

INTRODUCTION

Monitoring of heparin is important to adjust the heparin dose and manage anticoagulation therapy appropriately.

Revohem™ Anti-Xa LRT is a liquid, ready-to-use reagent which can be used for the measurement of heparin and DOACs (Rivaroxaban, Apixaban and Edoxaban)

Heparin assay of Revohem Anti-Xa LRT permits the measurement of both unfractionated heparin (UFH) and low molecular weight heparin (LMWH) by utilizing a single hybrid calibration curve. In this study, we evaluated the performance of heparin measurement by Revohem Anti-Xa LRT.

AIM

To evaluate the performance of the heparin measurement by Revohem Anti-Xa LRT.

METHOD

Calibration curve for heparin was prepared for Revohem Anti-Xa LRT with Revohem Heparin Hybrid Calibrator on CN-6000.

Below evaluations were conducted in accordance with CLSI guidelines^{1, 2, 3, 4, 5}.

- Measurement range (LoQ and Linearity)
- Precision (20 days, 2 runs/day, 2 replications)
- Trueness
- Method comparison

Reference: INNOVANCE® Anti-Xa
Sample: 200 samples (100 UFH samples and 100 LMWH samples; citrated plasmas from a private laboratory)

Sysmex CN-6000 was used for all measurements. All samples used in the evaluations were commercially purchased from vendors.



Revohem Anti-Xa LRT



CN-6000

CONTACT INFORMATION

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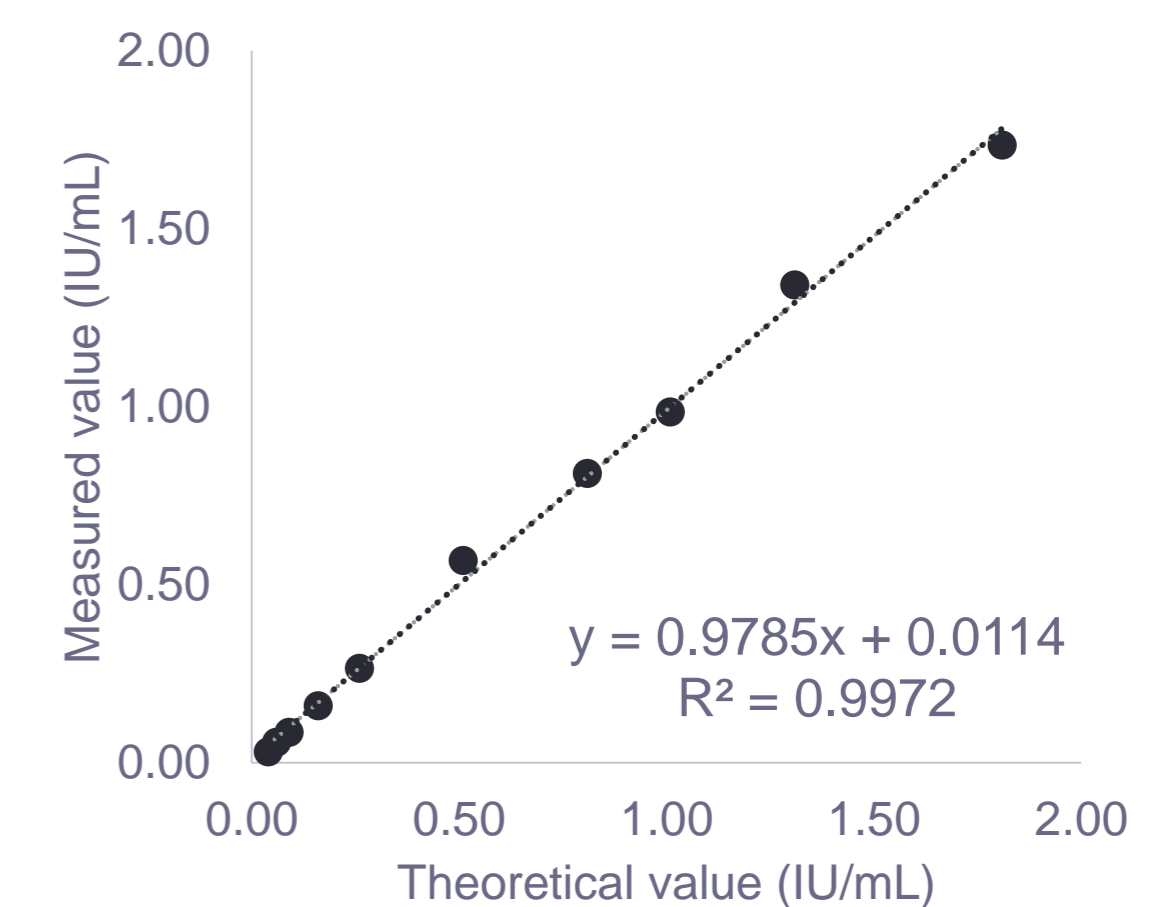
RESULTS

