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## ORIGINAL ARTICLE

# Evaluation of the Sysmex CN-6000 Coagulation Analyzer for Routine and Specialized Coagulation Testing in a Central Laboratory

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### SUMMARY

***Background:*** **The Sysmex CN-6000 is a fully automated high-throughput coagulation analyzer. The objective of this study was to evaluate the analytical performance of the analyzer for routine and special coagulation testing in a high-throughput central laboratory of a university hospital.**
***Methods:*** **The within- and between-day precision and accuracy of 29 coagulation parameters were evaluated on the Sysmex CN-6000 using commercially available quality control materials. Patient plasma samples were used to compare results of coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360, including plasma samples with visual interference. The sample throughputs of both analyzers were compared using plasma samples from healthy volunteers.**
***Results:*** **Within- and between-day coefficients of variation were acceptable for all assays tested on the Sysmex CN-6000. High correlation and good agreement were observed when comparing coagulation results from the Sysmex CN-6000 and the Atellica COAG 360. Samples with visual interference showed comparable coagulation results between the two analyzers, with slightly better detection by the Sysmex CN-6000. The sample throughput per hour for analysis of a panel of five coagulation parameters was higher with the Sysmex CN-6000 compared to the Atellica COAG 360 (247 vs. 193 tests).**
***Conclusions:*** **The Sysmex CN-6000 demonstrated excellent analytical performance for a large number of coagulation parameters and has a high throughput capacity, ideal for the needs of a central laboratory with a high volume of routine and specialized coagulation testing.**
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### KEYWORDS

hemostasis, coagulation, core laboratory, throughput, HIL check

### INTRODUCTION

Coagulation tests are of paramount importance in the assessment of patients presenting with unexplained bleeding, as well as thrombotic diseases, and in the monitoring of anticoagulant therapies [1]. It is convenient to differentiate between these tests, with the first category comprising routine coagulation tests, which are typically high-throughput screening tests performed by most clinical laboratories. The second category,

which is commonly referred to as "special coagulation" tests, comprises lower-throughput diagnostic hemostasis assays, which are typically performed by specialized hemostasis laboratories for the diagnosis and characterization of hemostatic disorders [2]. It is of the utmost importance to ensure accurate and reliable test results for both categories.

In the contemporary clinical laboratory, fully automated coagulation analyzers are an indispensable tool, as they facilitate a wide range of analyses, provide preanalytical test algorithms, and optimize the management of samples, reagents, and consumable materials [3]. Laboratories frequently encounter challenges associated with the processing of a high number of samples, a substantial proportion of which require rapid analysis. In light of these considerations, it is of paramount importance that modern coagulation analyzers are capable of providing high-quality testing while simultaneously enabling high sample throughput, short analysis times, and a low minimum volume requirement for measuring coagulation parameters.

The Sysmex CN-6000 (Sysmex Corp., Kobe, Japan) is a fully automated, high-volume coagulation analyzer that employs a wide spectrum of testing methodologies, including clotting, chromogenic, immunological, and aggregation assays, with 26 flexible reaction detector positions. The measuring principle is simultaneous five-wavelength photometry in all detector channels (340, 405, 575, 660, and 800 nm wavelengths). The analyzer incorporates a hemolysis, icterus, and lipemia (HIL) check with gain-switching technology. In comparison to the Atellica COAG 360 analyzer (Siemens Healthineers, Eschborn, Germany), the main unit of the instrument has a smaller footprint (720 x 906 x 1,350 mm versus 1,858 x 1,042 x 1,415 mm).

The objective of the present study was to assess the analytical performance of the Sysmex CN-6000 and to compare it against the Atellica COAG 360 as integrated analyzers in a total laboratory automation system for routine and special coagulation tests in a central laboratory of a university hospital.

## MATERIALS AND METHODS

### Study design and sample selection

The evaluation of the Sysmex CN-6000 was conducted at the Institute for Clinical Chemistry and Pathobiochemistry at the University Hospital of Tübingen, Germany. Patient blood samples were collected in citrate-containing tubes (Sarstedt, Numbrecht, Germany), out of which residual, anonymized material was used for comparison of coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360 analyzer. Blood samples were centrifuged twice at 4,000 g for 10 minutes and measured within two hours or stored at -80°C until analysis. Frozen samples were thawed within 10 minutes and subsequently analyzed. For all measurements the same reagents, calibrators, and controls were used on both coagulation analyzers (see Table 1). The throughput of the coagulation analyzers was evaluated using freshly collected plasma samples from healthy volunteers. All healthy volunteers provided written informed consent prior to blood sample collection. The study was approved by the local ethics committee of the Medical Faculty of Tübingen, Germany, and was conducted in accordance with the tenets of the Declaration of Helsinki.

