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Publication tweet (236/240 characters):

Performance evaluation of the INNOVANCE Antithrombin assay highlights its analytical performance at the lower end of the measuring range, supporting clinical management of fitusiran-treated people with hemophilia. #Hemophilia #Fitusiran

Abstract (249/250)

Background:

Fitusiran is an antithrombin (AT)-lowering therapy for hemophilia A and B, with dosing individually adjusted to maintain AT activity between 15–35%. The therapy, therefore, requires an AT activity assay with high analytical sensitivity and precision, especially at the lower end of the measuring range (≤20%).

Objectives:

Evaluating the analytical performance characteristics of the INNOVANCE Antithrombin assay at the low end of the measuring range and assessing equivalence between different analyzers.

Methods:

Performance data were generated on various analyzers from Siemens Healthineers according to CLSI guidelines, including limit of quantification (LoQ), interferences, and precision. System comparability was evaluated using samples from patients treated with fitusiran.

Results:

This study demonstrated high precision and reproducibility of results across reagent lots and systems with <10% coefficient of variation (CV) at 10% and 15% AT activity on all analyzers, except for the BCS XP system at the 10% AT level with a repeatability CV of 13.94%. Diluted control plasma showed similar precision characteristics to native samples and good recovery of expected AT value.

Therapeutics potentially being used by the hemophilia population were demonstrated to not interfere with the assay. LoQ was shown to be ≤8.78% of normal on all analyzers. System comparability was confirmed with correlation coefficients ≥0.997, slopes between 0.976–1.005 and intercepts between 0.5–2.1% of normal.

Conclusion:

The study confirms the INNOVANCE Antithrombin assay can precisely and reliably quantify AT activity at fitusiran clinical decision points and further supports its suitability for clinical management of people on fitusiran prophylaxis.

Keywords (max 5): hemophilia, fitusiran, antithrombin, assay, INNOVANCE

Essentials (max 98 characters inc. spaces):

- Fitusiran treatment requires an antithrombin activity (AT) assay with high precision (*87/98*)
- This analysis evaluated the analytical performance of the INNOVANCE Antithrombin assay *(89/98)*
- High precision and reproducibility were demonstrated across reagent lots and systems *(87/98)*
- The study confirms that the INNOVANCE Antithrombin assay can reliably quantify AT activity (90/98)

1 Introduction

Hemophilia A and B result from deficiencies in coagulation factors VIII (FVIII) and IX (FIX), respectively, resulting in insufficient thrombin generation and leading to reduced clot stability and bleeding events [1]. Antithrombin (AT) is a major physiological anticoagulant that regulates blood clotting and prevents excessive clot formation [2]. In people with hemophilia (PwH), AT deficiency results in increased thrombin generation, which decreases bleeding [3]. Fitusiran is an AT-lowering therapeutic that increases thrombin generation to restore hemostasis in PwHA/B, with or without inhibitors [4]. During the fitusiran clinical development program, prolonged periods of AT activity levels below 10% were identified as a potential modifiable target for thrombotic risk mitigation. The antithrombin-based dose regimen (AT-DR), targeting AT activity levels of 15–35%, was introduced to enhance the benefit–risk profile of fitusiran [4]. As fitusiran dosing is based on plasma AT activity levels, AT levels should be measured at months 1, 3, 5, and 6 after the starting dose and after any dose modification. Once the target dose has been identified based on AT activity of 15–35%, AT levels should be measured annually [5]. To test AT activity in patient plasma throughout the fitusiran clinical development program (Phase 1, 2, and 3 clinical trials, excluding China), the INNOVANCE Antithrombin assay was used with the BCS XP analyzer, both from Siemens Healthineers (Marburg, Germany).