Calibration curve

Heparin (IU/mL)	0.00 – 1.50
Raw value (OD/min)	0.729-0.122
Coefficient of determination (R ²)	0.998
Curve equation	$y=0.701e^{-1.183x}$

Measurement range

Measurement range confirmed by LoQ study and Linearity study was **0.05 – 1.80 IU/mL**

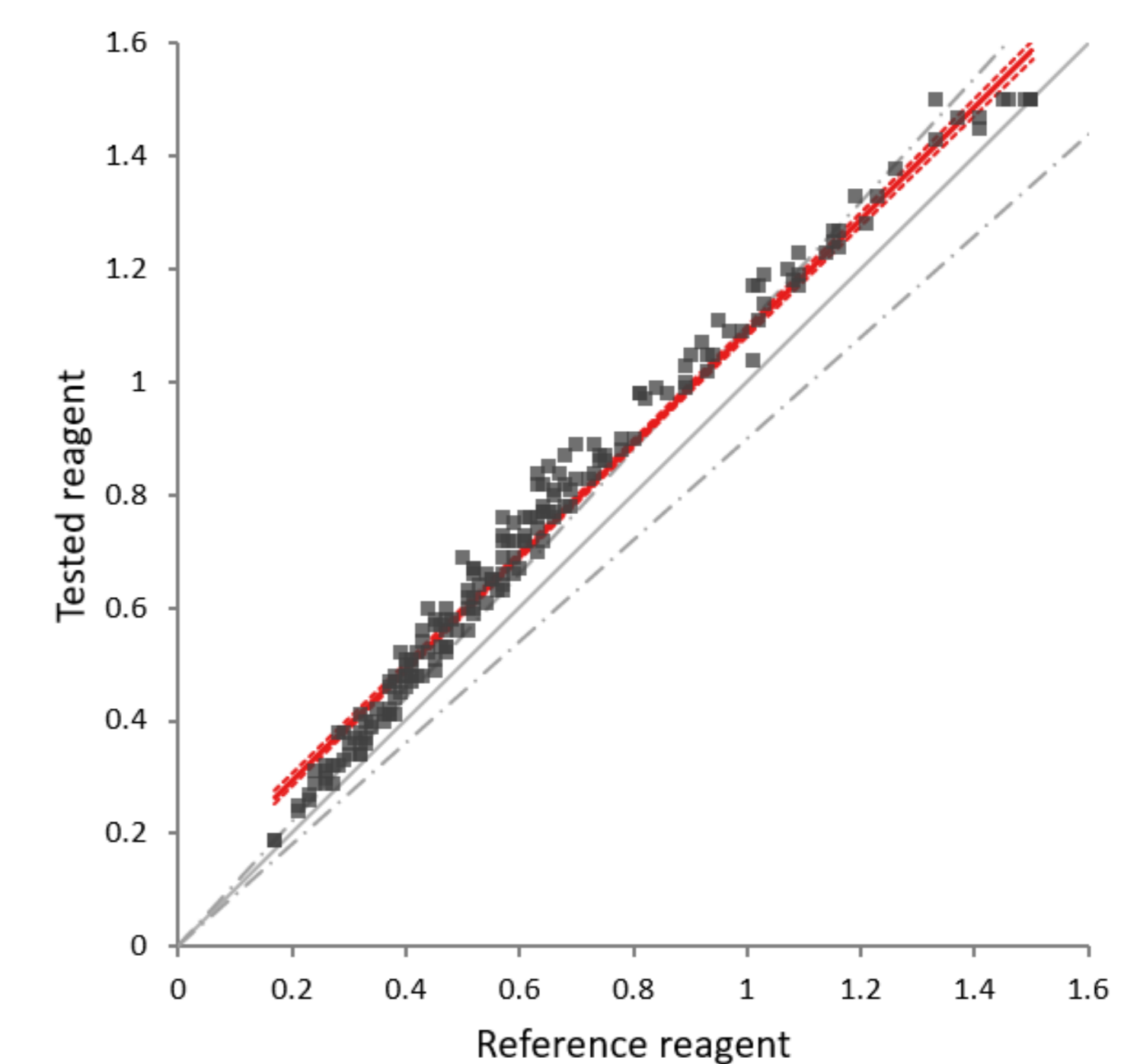


Precision

Samples	Repeatability			Within-Laboratory		
	n	Mean (IU/mL)	SD (IU/mL)	CV (%)	SD (IU/mL)	CV (%)
LMWH Control Level 1	80	0.28	0.01	2.8	0.01	3.5
LMWH Control Level 2	80	0.81	0.01	1.7	0.02	1.8
LMWH Plasma Pool	80	1.54	0.02	1.1	0.02	1.3
UFH Control Level 1	80	0.23	0.00	1.8	0.01	2.9
UFH Control Level 2	80	0.49	0.01	1.7	0.01	2.5
UFH Plasma Pool	80	0.88	0.01	1.0	0.02	2.3