### Analytical evaluation methods

Commercially available quality control (QC) material was used to evaluate the precision and accuracy of the Sysmex CN-6000 (all from Siemens Healthineers, unless otherwise indicated, (see Table 1). For within-day evaluation, normal and pathological QC samples were measured ten times in a row. Between-day precision was determined according to CLSI guideline EP15-A2 by measuring triplicates on five consecutive days for each QC level [4]. Accuracy was calculated using the manufacturer's target values for each coagulation parameter.

Linearity of coagulation measurements was determined using normal pool plasma (Technoclone, Vienna, Austria) or patient plasma samples in multiple dilution approaches (1:1, 1:2, 1:4, 1:6, 1:8). Results from diluted samples were compared with theoretically assigned values, and linear regression analysis was used to assess linearity. Linearity was assumed when $R^2 > 0.95$.

Patient plasma samples with visual interference (hemolytic, lipemic, or icteric) were collected and stored at -80°C until analysis. The corresponding lithium heparinized plasma samples (Sarstedt, Numbrecht, Germany) from the same blood collection were used for the determination of triglycerides or total bilirubin concentrations on a clinical chemistry module of an Atellica Solution analyzer (Siemens Healthineers). Plasma hemoglobin concentration was determined by a dual wavelength method (577/605 nm) on a Dimension EXL 200 system (Siemens Healthineers).

### Throughput analysis

To test the sample throughput capacity of the Sysmex CN-6000, plasma samples from healthy volunteers were used to measure a panel of five coagulation parameters (PT, aPTT, fibrinogen, antithrombin, and D-dimer). The same analysis was repeated using the Atellica COAG 360, and the number of results obtained within the first hour was compared between the two analyzers.

### Statistical analysis

Deming regression and Bland-Altman analyses were performed to compare coagulation measurement results of the Sysmex CN-6000 and the Atellica COAG 360. Correlation between measurement results of both analyzers was determined using Spearman's rank-order correlation. Statistical analyses were performed using GraphPad Prism 10.1.1 (GraphPad Software, San Diego, United States) and Analyse-it Software (Analyse-it

Software, Leeds, United Kingdom).

## RESULTS

### Analytical performance

Linearity of coagulation measurements was evaluated for coagulation, chromogenic, and immunological assays. Prothrombin time ($R^2$ = 0.994, 8.5% - 102%), fibrinogen ($R^2$ = 0.996, 0.3 g/L -3.5 g/L), antithrombin ($R^2$ = 0.998, 8% - 93%), D-dimer ($R^2$ = 0.998, 0.5 mg/L FEU - 36.0 mg/L FEU), FVIII ($R^2$ = 0.998, 9.0% - 110%), FIX ($R^2$ = 0.998, 10.0% - 130%), and FXIII ($R^2$ = 0.997, 7.5% - 90%) demonstrated high linearity over the evaluated concentration ranges. To assess potential carryover, heparin-spiked plasma samples (anti-Xa activity > 1.0 U/mL) were measured using the Sysmex CN-6000, and quintuplicate aPTT measurements were performed afterwards. The entire series was repeated three times. In non-spiked samples, aPTT results were within the reference range and anti-Xa activities were below the detection limit.

Within- and between-day precision of the Sysmex CN-6000 were determined using two levels of commercially available quality control (QC) samples covering clinically relevant ranges or thresholds. Results revealed within- and between-day coefficient of variations (CVs) of < 5% for most of the investigated parameters (see Table 2). Slightly increased within-day CVs were observed for FVII (pathological level: 7.5%), FVIII (clotting; pathological level: 5.9%), FX (normal level: 7.9%), and FXI (normal level: 5.1%). Between-day CVs were between 5% and 10% for FVII (normal level: 6.9%, pathological level: 7.8%), FVIII (clotting; normal level: 7.0%, pathological level: 7.7%), FIX (normal level: 6.8%, pathological level: 7.6%), FX (normal level: 8.1%, pathological level: 6.8%), and FXIII (normal level: 5.6%). All other between-day CVs were < 5%.

To assess the accuracy of coagulation measurements, the percentage difference of the Sysmex CN-6000 measurement result from the manufacturer's target value was calculated. Differences were < 10% for all evaluated parameters (see Table 2), except for Apixaban control 2 (-10.5%), Edoxaban control 1 (11.7%), and Rivaroxaban controls 1 + 2 (-12.4% and -10.9%).

### Comparison of coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360

Plasma samples from patients without coagulation disorders, critically ill patients, patients receiving anticoagulants, and patients with specific coagulation factor deficiencies were used to compare coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360 (see Table 3 and Figure 1 and 2).