The normal AT activity range in healthy individuals is approximately 80–120% of normal, while in individuals with heterozygous AT deficiency, AT activity usually ranges between 40–60% [6]. AT activity levels are typically quantified using functional *in vitro* diagnostic (IVD) AT assays [7], such as the INNOVANCE Antithrombin assay. A previous report on precision, method comparison, and reference interval studies of the INNOVANCE Antithrombin assay highlighted that the assay has a high sensitivity and is reliable, precise, and suitable for use in the diagnosis of congenital or acquired AT deficiencies [7]. IVD AT assays designed to evaluate congenital or acquired AT deficiency may not be capable of measuring very low AT levels (<15%) with sufficient accuracy and precision. Laboratories use a variety of approved IVD AT assays and, due to a combination of variables such as reagents, procedures, and analyzers used, there may be variability between results with different assays/systems [8-10].

Previously, a global AT field study was conducted to evaluate and compare the performance of commercially available IVD AT activity assays in clinical hemostasis laboratories, when measuring AT activity in plasma within the relevant range, including medical decision points for fitusiran dosing (AT activity of 15–35%) [11]. Based on this study, it was determined that the INNOVANCE Antithrombin assay from Siemens Healthineers can reliably measure AT activity at clinical decision points of 15% and 35% of normal and is most suitable for clinical management of patients on fitusiran prophylaxis in a real-world setting, as compared to the other AT activity assays assessed [11]. Building upon this existing evidence, the current study was designed to further evaluate the analytical performance characteristics of the INNOVANCE Antithrombin assay at the low end of the measuring range for AT activity levels relevant to guide fitusiran dosing, and to assess equivalence between different analyzers/systems using samples from patients on fitusiran prophylaxis.

2 Methods

Analytical performance data of the INNOVANCE Antithrombin assay (Siemens Healthineers), with applications on Siemens Healthineers and Sysmex systems, were generated on various coagulation analyzers from Siemens Healthineers (BCS XP, CA-660, CS-2500, CS-5100, and CN-6000) according to Clinical and Laboratory Standards Institute (CLSI) guidelines [12-16]. The data for precision and limit of quantification (LoQ) for the CN-6000 analyzer were taken from the CN-6000 analyzer 510(k) submission summary (K250965) from Sysmex to the Food and Drug Administration (FDA) [17]. Limit of quantification (LoQ) was assessed on the BCS XP and CA-660 analyzers using citrated plasma samples from patients receiving fitusiran treatment, diluted with assay buffer to AT activity levels at the low end of the measuring range (≤10% of normal). LoQ on the other analyzers was assessed with diluted citrate plasma samples from individuals not receiving fitusiran.

Precision studies were conducted to determine repeatability, within-device precision, impact of combined reagent lots, and combined instrument precision by calculating the standard deviation and coefficient of variation (CV). The repeatability and within-device precision of the CS-2500, CS-5100, and CN-6000 analyzers were evaluated using one reagent lot over 20 days in two runs per day and two replicates per run on a single analyzer/instrument (20x2x2). The impact of combined reagent lots, only evaluated with the BCS XP and the CA-660 analyzers, was performed using three reagent lots over 20 days in two runs per day and two replicates per run on a single instrument (3x20x2x2). Combined (multiple) instrument precision was assessed for the BCS XP, CA-660, CS-2500, and CS-5100 analyzers using one reagent lot tested on three different instruments (3 instruments x5 days x2 runs x3 replicates for the BCS XP and the CA-660 systems, and 3 instruments x20 days x2 runs x2 replicates for the CS-2500 and CS-5100 systems). Samples used for the BCS XP and the CA-660 instruments comprised native citrated plasma from PwH treated with fitusiran with AT activity levels around 10% and 15%. For all other instruments, plasma samples from individuals not receiving fitusiran were used. Control Plasma P (CPP, assigned concentration 33% of normal) was diluted 1:3 with INNOVANCE Antithrombin buffer and used to show comparability relative to native samples.

