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Performance Assessment of Sysmex CS-5100 Versus ACL Top 700 in Routine Coagulation Testing

Rutin Koagülasyon Testlerinde Sysmex CS-5100 ve ACL Top 700'ün Performans Değerlendirmesi

Seçkin Özgür Tekeli **Güzin Aykal**
Feyza Yağmur Tekeli **Nur Benil Yabacı**

Sağlık Bilimleri Üniversitesi Antalya Eğitim ve Araştırma Hastanesi, Klinik Biyokimya, Antalya, Türkiye

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ABSTRACT

Aim: This study aimed to evaluate the performance characteristics of preliminary coagulation tests on the Sysmex CS-5100 coagulation autoanalyzer and compare it with the ACL Top 700 autoanalyzer. Both analyzers were assessed for their ability to measure prothrombin time (PT), activated partial thromboplastin time (aPTT), fibrinogen, and D-dimer levels, using optical clot detection and immunological techniques.

Materials and Methods: Blood samples were analyzed on both platforms, and key performance metrics such as within-day and between-day imprecision, bias, and total error were evaluated following CLSI guidelines. Method comparison was conducted using Bland-Altman plots, Passing-Bablok regression, and correlation analyses.

Results: Our results demonstrated that both analyzers provided precise and reliable results for most parameters. However, significant differences were observed in D-dimer measurements, where the Sysmex CS-5100 consistently reported lower values compared to the ACL Top 700, particularly at higher concentrations. Despite these differences, no diagnostic discrepancies were found among patient samples, and strong correlations were observed for all other parameters.

Conclusion: The findings suggest that the Sysmex CS-5100 is a reliable alternative to the ACL Top 700, although further standardization, particularly for D-dimer measurements, may be needed to ensure consistency across platforms.

Keywords: Blood Coagulation tests, Precision, Method comparison.

Yazışma adresi: Seçkin Özgür Tekeli
Sağlık Bilimleri Üniversitesi Antalya Eğitim ve Araştırma Hastanesi, Klinik Biyokimya, Antalya,Türkiye
e-posta: tekeli.ozgur@gmail.com

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ÖZET

Amaç: Bu çalışmanın amacı, Sysmex CS-5100 koagülasyon otoanalizöründe yapılan temel koagülasyon testlerinin performans özelliklerini değerlendirmek ve bu cihazı ACL Top 700 otoanalizörü ile karşılaştırmaktır. Her iki analizör, protrombin zamanı (PT), aktive parsiyel tromboplastin zamanı (aPTT), fibrinojen ve D-dimer düzeylerini ölçme performansları açısından, optik pıhtı tespiti ve immünolojik teknikler kullanılarak değerlendirilmiştir.

Gereç ve Yöntem: Kan örnekleri her iki cihazda analiz edilmiştir ve gün içi ile günler arası imprecison, bias ve toplam hata gibi temel performans ölçütleri CLSI kılavuzları doğrultusunda değerlendirilmiştir. Yöntem karşılaştırması Bland-Altman grafikleri, Passing-Bablok regresyonu ve korelasyon analizleri kullanılarak gerçekleştirilmiştir.

Bulgular: Sonuçlarımız, her iki analizörün de çoğu parametre için kesin ve güvenilir sonuçlar verdiğini göstermiştir. Ancak, D-dimer ölçümlerinde anlamlı farklılıklar gözlenmiş, Sysmex CS-5100 özellikle yüksek konsantrasyonlarda ACL Top 700'e kıyasla sistematik olarak daha düşük değerler bildirmiştir. Bu farklara rağmen, hasta örneklerinde herhangi bir tanısal uyumsuzluk saptanmamış ve diğer tüm parametreler için güçlü korelasyonlar gözlenmiştir.

Sonuç: Bulgular, Sysmex CS-5100'ün ACL Top 700'e güvenilir bir alternatif olduğunu göstermektedir. Ancak, özellikle D-dimer ölçümleri için cihazlar arası tutarlılığın sağlanabilmesi adına ilave standardizasyon gerekebilir.

