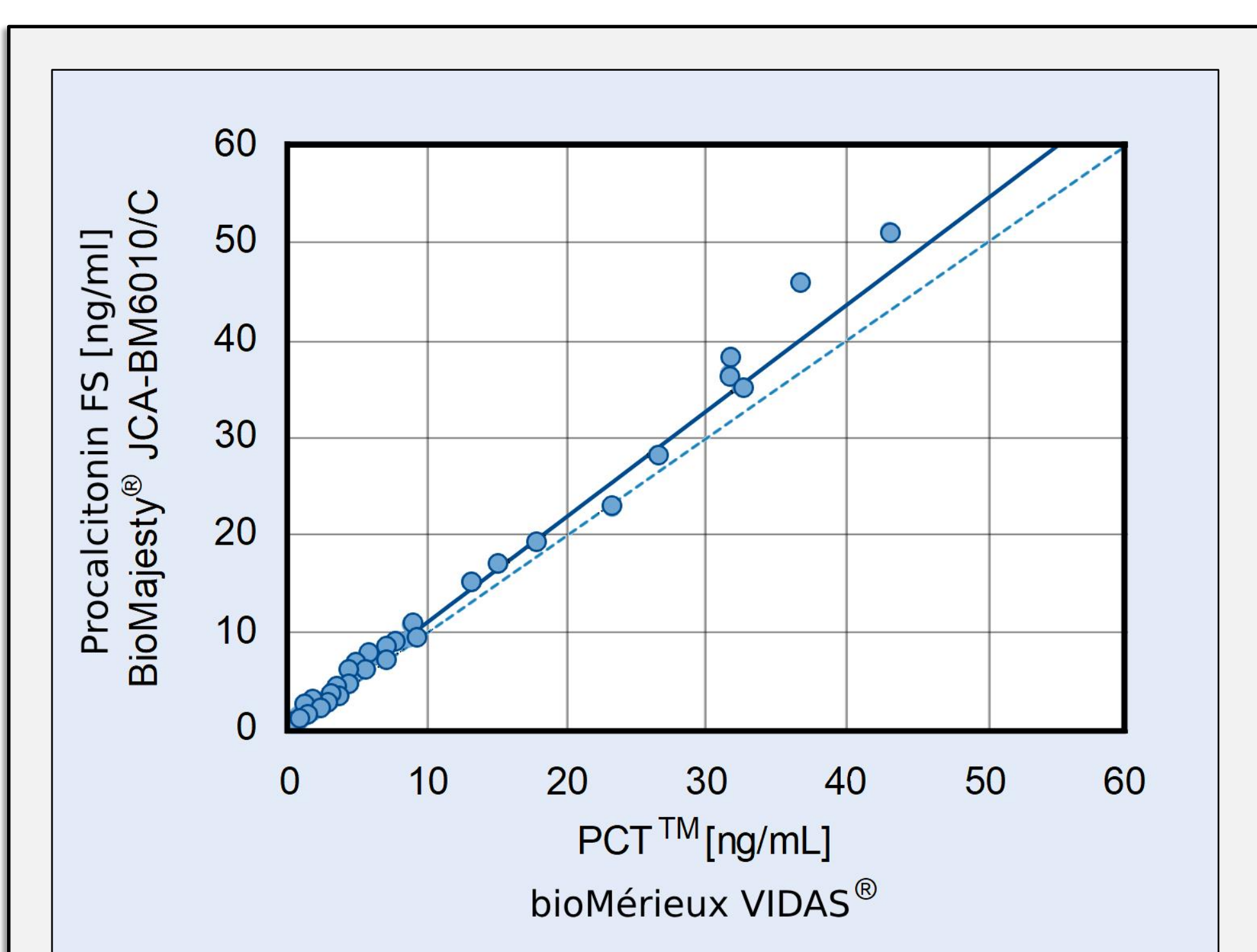|	Jeol BioMajesty® JCA-BM6010/C	DiaSys respons®940	DiaSys respons®920	Roche cobas c501	Abbott Architect c8000	Abbott Alinity c	Beckman Olympus AU680
Measuring range	0.27 – 50 ng/mL	0.31 – 50 ng/mL	0.26 – 50 ng/mL	0.25 – 50 ng/mL	0.23 – 50 ng/mL	0.25 – 50 ng/mL	0.28 – 50 ng/mL
LoB	0.06 ng/mL	0.13 ng/mL	0.11 ng/mL	0.12 ng/mL	0.09 ng/mL	0.05 ng/mL	0.13 ng/mL
Stability	With chimney: OBS: 8 weeks Calibration: 4 weeks	With chimney: OBS: 60 days Calibration: 4 weeks	OBS: 20 days Calibration: 1 week With chimney: OBS: 2 weeks Calibration: 2 weeks	OBS: 21 weeks Calibration: 21 weeks	OBS: 9 weeks Calibration: 3 weeks	OBS: 13 weeks Calibration: 11 weeks	OBS: 13 weeks Calibration: 6 weeks
Prozone security	up to 1000 ng/mL	up to 1000 ng/mL	up to 1000 ng/mL	up to 1000 ng/mL	up to 1000 ng/mL	up to 1000 ng/mL	up to 1000 ng/mL
Total precision (CLSI) [CV]	5.94% (0.57 ng/mL) 2.90% (2.23 ng/mL) 2.04% (10.8 ng/mL)	5.64% (0.62 ng/mL) 3.31% (2.16 ng/mL) 3.26% (10.2 ng/mL)	6.95% (0.58 ng/mL) 3.78% (2.17 ng/mL) 3.92% (10.1 ng/mL)	3.99% (0.63 ng/mL) 1.61% (2.21 ng/mL) 1.38% (10.3 ng/mL)	5.64% (0.57 ng/mL) 2.34% (2.23 ng/mL) 1.93% (10.5 ng/mL)	5.90% (0.63 ng/mL) 4.30% (1.96 ng/mL) 3.99% (10.1 ng/mL)	9.62% (0.68 ng/mL) 2.71% (1.96 ng/mL) 3.98% (10.8 ng/mL)
Method comparison n = 120	y = 1.08 x + 0.092 ng/mL r = 0.991	y = 1.10 x + 0.156 ng/mL r = 0.986	y = 1.06 x + 0.103 ng/mL r = 0.989	y = 1.11 x + 0.064 ng/mL r = 0.989	y = 1.08 x + 0.105 ng/mL r = 0.991	y = 0.933 x + 0.068 ng/mL r = 0.990	y = 0.943 x + 0.097 ng/mL r = 0.990