System comparability (BCS XP versus CS-2500/CS-5100/CA-660/CN-6000 systems) was evaluated by method comparison studies by Passing–Bablok regression using samples from PwH treated with fitusiran and from PwH not receiving fitusiran, as well as AT-depleted samples spiked with an AT concentrate (Kybernin, CSL Behring). The proportion of spiked samples was less than 10%.

To determine the analytical specificity of the INNOVANCE Antithrombin assay for the hemophilia patient population, interference studies were performed to evaluate the effect of therapeutics that may be co-administered with fitusiran on AT quantification. Native citrated plasma from patients treated with fitusiran with AT levels at ~15% and control plasma (AT levels 90–100%) were tested on the BCS XP system using the paired-difference method. The assessed doses of therapeutics were determined based on possible doses that can be given to hemophilia patients to restore normal hemostasis: FVIII (0.96 IU/mL), FIX (1.44 IU/mL), recombinant activated FVII (2.16 µg/mL), and activated prothrombin complex concentrate (2.40 IU/mL). In addition, the effect of concomitant drugs as desmopressin and tranexamic acid used as an adjunctive hemostatic therapy was also tested in interference studies. Tranexamic acid was tested up to 0.48 mg/mL and desmopressin was tested up to 0.0144 µg/mL, based on the respective product labels.

3 Results/Discussion

The LoQ of the INNOVANCE Antithrombin assay on the different analyzers (BCS XP, CA-660, CS-2500, CS-5100, CN-6000) was determined to be between 7.32–8.78% (**Figure 1**). These levels of quantification are well below the AT activity range targeted by the fitusiran AT-DR (15–35%) [4], highlighting the potential for reliable measurements to guide fitusiran dosing with the INNOVANCE Antithrombin assay.

The precision data for the INNOVANCE Antithrombin assay on various analyzers are presented in **Table 1**. For the BCS XP analyzer, the total combined lots and total combined instrument CV were <20% for the 10% AT pool, and <10% for the 15% AT pool. The measured mean AT level for the diluted CPP sample, with CVs comparable to the 10% pool, was 12.1%, showing good recovery relative to the expected value of 11%. For the CA-660 analyzer, the total combined lots and total combined instrument CV were <6% for the 10% and 15% AT pools. The within-device/lab CV for CPP and the medium pools were <10% on the BCS XP and CA-660 analyzers. Similarly, the total combined instruments CV was <6% for the 10%, 15%, and medium AT pools and CPP with the CS-5100 analyzer. With the CS-2500 analyzer, the total combined instrument CV was <10% for the 10%, 15%, and medium AT pools and CPP. Within-device/lab CV for the 15%, medium AT pools and CPP with the CN-6000 analyzer were <6% and <2%, respectively.

Outputs from the method comparisons studies mainly using samples from patients treated with fitusiran showed a high correlation between instruments ($r \geq 0.997$, slope 0.976–1.005, intercept 0.5–2.1% of normal activity; **Figure 2**). These data demonstrate system comparability across the various analyzers used. This is especially important because the BCS XP analyzer was used during the fitusiran clinical development program to test AT activity in patient plasma. The data presented here demonstrate that all available systems from Siemens Healthineers can be used to reliably measure AT activity in PwH treated with fitusiran.

Within the interference studies, the mean difference in AT measurements between low control sample (prepared from samples from patients under fitusiran treatment with AT activity between 10–15% of normal) and the plasma spiked with hemophilia therapeutics was <0.25% of normal (**Table 2**). Similarly, no interference was observed for an additional tested control plasma sample with an AT activity between 90–100% of normal (data not shown). Therefore, this study revealed no relevant interfering impact on AT quantification by any of the assessed substances.