Anahtar Kelimeler: Kan koagülasyon testleri, Presizyon, Metod karşılaştırma

INTRODUCTION

Today, preliminary coagulation tests are among the basic tests conducted in the biochemistry laboratories of large-scale hospitals (1). In Turkey, the number of prothrombin time tests performed in the biochemistry laboratories of these hospitals can approach up to 1000 test/day. Coagulation autoanalyzers play a crucial role in diagnosing and managing bleeding and clotting disorders, delivering precise and reliable results quickly and efficiently.

There are numerous coagulation autoanalyzers and coagulation test kits marketed by various manufacturers. These kits can exhibit differences that may be reflected in test results, primarily due to the components they contain—particularly thromboplastin—being sourced from different origins (2). However, coagulation test results must be comparable and standardized for patient safety and medical advancement. For these reasons, it is necessary to evaluate the performance of coagulation test methods and conduct comparison studies.

Recent work has continued to evaluate high-throughput hemostasis systems and to characterize inter-assay variability that directly affects clinical interpretation. Since 2022, studies using the Sysmex CS-5100 coagulation autoanalyzer (Siemens Healthcare Diagnostics, Erlangen, Germany) have reported solid analytical performance in routine settings (e.g., Six-Sigma and analytical-phase evaluations) and explored preanalytical effects such as hemolysis on common coagulation tests measured on the Sysmex CS-5100. These reports collectively reinforce that platform-specific detection principles, reagent formulations, and calibration strategies can yield systematic differences that matter in practice—especially for D-dimer, where assay heterogeneity is well-documented and continues to influence diagnostic pathways and imaging yields (3-5).

Against this backdrop, our study compares two high-capacity analyzers [Sysmex CS-5100 as a candidate measurement procedure (MP) and ACL Top 700 (Instrumentation Laboratory, Milan, Italy) as a comparative MP] that are widely used in tertiary-care laboratories. By quantifying precision, bias, and agreement across PT, INR, aPTT, fibrinogen, and D-dimer—and by interpreting differences considering current evidence on inter-assay variability—we aim to provide actionable guidance for result interpretation, analyzer harmonization, and reflex testing policies in busy core labs.

MATERIALS and METHODS

2.1. Analyzers and choice of reagents

This study was conducted to evaluate the analytical performance of two fully automated coagulation analyzers: the Sysmex CS-5100 (Siemens Healthcare Diagnostics, Germany) and the ACL Top 700 (Instrumentation Laboratory, Werfen Group, Germany). Both systems can perform routine coagulation tests including PT, aPTT, fibrinogen, and D-dimer, utilizing optical clot detection methods.

The Sysmex CS-5100 is equipped with multi-wavelength optical detection technology (340, 405, 575, 660, and 800 nm) and provides additional capabilities such as pre-analytical sample integrity checks, including automatic detection of hemolysis, icterus, and lipemia (HIL indices). The analyzer also verifies sample volume and performs automatic cuvette loading and reagent monitoring, enhancing its suitability for high-throughput laboratories.

The ACL Top 700 analyzer also utilizes optical clot detection but lacks integrated pre-analytical HIL checks. Both analyzers use different reagents for the same test parameters, which is an important source of variability in result comparison. The reagents and reference intervals are summarized in Table 1. All reagents were used according to the manufacturers' instructions, and calibration and quality control procedures were performed using manufacturer-recommended calibrators and controls.

2.2. Collection of blood samples

Sterile vacutainer tubes (Vacusera, Disera, İzmir, Türkiye) containing 3,2% sodium citrate as an anticoagulant were used to draw venous blood samples from patients. The blood was collected by a trained phlebotomist following aseptic techniques. After collection, the samples were centrifuged at 1500 g for 15 minutes at 20°C to obtain platelet-poor plasma, which was then analyzed within 4 hours. The samples were directly tested on both the ACL Top 700 and Sysmex CS-5100 instruments.

Only excess material from patient samples, previously collected during standard clinical care, was used in the study. Additionally, all samples used in the study were anonymized to protect patient privacy. Our study was approved by the Ethics Committee of Health Science University Antalya Research and Training Hospital (2024-329) and conducted in accordance with the ethical principles of the Declaration of Helsinki (1964).