Fig 1: Method comparison DiaSys *Procalcitonin FS* on Jeol BioMajesty® JCA-BM6010/C vs. B.R.A.H.M.S - bioMérieux PCT™ on VIDAS®
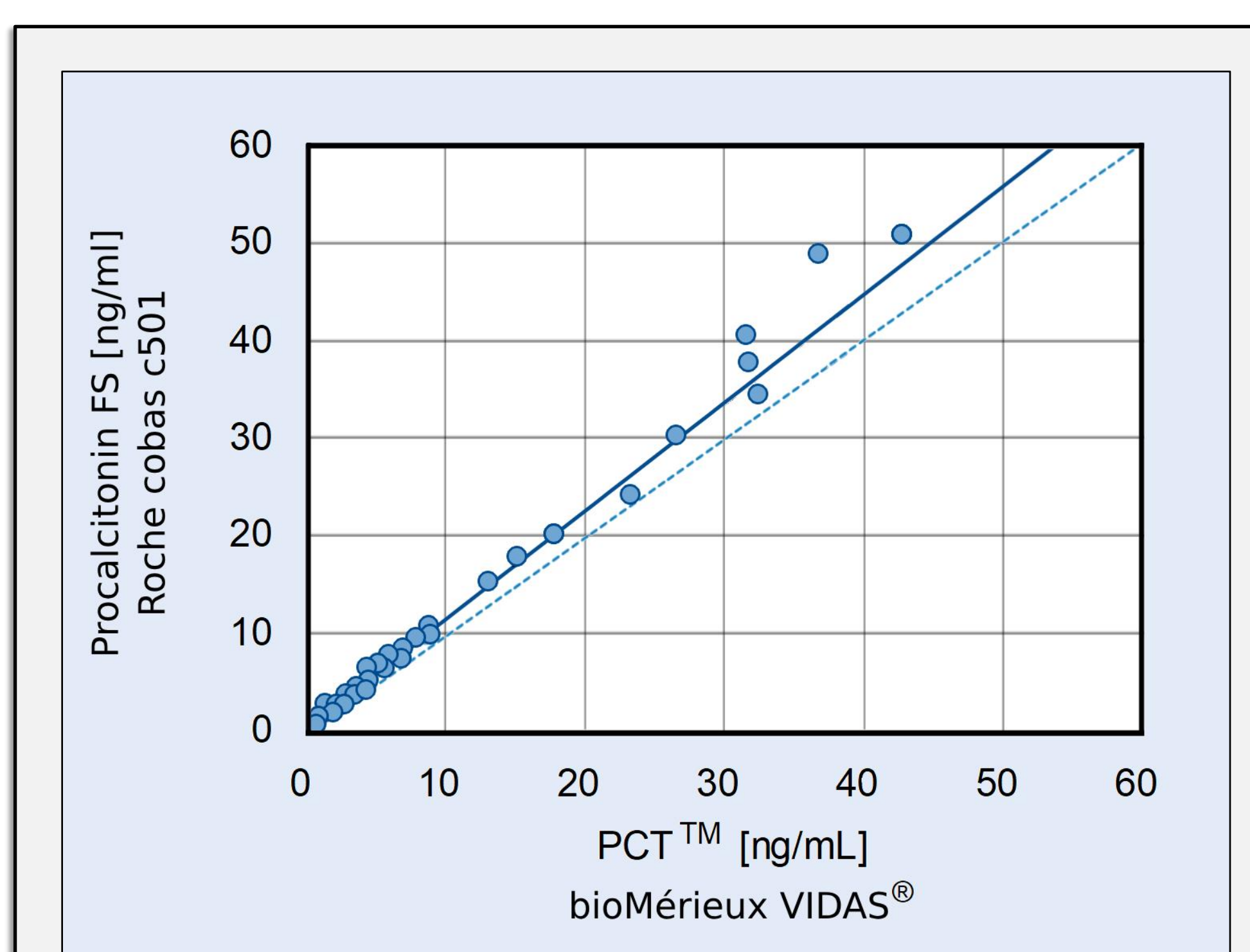