4 Conclusions

The analytical performance evaluation of the INNOVANCE Antithrombin assay demonstrated high precision and reproducibility across reagent lots and systems (<10% CV at 15% AT activity levels). The diluted CPP showed similar precision characteristics to the native samples and good recovery of the expected AT value. The study proved high analytical sensitivity for all systems as well as tight correlations between these systems. In addition, hemophilia therapeutics which may be used concomitantly in patients receiving fitusiran prophylaxis were not found to interfere with the assay. Data from these studies, along with clinical data [4], supported the FDA clearance of the INNOVANCE Antithrombin assay as a companion diagnostic (CDx) test for the clinical management of patients receiving fitusiran prophylaxis. Overall, this analysis confirmed that the INNOVANCE Antithrombin assay can precisely and reliably quantify AT activity at clinical decision points (15–35% of normal activity). These data add to the existing evidence that the INNOVANCE Antithrombin assay is an accurate, reliable, and precise assay, suitable for clinical management of patients on fitusiran prophylaxis.

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Relationship Disclosures

C.F., M.B.-W., and C.D. are employees of Siemens Healthineers and may be shareholders.

M.D., H.W., M.L., S.A., and E.S.C. are employees of Sanofi and may be shareholders.

References

1. Negrier C, Shima M, Hoffman M. The central role of thrombin in bleeding disorders. *Blood Rev*. 2019;38:100582.
2. Rodgers GM, Mahajerin A. Antithrombin therapy: current state and future outlook. *Clin Appl Thromb Hemost*. 2023;29:10760296231205279.
3. Shetty S, Vora S, Kulkarni B, Mota L, Vijapurkar M, Quadros L et al. Contribution of natural anticoagulant and fibrinolytic factors in modulating the clinical severity of haemophilia patients. *Br J Haematol*. 2007;138:541–4.
4. Young G, Kavakli K, Klamroth R, Matsushita T, Peyvandi F, Pipe SW et al. Safety and efficacy of a fitusiran antithrombin-based dose regimen in people with hemophilia A or B: the ATLAS-OLE study. *Blood*. 2025;145:2966–77.
5. Food and Drug Administration. QFITLIA (fitusiran) injection, for subcutaneous use. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219019s000lbl.pdf; 2025 [accessed 29 October 2025].
6. Patnaik MM, Moll S. Inherited antithrombin deficiency: a review. *Haemophilia*. 2008;14:1229–39.
7. Merz M, Böhm-Weigert M, Braun S, Cooper P, Fischer R, Hickey K et al. Clinical multicenter evaluation of a new FXa-based antithrombin assay. *Int J Lab Hematol*. 2011;33:498–506.
8. Bereczky Z, Gindele R, Speker M, Kállai J. Deficiencies of the natural anticoagulants–novel clinical laboratory aspects of thrombophilia testing. *EJIFCC*. 2016;27:130–46.
9. Rojnik T, Sedlar N, Turk N, Kastrin A, Debeljak M, Božič Mijovski M. Comparison of antithrombin activity assays in detection of patients with heparin binding site antithrombin deficiency: systematic review and meta-analysis. *Sci Rep*. 2023;13:16734.
10. Orlando C, Drèze C, Evenepoel A, Seneca S, Jochmans K. Diagnostic performance of commercial antithrombin activity assays: do we get what we expect? *Thromb Haemost*. 2025; (Published online ahead of print): doi:10.1055/a-2628-4046.
11. Chhabra ES, Sadeghi-Khomami A, Liu M, Young G, Pipe SW, Ozelo MC et al. Global comparative antithrombin field study: impact of laboratory assay variability on the assessment of antithrombin activity measurement at fitusiran clinical decision-making points. *Haemophilia*. 2025;31:566–74.
12. CLSI: Evaluation of detection capability for clinical laboratory measurement procedures; approved guideline — second edition. CLSI document EP17-A2. Wayne, PA: Clical and Laboratory Standards Institute; 2012.
13. CLSI: Evaluation of precision of quantitative measurement procedures; approved guideline — third edition. CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
14. CLSI: Interference testing in clinical chemistry. 3rd Edition. CLSI guideline EP07. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
15. CLSI: Measurement procedure comparison and bias estimation using patient samples. 3rd Edition. CLSI guideline EP09c. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
16. NCCLS: Evaluation of precision performance of quantitative measurement methods; approved guideline — second edition. NCCLS document EP5-A2. Wayne, PA: National Committee for Clinical Laboratory Standards; 2004.
17. Food and Drug Administration. System, multipurpose for in vitro coagulation studies. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K250965; 2025 [accessed 29 October 2025].