Comparison analyses showed good correlation between the two coagulation analyzers for all reported parameters (Spearman's $r > 0.89$, $p < 0.0001$). Deming regression analysis and Bland-Altman plots showed a strong association and high agreement between the two analyzers for PT, aPTT, D-dimer, FXIII, Anti-Xa (Heparin), Apixaban, Edoxaban, Rivaroxaban, and von Willebrand factor antigen/activity. Analysis of agreement for fibrinogen (bias: -0.5 ± 0.4 g/L) and antithrombin (bias: -8.4 ± 7.6%) showed lower values obtained by the Sysmex CN-6000 compared to the Atellica COAG 360.

### Assessment of plasma sample quality

Plasma sample quality (HIL check, level 0 - 5) is routinely assessed using the Sysmex CN-6000. To test the performance of coagulation measurements in samples with visual interference, hemolytic (plasma hemoglobin concentration: 13.4 - 120.6 mg/dL), icteric (total bilirubin concentration: 12.0 - 30.9 mg/dL), and lipemic (triglyceride concentration: 285 - 1,424 mg/dL) samples were collected. Both analyzers correctly assessed sample quality in the majority of samples. The Atellica COAG 360 failed to obtain aPTT results in three samples with high triglyceride concentrations (> 650 mg/dL). In contrast, the Sysmex CN-6000 correctly identified aPTT results in these samples. To assess the impact on coagulation measurements, the results of PT, aPTT, fibrinogen, antithrombin, and D-dimer measurements were compared between the two analyzers, and biases were calculated as shown in Table 4.

### Sample throughput

We used 50 samples from healthy volunteers for the determination of five routine coagulation parameters, including PT, aPTT, fibrinogen, antithrombin, and D-dimer. Front loading was used to start the coagulation measurements, and initial results were obtained within six minutes from both analyzers. Complete results for the first sample were obtained within seven (CN-6000) and eight (Atellica COAG 360) minutes. After one hour, the Sysmex CN-6000 had completed 247 individual tests, while the Atellica COAG 360 had completed 193 individual tests. All 50 samples were measured within 62 and 77 minutes using the Sysmex CN-6000 and the Atellica COAG 360, respectively.

## DISCUSSION

The present study comprehensively evaluated the analytical performance of the Sysmex CN-6000 analyzer for routine and specialized coagulation testing. Within- and inter-assay imprecision was optimal for most assays (CV < 5%). Only a few parameters showed slightly elevated CVs in the normal and/or pathological range, but they were still within the manufacturer's specifications for both levels and similar to previously published studies of the CN-6000 [5,6].

Overall, the Sysmex CN-6000 showed good agreement with the Atellica COAG 360, with acceptable mean differences observed for the majority of the parameters studied. Measurements included the major hemostasis parameters, and results spanned the entire clinically relevant concentration ranges or thresholds. Among these,

**Table 1. Reagents, controls, and calibrators used in the evaluation study on the Sysmex CN-6000 and the Atellica COAG 360.**

| Parameter | Reagents | Controls | Calibrators |
|---|---|---|---|
| Prothrombin time (PT) | Innovin | Ci-Trol 2<br>Control N | -/PT Multi Calibrator |
| INR | Innovin | Ci-Trol 2<br>Control N | PT Multi Calibrator |
| Thrombin time | Test Thrombin | Control N<br>Ci-Trol 2 | - |
| aPTT | Actin FS<br>Actin FSL | Ci-Trol 2<br>Control N | - |
| Fibrinogen | Dade Thrombin | Control N/P | Standard Human Plasma |
| Antithrombin | Innovance Antithrombin | Control N/P | Standard Human Plasma |
| D-dimer | Innovance D-dimer | D-Dimer Control 1/2 | D-Dimer Calibrator |
| FII/V/VII/X | FII/V/VII/X deficient plasma Innovin | Control N/P | Standard Human Plasma |
| FVIII/IX/XI/XII | FVIII/IX/XI/XII deficient plasma Actin FS | Control N/P | Standard Human Plasma |
| FVIII chromogenic assay | FVIII chromogenic | Control N/P | Standard Human Plasma |
| FXIII | Berichrom FXIII | Control N/P | Standard Human Plasma |
| Protein C | Berichrom Protein C | Control N/P | Standard Human Plasma |
| Protein S | Innovance Free PS Ag | Control N/P | Standard Human Plasma |
| vWF Ag/Ac | vWF reagent/ Innovance vWF Ac | Control N/P | Standard Human Plasma |
| LA1/2 | LA 1/2 Screening/Confirmation | LA Control low/high | - |
| Anti-Xa | Innovance Anti-Xa | Heparin UF Control<br>Heparin LMW Control | Heparin Calibrator |
| Dabigatran | Innovance DTI | Dabigatran Control low/high | Dabigatran Standards |
| Apixaban | Innovance Anti-Xa | Apixaban Control 1/2 | Innovance Apixaban Standard |
| Edoxaban | Innovance Anti-Xa | Biophen™ Edoxaban Control 1/2 | Biophen™ DiXal Edoxaban Calibrator |
| Rivaroxaban | Innovance Anti-Xa | Rivaroxaban Control 1/2 | Innovance Rivaroxaban Standard |