Method comparison

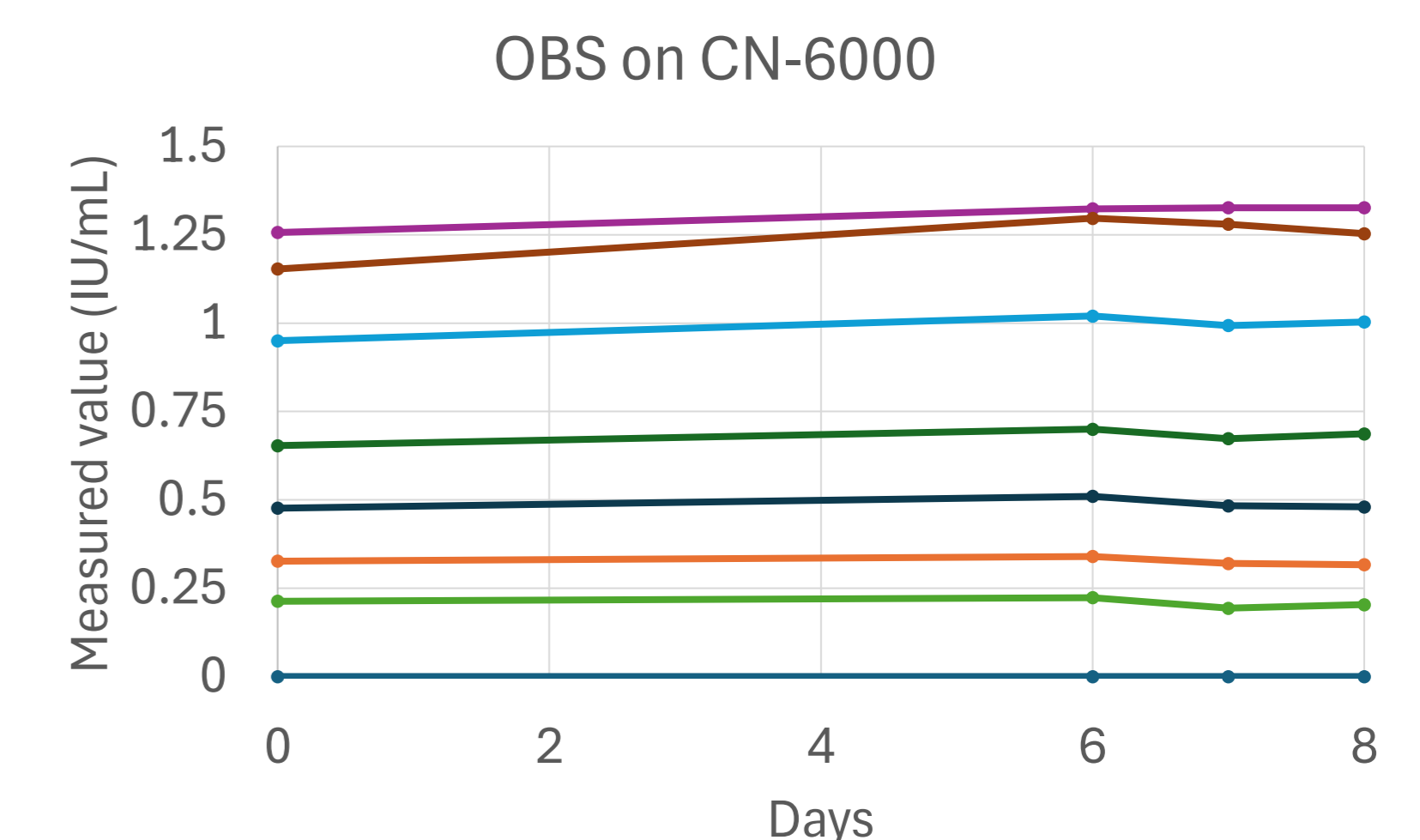
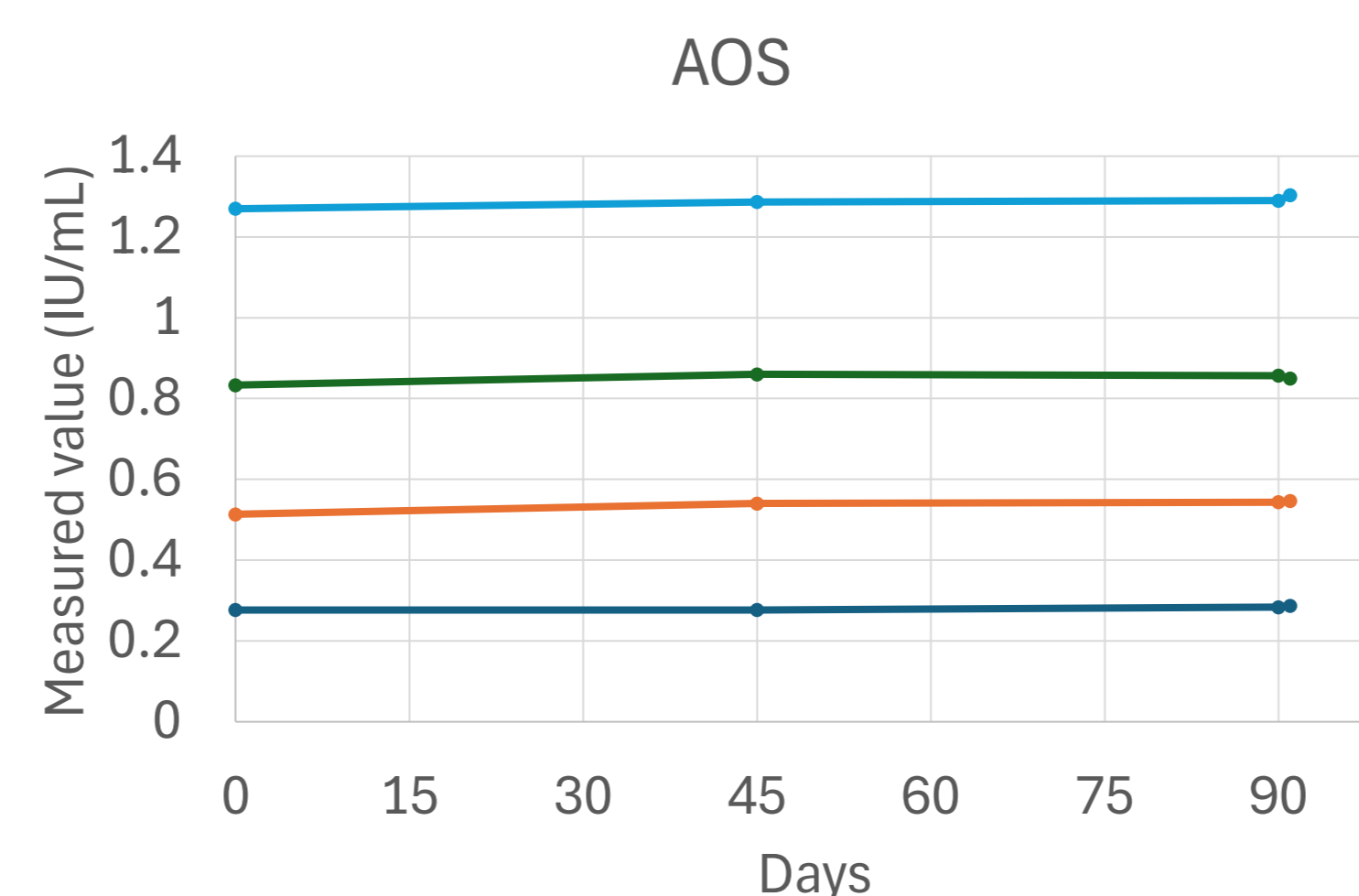
Reference method	INNOVANCE® Anti-Xa (Sysmex CN-6000)
Tested method	Revohem Anti-Xa LRT (Sysmex CN-6000)
Number of samples (n)	200
Linear regression	$y = 0.993x + 0.096$
Coefficient of correlation (r)	0.991
Standard error of the estimate (Sy.x)	0.05



Stability

After opening stability (AOS): Reagent was stored with cap at the 2-8 °C after opening. The reagent was stable until 91 days thus AOS claim at 2-8 °C was determined to be **90 days**.

On-board Stability (OBS): Reagent was placed and remained on the analyzer without capping. The reagent was stable until 8 days onboard thus OBS claim was determined to be **7 days**.



CONCLUSIONS

The new anti-Xa heparin assay using hybrid calibration with Revohem Anti-Xa LRT is a fully automatable, simple, standardized and highly sensitive assay, to rapidly assess Heparin concentrations in human citrated plasma. With low CVs, a wide measuring range, and long on-board stability, this assay is safe and accurate for monitoring patients on heparin therapy (UFH/LMWH).

REFERENCES

1. CLSI Evaluation of Precision of Quantitative Measurement Procedures. CLSI document EP05-A3 Wayne, PA: Clinical and Laboratory Standards Institute. 2014
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3. CLSI. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedure. CLSI document EP17-A2 Wayne, PA: Clinical and Laboratory Standards Institute. 2012.
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5. CLSI. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. CLSI document EP09c-3rd ed Wayne, PA: Clinical and Laboratory Standards Institute. 2018.