Figures

Figure 1: Limit of quantification (LoQ) of the INNOVANCE Antithrombin assay on different analyzers.

*Data taken from 510(k) submission K250965 [17].
AT, antithrombin; AT-DR, antithrombin-based dose regimen; LoQ, limit of quantification.

Figure 2: Systems comparability of the BCS XP analyzer versus CA-660 (**A**), versus CS-5100 (**B**), versus CS-2500 (**C**), and versus CN-6000 (**D**) analyzers.

The green circles represent the native plasma samples from fitusiran-treated as well as fitusiran-naïve subjects, and the orange diamonds represent the spiked plasma samples.

Tables

Table 1: Precision assessments with the various analyzers.

Sample	Analyzer	Combined reagent lots: Three lots, 20 days, 2 runs per day / 2 replicates per run (n=240) 3x20x2x2					Combined (multiple) instrument: Three instruments, 5 days, 2 runs per day / 3 replicates per run (n=90) 3x5x2x3			
		Mean AT (%)	Repeatability, SD (% CV)	Within device/ lab, SD (% CV)	Between lot, SD (% CV)	Total (combined lots), SD (% CV)	Mean (%)	Repeatability, SD (% CV)	Between instruments, SD (% CV)	Total (combined instruments), SD (% CV)
Plasma from PwH receiving fitusiran prophylaxis (10% and 15% pool), medium pool and pathological control plasma	**BCS XP, % AT**									
	10% pool	9.75	1.36 (13.94)	1.59 (16.28)	0.09 (0.97)	1.59 (16.31)	11.05	0.81 (7.31)	1.30 (11.79)	2.19 (19.82)
	Diluted CPP*	12.07	1.24 (10.31)	2.18 (18.06)	0.37 (3.09)	2.21 (18.32)	ND	ND	ND	ND
	15% pool	15.73	1.38 (8.77)	1.52 (9.65)	0.39 (2.45)	1.57 (9.95)	15.54	0.92 (5.93)	0.97 (6.21)	1.38 (8.85)
	CPP†	31.40	0.82 (2.60)	1.41 (4.50)	ND	ND	ND	ND	ND	ND
	Medium pool	61.70	1.17 (1.90)	2.16 (3.50)	ND	ND	ND	ND	ND	ND
	CA-660, % AT									
	10% pool	12.34	0.21 (1.67)	0.46 (3.75)	0.09 (0.70)	0.47 (3.82)	11.93	0.24 (2.02)	0.49 (4.09)	0.70 (5.90)
	15% pool	17.34	0.40 (2.31)	0.53 (3.05)	0.22 (1.25)	0.57 (3.29)	16.94	0.39 (2.32)	0.47 (2.79)	0.78 (4.62)
	CPP†	29.10	0.93 (3.20)	2.01 (6.90)	ND	ND	ND	ND	ND	ND
	Medium pool	56.60	0.85 (1.50)	2.55 (4.50)	ND	ND	ND	ND	ND	ND