**INR - international normalized ratio, aPTT - activated partial thromboplastin time, F - factor, vWF Ag - von Willebrand factor antigen, vWF Ac - von Willebrand factor activity, LA1/2 - lupus anticoagulants, Anti-Xa - anti-factor Xa.**

fibrinogen and antithrombin showed the greatest mean bias in terms of total values, with the Sysmex CN-6000 showing lower values. Interestingly, our previous study showed similar differences between the Atellica COAG 360 and the Sysmex CS-5100 for these two parameters [7]. Consequently, the Sysmex CN-6000 and the predictive instrument perform similarly with respect to fibrinogen and antithrombin. Of note, it is imperative that each laboratory establishes and validates reference ranges for coagulation parameters, considering the specific characteristics of their coagulation analyzer. Furthermore, our results are consistent with those of Gardiner et al., who performed an evaluation of the Sysmex CN-6000 against the Sysmex CS-5100 analyzer using the same reagents from Siemens Healthineers [5]. The study by Kim et al. also showed optimal performance of the Sysmex CN-6000, but different reagents were used, so it is not comparable to our study [8].

The study evaluated HIL flagging in 34 samples and detected sample interference in the majority of hemolytic, icteric, and lipemic samples. Both instruments demonstrated excellent sensitivity for optical interference due to HIL, but the Sysmex CN-6000 showed improved specificity. Both the Sysmex CN-6000 and the Atellica COAG 360 use photo-optical coagulation detection. Therefore, the possibility of systematic bias due to wavelength interference cannot be excluded. Nevertheless, the results are consistent with those of a previous

**Table 2. Precision and accuracy of the Sysmex CN-6000.**

| Parameter | Within-day | | | | Between-day | | | |
|---|---|---|---|---|---|---|---|---|
| | mean | ± SD | CV (%) | difference to target value (%) | mean | ± SD | CV (%) | difference to target value (%) |
| PT (%) | 99.0 | 1.03 | 0.4 | 7.7 | 95.7 | 2.19 | 2.3 | 4.1 |
| | 36.7 | 0.28 | 0.6 | 1.6 | 36.0 | 0.35 | 1.0 | -0.2 |
| PT (seconds) | 11.3 | 0.05 | 1.0 | 2.2 | 11.5 | 0.11 | 1.0 | 3.6 |
| | 20.3 | 0.13 | 0.8 | 4.4 | 20.6 | 0.17 | 0.8 | 5.8 |
| aPTT FS (seconds) | 24.4 | 0.28 | 1.2 | -3.0 | 24.8 | 0.36 | 1.4 | -1.0 |
| | 46.7 | 0.16 | 0.3 | -0.9 | 48.9 | 0.39 | 0.8 | 3.9 |
| aPTT FSL (seconds) | 26.1 | 0.12 | 0.5 | 2.0 | 26.4 | 0.33 | 1.2 | 3.1 |
| | 47.1 | 0.31 | 0.6 | 2.6 | 48.8 | 0.35 | 0.7 | 5.9 |
| Fibrinogen (g/L) | 2.57 | 0.08 | 3.2 | 1.6 | 2.62 | 8.43 | 3.2 | 3.5 |
| | 0.75 | 0.02 | 3.0 | 0.1 | 0.82 | 0.03 | 4.2 | 4.3 |
| Antithrombin (%) | 89 | 1.19 | 3.3 | -5.3 | 91 | 4.15 | 4.6 | -2.9 |
| | 30 | 0.99 | 1.3 | -5.6 | 29 | 2.13 | 2.1 | 9.7 |
| D-Dimer (mg/L FEU) | 0.27 | 0.01 | 3.6 | -6.2 | 0.27 | 0.01 | 3.6 | -6.2 |
| | 2.55 | 0.03 | 1.1 | -2.5 | 2.64 | 0.03 | 1.2 | 1.3 |
| Thrombin time (seconds) | 21.3 | 0.43 | 2.0 | 3.1 | 21.0 | 0.20 | 1.0 | 1.4 |
| | 25.6 | 0.83 | 3.3 | 0.4 | 25.2 | 0.48 | 1.9 | -1.3 |
| FII (%) | 109 | 4.36 | 2.8 | 9.0 | 107 | 3.28 | 3.1 | 6.7 |
| | 34 | 0.97 | 4.0 | -2.8 | 34 | 0.87 | 2.6 | 6.8 |
| FV (%) | 101 | 3.78 | 3.4 | 2.9 | 93 | 2.78 | 3.0 | -4.9 |
| | 23 | 0.78 | 3.8 | -3.4 | 23 | 0.52 | 2.3 | 0.7 |
| FVII (%) | 112 | 3.98 | 1.1 | -1.6 | 102 | 7.00 | 6.9 | 1.5 |
| | 37 | 0.40 | 7.5 | -1.1 | 42 | 3.28 | 7.8 | 5.3 |
| FVIII clotting (%) | 103 | 2.15 | 2.1 | 4.3 | 90 | 6.33 | 7.0 | -8.9 |
| | 25 | 0.89 | 5.9 | 4.7 | 29 | 2.23 | 7.7 | -0.3 |
| FVIII chromogenic assay (%) | 106 | 1.44 | 1.4 | 7.4 | 93 | 3.44 | 3.7 | -6.2 |
| | 23 | 0.27 | 2.8 | 4.3 | 31 | 1.16 | 3.7 | -0.1 |
| FIX (%) | 112 | 2.56 | 4.6 | 0.7 | 92 | 6.26 | 6.8 | -5.2 |
| | 39 | 1.16 | 3.1 | 5.8 | 31 | 2.32 | 7.6 | -0.9 |
| FX (%) | 112 | 3.74 | 7.9 | -0.9 | 104 | 8.46 | 8.1 | 1.5 |
| | 33 | 0.71 | 2.2 | 2.7 | 35 | 2.39 | 6.8 | 9.3 |
| FXI (%) | 118 | 6.07 | 5.1 | -0.7 | 118 | 1.75 | 1.5 | -0.6 |
| | 30 | 0.54 | 1.8 | 1.4 | 29 | 0.78 | 2.7 | -4.7 |
| FXII (%) | 122 | 4.61 | 3.8 | 7.4 | 111 | 3.09 | 2.8 | -2.3 |
| | 40 | 0.94 | 3.5 | 6.9 | 38 | 1.39 | 3.7 | 8.5 |
| FXIII (%) | 97 | 2.81 | 2.9 | -0.1 | 93 | 5.26 | 5.6 | -3.9 |
| | 30 | 0.81 | 2.7 | 3.7 | 30 | 3.32 | 4.4 | 4.3 |
| Protein C (%) | 102 | 2.24 | 2.2 | 4.2 | 92 | 0.86 | 0.9 | -5.8 |
| | 30 | 0.41 | 1.9 | 2.1 | 29 | 0.77 | 2.6 | -0.1 |
| Protein S (%) | 86 | 1.55 | 1.8 | -0.1 | 79 | 1.02 | 1.3 | -8.0 |
| | 27 | 0.41 | 1.5 | -2.1 | 25 | 0.38 | 1.5 | -9.7 |
| vWF antigen (%) | 144 | 1.43 | 1.0 | 3.4 | 141 | 5.46 | 3.9 | 1.2 |
| | 46 | 0.36 | 0.8 | 5.2 | 46 | 1.21 | 2.6 | 4.6 |