2.3. Performance Characteristics

Within-day and between-day imprecision, bias, and total error were assessed following the CLSI EP15-A3 guideline (6). This study was conducted at three levels using lyophilized control materials (Siemens Healthcare Diagnostics). In addition to normal and pathological levels, a third level was created by mixing these two controls in equal proportions. Each control material was tested five times a day for five consecutive days. On each testing day, a new control material from the same lot was reconstituted. Desirable imprecision (CVA), bias and total allowable error (TAE) goals was determined according to the following formulae (7):

$CV_A < 0.5CV_I$

$$\text{Bias} < 0.25\sqrt{CV_I^2 + CV_G^2}$$

$TAE < 1.65CV_A + \text{Bias}$

(CV_I: within-subject biological variation, CV_G: between-subject biological variation).

Updated CVI and CVG values of PT, INR, aPTT, fibrinogen and D-dimer were obtained from European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Biological Variation Database (8). Additionally, between-day imprecision values were compared with the manufacturer's stated imprecision values. The precision design and targets are summarized in Table 2.

Table 1. Charactheristics of the assays on the ACL Top 700 and SYSMEX Cs-5100.
Tablo 1. ACL Top 700 ve SYSMEX CS-5100 koagülasyon testlerinin özellikleri

	ACL Top 700			SYSMEX CS-5100		
	Reagent[a]	Method	Ref. Int.[b]	Reagent[a]	Method	Ref. Int.[b]
aPTT(s)	aPTT-SP silica dispersion with synthetic phospholipid activator (liq)	Opticalclotdetection	23.4–36.9	Actin FS with ellagic acid activator(liq)	Opticalclot detection	21.6–28.7
PT(s)	RecombiPlasTin 2G withrecombinanthumantissue factor (lyo)	Optical clotdetection	9.4–12.3	Thromborel® S withhuman placental thromboplastin (lyo)	Optical clotdetection	9.9–12.3
D-dimer (µg/L)	D-Dimer HS 500 (liq)	Particle-enhancedimmuno turbidimetry	<230	INNOVANCE® D-Dimer(lyo)	Particle-enhancedimmuno turbidimetry	<550
Fibrinogen (mg/dL)	HemosIL Q.P.A. with bovine thrombin (lyo)	Claussclottingassay withopticaldetection	200–393	Dade® Thrombinwithbovinethrombin(lyo)	Claussclottingassaywith optical detection	170-420

aPTT: activated partial thromboplastin time. PT: prothrombin time.
[a]liq: liquid reagent; lyo: lyophilized reagent.
[b]Ref. Int.: reference interval (as stated by the manufacturer).

Table 2. Precision and accuracy indicators of the coagulation tests on the SYSMEX CS-5100 coagulation autoanalyzer.
Tablo 2. SYSMEX CS-5100 koagulasyon otoanalizöründe koagulasyon testlerinin doğruluk ve kesinlik göstergeleri.

Control Material	Assay	Target Value	Within-day Imprecision (%)	Criteria Sysmex (%)	Between-day Imprecision (%)	Criteria Sysmex (%)	Minimum Criteria Imprecision Ricos (%)	Desirable Criteria Imprecision Ricos (%)	Bias (%)	Minimum Criteria bias Ricos (%)	Desirable Criteria bias Ricos (%)	Total Error (%)	Minimum Criteria total error Ricos (%)	Desirable Criteria total error Ricos (%)
Control N	PT (s)	12.6	0.9	≤2	0.1	≤5	2	1.3	-2	2.1	1.4	3.73	5.4	3.6
	INR	1.09	0.9	≤2	0.2	≤5	1.9	1.3	**3.3**	2	1.3	5.1	5.1	3.4
	aPTT (s)	24.3	0.6	≤2	0.4	≤5	2.1	1.4	0.8	2.9	1.9	1.3	6.4	4.2
	Fibrinogen (mg/dL)	256	3.5	≤4	0.1	≤10	7.7	5.1	0.5	7.5	5	7.6	20.1	13.4
Control P	PT (s)	20	1.1	≤2	0.8	≤5	2	1.3	**-4.6**	2.1	1.4	**7.2**	5.4	3.6
	INR	1.77	1	≤2	0.6	≤5	1.9	1.3	1.6	2	1.3	3.9	5.1	3.4
	Fibrinogen (mg/dL)	98	1.2	≤2	2.5	≤10	7.7	5.1	**-8.8**	7.5	5	13.9	20.1	13.4
Citrol	aPTT (s)	43.9	0.4	≤2	0.5	≤5	2.1	1.4	2.3	2.9	1.9	3.5	6.4	4.2
D-Dimer Control 1	D-Dimer (µg/L)	380	1.9	≤10	0.5	≤15	18.9	12.6	7	16.3	10.9	11.6	47.5	31.7
D-Dimer Control 2	D- Dimer (µg/L)	2530	1.2	≤10	0.1	≤15	18.9	12.6	3.5	16.3	10.9	5.9	47.5	31.7