Fig 2: Method comparison DiaSys *Procalcitonin FS* on Roche cobas c501 vs. B.R.A.H.M.S - bioMérieux PCT™ on VIDAS®
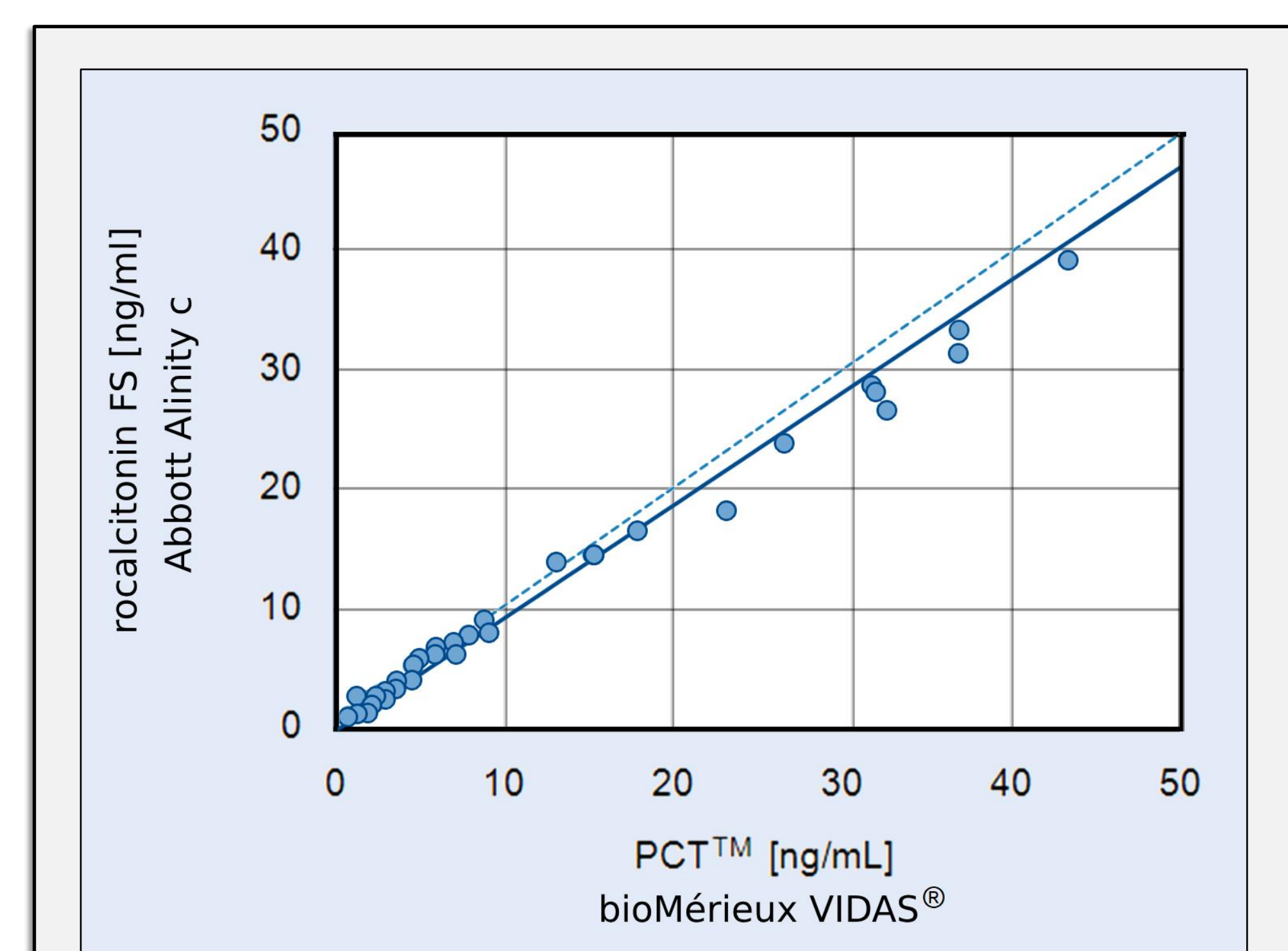

Fig 3: Method comparison DiaSys *Procalcitonin FS* on Abbott Alinity c vs. B.R.A.H.M.S - bioMérieux PCT™ on VIDAS®

CONCLUSION

Evaluation confirms an excellent performance for the DiaSys PETIA reagent *Procalcitonin FS* on all seven clinical chemistry analyzers. In addition, the high comparability between the seven analyzers enables the reliable and instrument-independent monitoring of PCT in the management of sepsis, thus offering a solution to the current landscape of deviating PCT measurement results.

REFERENCES

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