**Table 2. Precision and accuracy of the Sysmex CN-6000 (continued).**

| Parameter | Within-day | | | | Between-day | | | |
|---|---|---|---|---|---|---|---|---|
| | mean | ± SD | CV (%) | difference to target value (%) | mean | ± SD | CV (%) | difference to target value (%) |
| vWF activity (%) | 118 | 2.61 | 2.2 | 5.1 | 113 | 5.02 | 4.4 | 1.1 |
| | 34 | 1.01 | 3.0 | 1.6 | 33 | 1.09 | 3.3 | -0.8 |
| Anti-Xa (U/mL) | 0.40 | 0.01 | 1.9 | 5.3 | 0.38 | 0.02 | 4.0 | -1.1 |
| | 0.70 | 0.01 | 0.8 | 3.1 | 0.73 | 0.03 | 4.7 | 7.6 |
| Apixaban (ng/mL) | 66 | 1.08 | 1.6 | 3.1 | 78 | 1.60 | 2.1 | 5.1 |
| | 259 | 1.45 | 0.6 | -10.5 | 287 | 7.67 | 2.7 | 9.5 |
| Rivaroxaban (ng/mL) | 61 | 0.90 | 1.5 | -12.4 | 74 | 3.32 | 4.5 | 5.1 |
| | 224 | 3.03 | 1.4 | -10.9 | 262 | 6.80 | 2.6 | 4.2 |
| Edoxaban (ng/mL) | 27 | 0.87 | 3.3 | 11.7 | 26 | 1.45 | 3.5 | 2.1 |
| | 93 | 0.49 | 0.5 | -0.6 | 98 | 1.10 | 4.7 | 2.0 |
| Dabigatran (ng/mL) | 52 | 1.92 | 3.7 | -5.3 | 56 | 0.47 | 0.8 | -4.0 |
| | 205 | 6.04 | 2.9 | -0.9 | 218 | 2.62 | 1.2 | -6.2 |
| LA1 (seconds) | 31.8 | 0.44 | 1.4 | -5.3 | 34.3 | 0.89 | 4.4 | 2.1 |
| | 82.7 | 0.32 | 0.4 | 6.4 | 93.1 | 3.24 | 3.2 | 4.0 |
| LA2 (seconds) | 32.8 | 0.19 | 0.6 | -6.3 | 35.1 | 0.98 | 4.4 | 0.3 |
| | 43.3 | 0.18 | 0.4 | 5.5 | 44.2 | 0.92 | 2.1 | -0.5 |