Sample	Analyzer	Three instruments, 20 days, 2 runs per day / 2 replicates per run (n=240)			
		Mean (%)	Repeatability, SD (% CV)	Between instruments, SD (% CV)	Total (combined instruments), SD (% CV)
Diluted or native plasma pools and pathological control plasma	**CS-5100, % AT**				
	10% pool	10.17	0.32 (3.11)	0.29 (2.88)	0.57 (5.64)
	15% pool	14.80	0.35 (2.38)	0.30 (2.02)	0.55 (3.74)
	CPP	29.75	0.45 (1.52)	0.61 (2.02)	0.87 (2.91)
	Medium pool	49.52	0.54 (1.10)	0.84 (1.69)	1.12 (2.25)
	CS-2500, % AT				
	10% pool	11.97	0.61 (5.08)	0.77 (6.46)	1.10 (9.20)
	15% pool	14.59	0.60 (4.11)	0.93 (6.35)	1.22 (8.38)
	CPP	32.35	0.80 (2.48)	0.31 (0.95)	1.10 (3.39)
	Medium pool	54.85	0.87 (1.59)	0.82 (1.49)	1.53 (2.78)

Sample	Analyzer	20 days, 2 runs per day / 2 replicates per run 20x2x2		
		Mean (%)	Repeatability, SD (% CV)	Within device/lab, SD (% CV)
Diluted or native plasma pools and pathological control plasma	**CN-6000, % AT‡**			
	15% pool	17.50	0.78 (4.50)	0.90 (5.20)
	CPP	31.50	0.66 (2.10)	0.77 (2.50)
	Medium pool	40.90	0.78 (1.90)	0.79 (1.90)

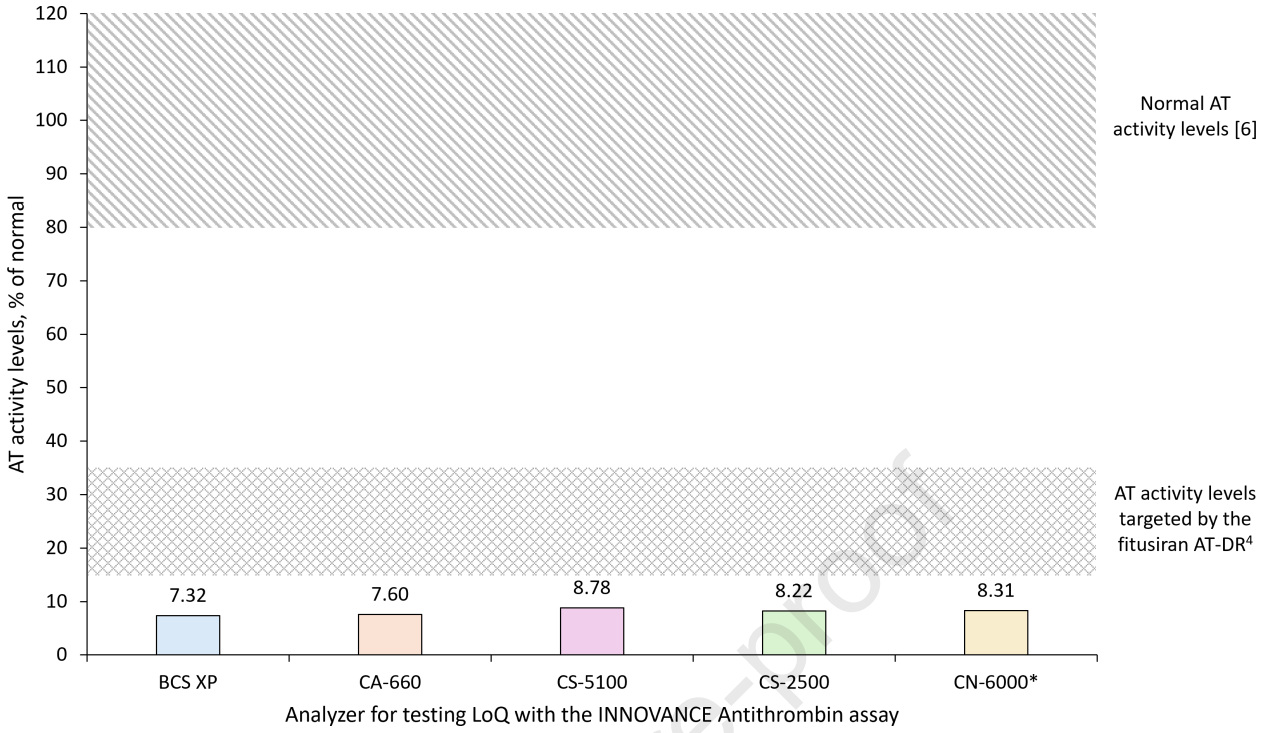
Different plasma pools and controls were used across the systems in the study, resulting in variations in mean values between them.
*The assigned AT value for CPP is 33%. Therefore, the expected value for the diluted CPP is 11%.

