Multicenter Performance Evaluation of the Automated Blood Coagulation Analyzer CN-6000

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Introduction and Aim

The Automated Blood Coagulation Analyzer CN-6000 (CN-6000 system[a]) is an automated, high throughput coagulation analyzer for routine and specialty testing that has recently received FDA clearance. It is a member of the CN-3000/CN-6000 family of instruments. (The CN-3000 system[b] was also recently authorized for the US market).

The aim of this study was the performance evaluation of the CN-6000 system in regard to precision and comparability to the Automated Blood Coagulation Analyzer CS-5100 (CS-5100) for five selected applications: Coagulation Factor VIII (FVIII), Coagulation Factor IX (FIX), Coagulation Factor V (FV), Coagulation Factor VII (FVII), and Factor V Leiden. All reagents and systems are from Siemens Healthineers.

Methods:

- Coagulation Factor V with Dade Innovin reagent
- Coagulation Factor VII with Dade Innovin reagent
- Coagulation Factor VIII with Dade Actin FSL Activated PTT Reagent
- Coagulation Factor IX with Dade Actin FSL Activated PTT Reagent
- Factor V Leiden with Factor V Leiden assay[c]
- Analyzer-specific applications for the CN-6000 and CS-5100 systems.

Precision

- IRB-approved studies were internally performed and evaluated in accordance with CLSI Guideline EP05-A3.[1] CONTROL N (all assays), CONTROL P (factor assays only), ProC CONTROL (FV Leiden assay only) and plasma samples spanning each test's respective measuring interval were measured on the CN-6000 system over 20 days (two runs with two determinations per day).
- Repeatability and within-device CV were calculated.

Method comparison:

- IRB approved studies were performed in accordance with CLSI EP09-A3[1] at four clinical study sites using human citrated plasma samples derived from the intended use population of the selected assays.
- The applications on the CN-6000 system were compared to the CS-5100 system applications.
- Statistical evaluations were conducted using Passing-Bablok regression. Outlier according to Generalized ESD Test were excluded from this evaluation (n = 2 to n = 9 measurements per application).

a. CN-6000 System refers to Automated Blood Coagulation Analyzer CN-6000
b. CN-3000 System refers to Automated Blood Coagulation Analyzer CN-3000
c. Factor V Leiden assay (US only) is equivalent to the ProC Ac R assay (OUS only).

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Results

Precision

Table 1. Precision results for the CN-6000 system.

Parameter (Reagent or assay)	Plasma	Reporting Unit	Mean	Repeatability (%CV)	Within Device (%CV)
Coagulation Factor V (Dade Innovin)	Plasma Sample 1	% of norm	9.24	2.12	2.98
	Control Plasma P	% of norm	23.39	2.82	4.42
	Plasma Sample 2	% of norm	75.26	2.44	4.56
	Control Plasma N	% of norm	89.80	3.10	3.61
	Plasma Sample 3	% of norm	135.75	2.55	3.78
Coagulation Factor VII (Dade Innovin)	Plasma Sample 1	% of norm	11.17	2.34	3.39
	Control Plasma P	% of norm	37.11	2.44	3.34
	Plasma Sample 2	% of norm	64.88	2.34	3.17
	Control Plasma N	% of norm	95.80	2.20	3.21
	Plasma Sample 3	% of norm	137.10	3.70	4.16
Coagulation Factor VIII (Dade Actin FSL)	Plasma Sample 1	% of norm	6.82	3.04	4.08
	Control Plasma P	% of norm	25.95	3.37	3.65
	Plasma Sample 2	% of norm	40.06	3.18	3.86
	Plasma Sample 3	% of norm	65.99	2.76	3.53
	Control Plasma N	% of norm	88.74	3.11	3.77
	Plasma Sample 4	% of norm	174.36	1.75	2.54
Coagulation Factor IX (Dade Actin FSL)	Plasma Sample 1	% of norm	7.32	2.36	3.29
	Control Plasma P	% of norm	29.89	2.05	2.77
	Plasma Sample 2	% of norm	41.69	1.80	3.49
	Plasma Sample 3	% of norm	73.98	2.40	3.77
	Control Plasma N	% of norm	88.84	2.16	3.45
	Plasma Sample 4	% of norm	134.68	2.16	2.93
Factor V Leiden with Factor V Leiden Assay	Plasma Sample 1	Ratio	0.931	0.61	0.93
	ProC Control Plasma	Ratio	1.157	1.88	2.22
	Plasma Sample 2	Ratio	1.866	0.61	1.33
	Control Plasma N	Ratio	3.203	1.09	3.18
	Plasma Sample 3	Ratio	5.707	1.28	1.54

Passing-Bablok regression results for the CN-6000 system vs. CS-5100 system method comparisons of the five indicated applications.