**PT - prothrombin time, aPTT - activated partial thromboplastin time, F - factor, vWF Ag - von Willebrand factor antigen, vWF Ac - von Willebrand factor activity, LA1/2 - lupus anticoagulants, Anti-Xa - anti-factor Xa.**

**Table 3. Comparison of coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360.**

| Parameter | n | Range | Bias ± SD | Intercept | Slope | Spearman's r |
|---|---|---|---|---|---|---|
| PT (%) | 268 | 8.9 - 148.5 | 1.4 ± 4.2 | -4.30 (-5.98 to -2.62) | 1.03 (1.01 to 1.05) | 0.98 (0.98 to 0.99) |
| aPTT (seconds) | 268 | 17.7 - 136.4 | -1.0 ± 3.1 | 0.06 (-1.80 to 1.91) | 1.03 (0.96 to 1.10) | 0.98 (0.98 to 0.99) |
| Fibrinogen (g/L) | 175 | 0.61 - 9.00 | -0.5 ± 0.4 | 0.28 (0.13 to 0.42) | 1.06 (1.02 to 1.10) | 0.96 (0.95 to 0.97) |
| Antithrombin [%] | 178 | 21 - 132 | -8.4 ± 7.6 | 1.88 (-1.59 to 5.35) | 1.08 (1.04 to 1.11) | 0.90 (0.87 to 0.93) |
| D-dimer (mg/L FEU) | 112 | 0.19 - 65.21 | -0.5 ± 1.2 | -0.02 (-0.34 to 0.30) | 1.10 (1.00 to 1.20) | 0.99 (0.99 to 0.99) |
| FXIII (%) | 104 | 23 - 150 | -0.9 ± 4.3 | 2.08 (-0.73 to 4.89) | 0.99 (0.95 to 1.02) | 0.99 (0.98 to 0.99) |
| Anti-Xa (IU/mL) | 25 | 0.10 - 1.50 | 0.0 ± 0.02 | -0.01 (-0.02 to 0.01) | 1.01 (0.98 to 1.04) | 0.99 (0.99 to 0.99) |
| Apixaban (ng/mL) | 25 | 20 - 350 | -4.4 ± 8.0 | 7.40 (3.45 to 11.36) | 0.97 (0.95 to 0.99) | 0.98 (0.96 to 0.99) |
| Edoxaban (ng/mL) | 25 | 20 - 350 | -7.1 ± 11.6 | 11.96 (4.29 to 19.63) | 0.95 (0.88 to 1.03) | 0.95 (0.88 to 0.98) |
| Rivaroxaban (ng/mL) | 25 | 20 - 350 | -6.0 ± 8.0 | 8.35 (3.99 to 12.71) | 0.98 (0.96 to 0.99) | 0.96 (0.91 to 0.98) |
| vWF antigen (%) | 28 | 15 - 600 | -8.5 ± 15.9 | 13.13 (5.29 to 20.96) | 0.98 (0.94 to 1.02) | 0.99 (0.99 to 0.99) |
| vWF activity (%) | 28 | 15 - 600 | 5.9 ± 36.0 | 12.52 (-3.01 to 28.05) | 0.93 (0.85 to 1.01) | 0.96 (0.91 to 0.98) |

**PT - prothrombin time, aPTT - activated partial thromboplastin time, F - factor, vWF Ag - von Willebrand factor antigen, vWF Ac - von Willebrand factor activity, LA1/2 - lupus anticoagulants, Anti-Xa - anti-factor Xa.**

**Table 4. Coagulation measurements in samples with visual interference.**

| | PT (%) | aPTT (seconds) | Fibrinogen (g/L) | Antithrombin (%) | FXIII (%) | D-dimer (mg/L FEU) |
|---|---|---|---|---|---|---|
| **Hemolytic (n = 12)** | **1.8 ± 3.6** | **-1.5 ± 11.5** | **-0.3 ± 0.4** | **-1.6 ± 10.4** | **-0.6 ± 4.5** | **0.11 ± 0.49** |
| **Icteric (n = 12)** | **0.6 ± 15.1** | **-4.9 ± 12.6** | **-0.4 ± 0.4** | **-3.3 ± 4.1** | **-4.0 ± 4.9** | **-0.09 ± 0.90** |
| **Lipemic (n = 10)** | **3.7 ± 2.1** | **5.3 ± 25.4** | **-0.6 ± 0.4** | **2.3 ± 10.0** | **-8.5 ± 17.7** | **-0.04 ± 0.36** |