[†]The CPP and medium pool samples for the BCS XP and CA-600 analyzers were assessed using one lot over 20 days, with two runs of two replicates per day (n=80).
[‡]Precision data for the CN-6000 analyzers were taken from the CN-6000 analyzer 510(k) submission K250965 [17].
AT, antithrombin; CPP, Control Plasma P; CV, coefficient of variation; ND, not determined, sample was not measured within the study; PwH, people with hemophilia; SD, standard deviation.

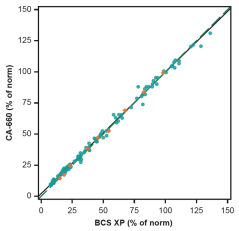
Table 2: Interference of hemophilia-specific therapeutics on AT quantification with the INNOVANCE Antithrombin assay for the low control sample (10–15% of normal).

Interferent	Spiking level	Mean AT levels, % of normal	Mean (SD) difference versus control, % of normal	95% confidence interval of mean difference, % of normal
rFVIII	0%	11.98	0.10 (0.52)	-0.83–1.03
	100% (0.96 IU/mL)	12.08		
rFIX	0%	12.36	-0.24 (0.46)	-1.08–0.60
	100% (1.44 IU/mL)	12.13		
rFVIIa	0%	12.04	-0.08 (0.49)	-0.94–0.79
	100% (2.16 µg/mL)	11.96		
aPCC	0%	10.96	0.05 (0.45)	-0.75–0.85
	100% (2.40 IU/mL)	11.01		
Tranexamic acid	0%	11.64	0.08 (0.54)	-0.89–1.04
	100% (0.48 mg/mL)	11.71		
Desmopressin	0%	12.19	-0.09 (0.57)	-1.10–0.92
	100% (0.0144 µg/mL)	12.10		

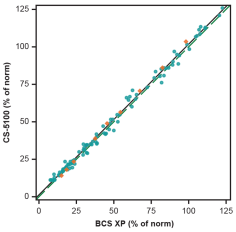
aPCC, activated prothrombin complex concentrate; AT, antithrombin; rFVIII, recombinant factor VIII; rFVIIa, recombinant activated factor VII; rFIX, recombinant factor IX; SD, standard deviation.



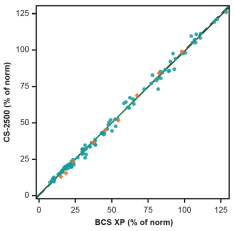
A. BCS XP versus CA-660



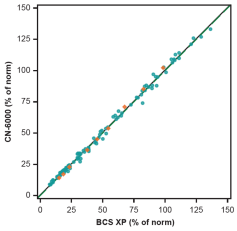
B. BCS XP versus CS-5100



C. BCS XP versus CS-2500



D. BCS XP versus CN-6000



	BCS XP versus CA-660	BCS XP versus CS-5100	BCS XP versus CS-2500	BCS XP versus CN-6000
Intercept	2.120	1.249	0.704	0.500
Slope	0.976	1.005	0.985	1.000
Correlation coefficient (r)	0.997	0.997	0.997	0.998
Predicted bias 15% [relative %]	11.73	8.87	3.20	3.33
Predicted bias 35% [relative %]	3.60	4.01	0.54	1.42