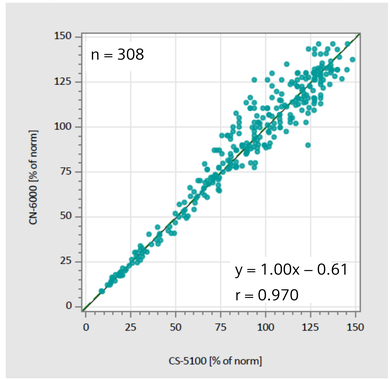

Figure 1. Method comparison for Coagulation Factor V using the Dade Innovin reagent.

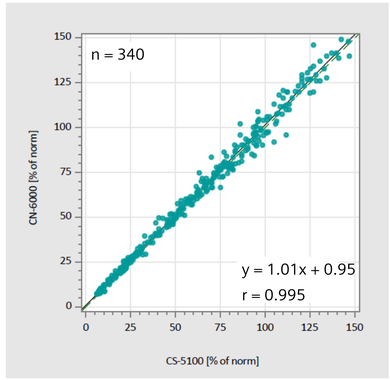

Figure 2. Method comparison for Coagulation Factor VII using the Dade Innovin reagent.

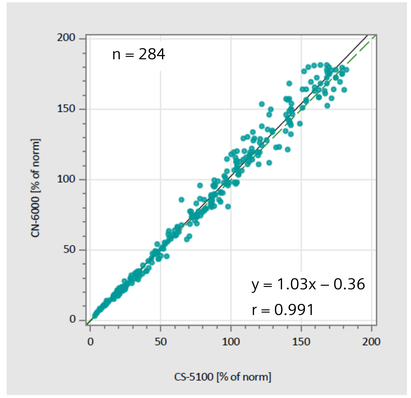

Figure 3. Method comparison for Coagulation Factor VIII using the Dade Actin FSL reagent.

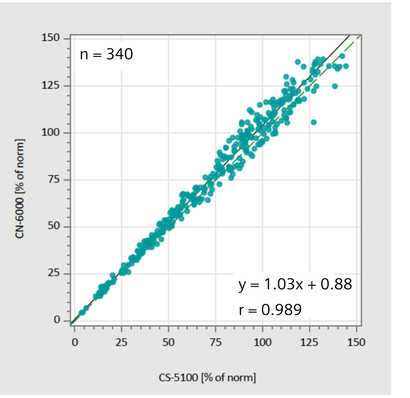

Figure 4. Method comparison for Coagulation Factor IX using the Dade Actin FSL reagent.

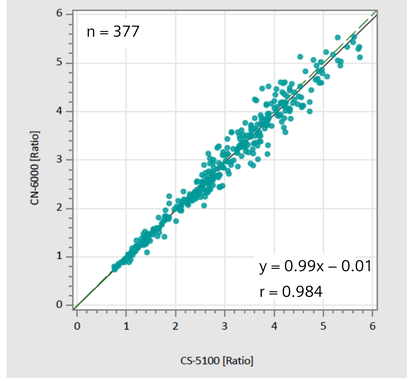

Figure 5. Method comparison for Factor V Leiden using the FV Leiden Assay.

Conclusion

- The CN-6000 system demonstrated high precision (≤ 4.56 %CV) for both repeatability and within device, and high comparability (correlation coefficient r ranges from 0.970 to 0.995) to the CS-5100 system when testing certain factor deficiency assays and the factor V Leiden assay.
- The study thus demonstrates the accuracy and reliability of results generated with the CN-6000 system.The data presented herein are also valid for the CN-3000 system because of the high agreement of system design between the CN-6000 and CN-3000 systems.

References

1. All CLSI Guidelines can be found on the CLSI website: https://clsi.org

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