**Mean biases ± standard deviations were calculated from Bland-Altman analyses between the Sysmex CN-6000 and the Atellica COAG 360. PT - prothrombin time, aPTT - activated partial thromboplastin time, F - factor.**

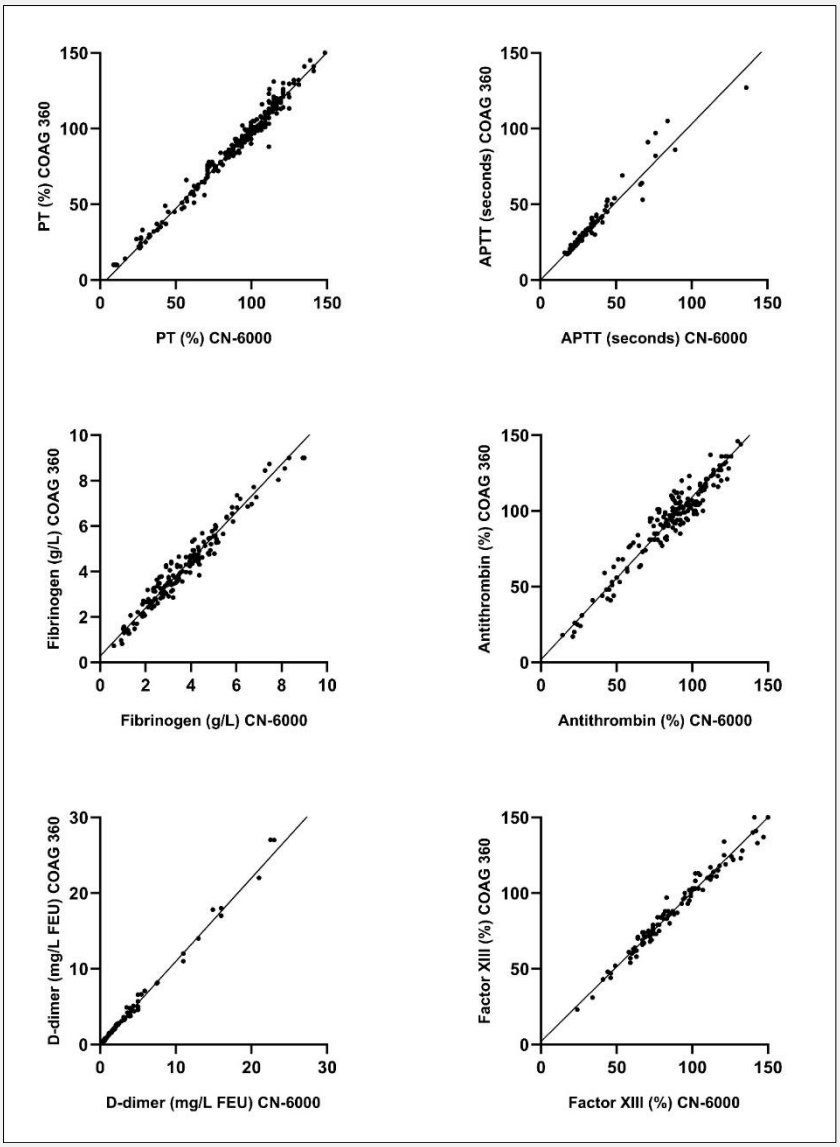


**Figure 1. Deming regression analyses showing the comparison of coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360.**