Bolded values exceed the minimum criteria defined. Ricos criteria have been established considering biological variation (7).

2.4. Method comparison

The method comparison study was carried out in accordance with the CLSI EP09-A3 guideline (9). We identified Sysmex CS-5100 as the candidate measurement procedure and ACL Top 700 as the comparative measurement procedure. Table III presents data on the number of samples used and the range of values compared for each test. The Comparison results between the two analyzers were visualized and assessed by Bland–Altman difference plots, Passing–Bablok regression analysis, and a Spearman's Rank correlation coefficient. Acceptable method comparison performance criteria were as follows: The 95% confidence interval of the intercept and slope included point zero and point one respectively in Passing -Bablok regression analysis, the magnitude of the percentual difference between the two analytical methods was below the desirable criteria for total error of Ricos, and the Spearman's Rank correlation coefficient was greater than 0.95.

2.5. Statistical Analysis

All statistical analysis were performed using Analyse-it (Analyse-it Software Ltd, Leeds, UK).

RESULTS

3.1. Performance Characteristics

Precision, bias, and total error were assessed using lyophilized control materials across three concentration levels—normal (Control N), pathological (Control P), and an intermediate level created by mixing equal parts of both controls. Measurements followed CLSI EP15-A3 guidelines, and analytical performance was evaluated using biological variation-based targets (Ricos et al.), including both minimum and desirable criteria.

As shown in Table 2, within-day and between-day imprecision results for all parameters, including D-dimer, were well within both the manufacturer's specifications and the desirable biological variation limits. This indicates acceptable analytical precision of the Sysmex CS-5100 for PT, INR, aPTT, fibrinogen, and D-dimer measurements.

Bias analysis revealed that most parameters demonstrated satisfactory agreement with biological variation-based criteria. However, notable deviations were observed in PT (Control P), INR (Control N), and fibrinogen (Control P), where bias values exceeded both the minimum and desirable thresholds defined by Ricos et al. These values suggest a tendency toward systematic deviation, particularly at pathological levels. In contrast, the remaining parameters—including aPTT and both D-dimer controls—showed bias values well within acceptable limits, indicating strong analytical consistency across a broad measurement range.

Total error (TE%) analysis further supported the analytical performance of the Sysmex CS-5100. Most test results fell within the minimum and desirable total allowable error limits defined by biological variation data. Exception was observed in PT (Control P), which exceeded both minimum and desirable criteria. Despite these deviations, all other parameters—including aPTT, fibrinogen (Control N), and D-dimer at both concentration levels—remained well within acceptable boundaries. Notably, D-dimer total error values (Control 1: 11.6%, Control 2: 5.9%) were significantly lower than both Ricos thresholds, underscoring the robustness of the method in measuring fibrin degradation products.

3.2. Method Comparison

Method comparison was conducted to evaluate the agreement between the Sysmex CS-5100 and ACL Top 700 analyzers for PT, INR, aPTT, fibrinogen, and D-dimer. Statistical assessments included Bland-Altman difference plots and Passing-Bablok regression analysis.

Figure 1 illustrates the Bland-Altman difference plots for all parameters. The mean differences for PT, INR, and fibrinogen were within acceptable bias limits, indicating good agreement. For aPTT, the 95% confidence

interval of the estimated bias was close to the lower limit of acceptability. However, for D-dimer, the bias was outside the acceptable range and exhibited increasing divergence at higher concentrations, suggesting a proportional bias between the two methods.