**Detailed information are provided in Table 3.**

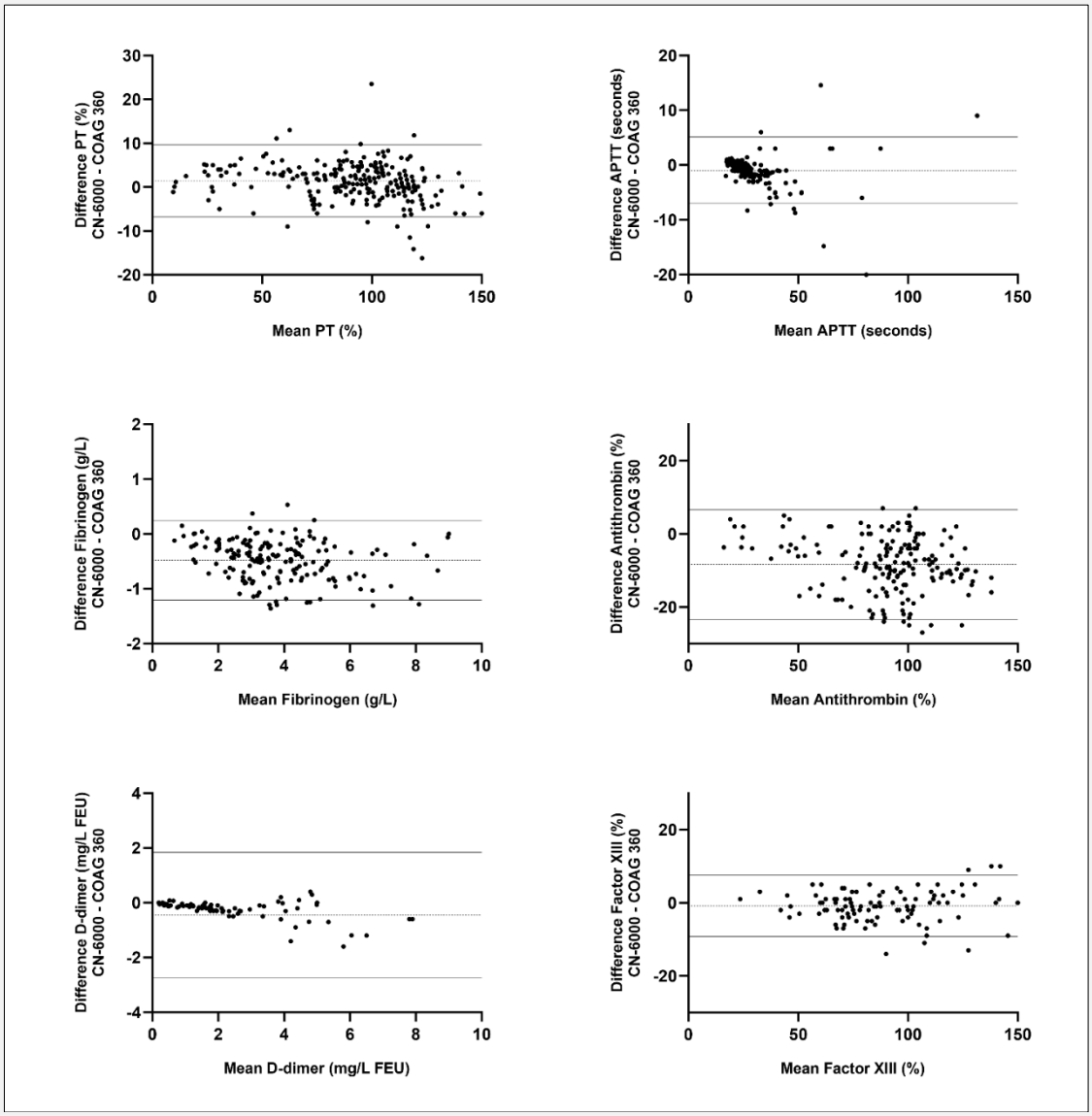


**Figure 2. Bland-Altman analyses showing mean biases of coagulation measurements between the Sysmex CN-6000 and the Atellica COAG 360.**

**Detailed information are provided in Table 3.**

study by Ratzinger et al. and our group comparing the Sysmex CS-5100 and the Atellica COAG 360 with an analyzer using mechanical coagulation detection [7,9]. The Sysmex CN-6000 is designed for use in a high throughput central laboratory. Depending on the laboratory workflow, it can be connected to a total laboratory automation track system. For the purposes of this evaluation, however, we used direct sample loading into the analyzer. A sample throughput rate of approximately 250 tests per hour was determined for a mixed panel of coagulometric (PT, aPTT, fibrinogen, and antithrombin) and immunological (D-dimer) assays. The same evaluation was performed on the Atellica COAG 360, which showed a reduced throughput rate (approximately 195 tests per hour) for the same panel. This panel included commonly requested hemostatic assays and can be considered representative of the needs of a maximum care hospital. In comparison to the study by Gardiner and colleagues, we found a slightly reduced sample throughput rate [5]. However, we tested two additional parame-

ters, including an immunological assay. Nguyen and colleagues reported a 30% higher throughput rate (258 tests per hour vs. 185) using the Sysmex CN-6000 compared to the Stago STAR-Max2 [6]. However, plasma throughput rates are not readily comparable due to the lack of standardization for sample throughput studies. From a personal perspective, this analyzer offers a user-friendly interface and facilitates routine maintenance. The small size of the CN-6000 system allows it to be easily integrated into existing laboratory setups, thereby freeing up space for future expansion. Compared to the Atellica COAG 360, the Sysmex CN-6000 does not offer plasma protein measurement or continuous reagent loading.

In conclusion, the results of the evaluation study demonstrate that the Sysmex CN-6000 offers high analytical performance and good comparability with the Atellica COAG 360 for routine and specific coagulation testing.

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**Declaration of Interest:**
None declared.

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