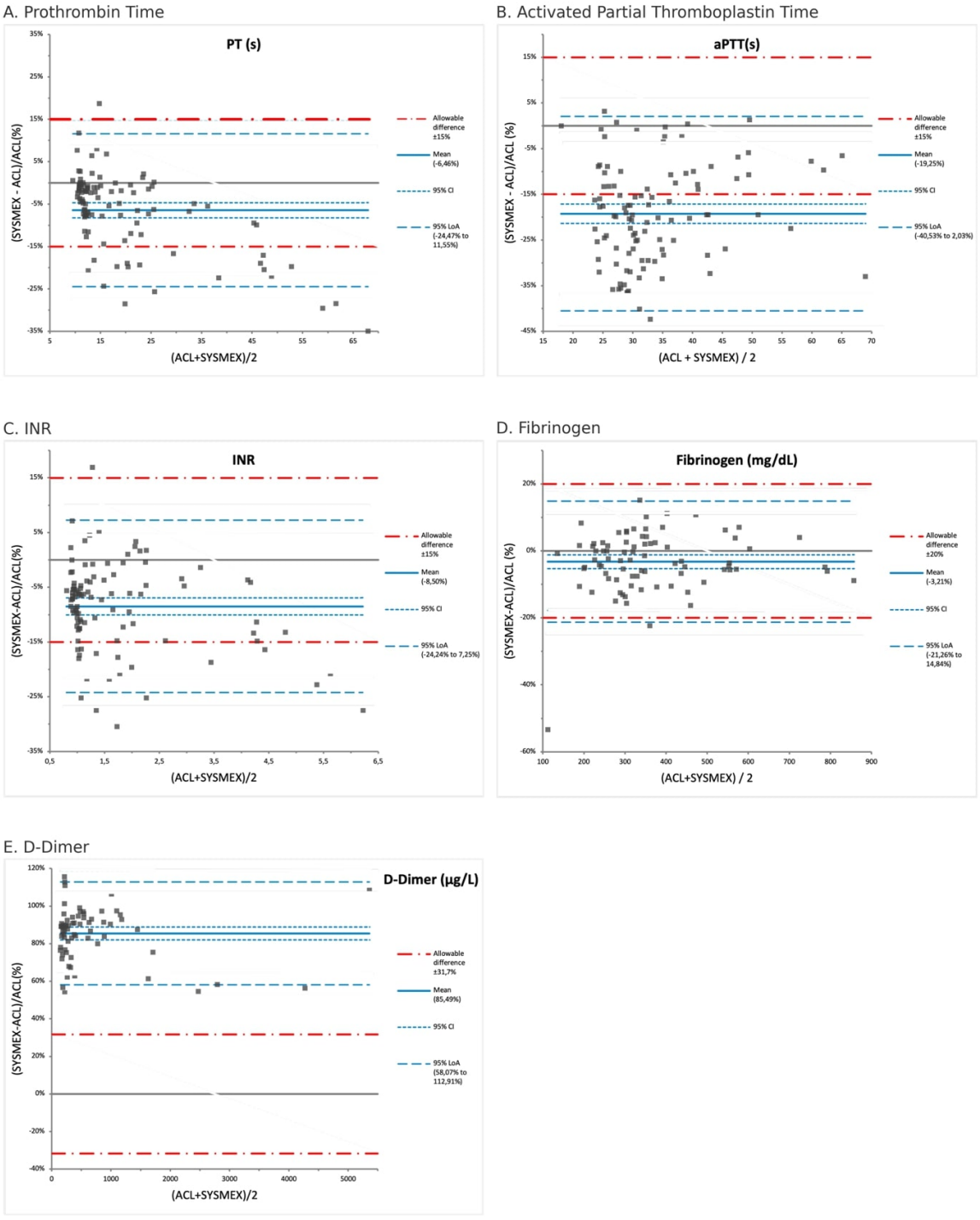

Figure 1. Method comparison analysis: Bland-Altman difference plots.
Şekil 1. Metod karşılaştırma analizi: Bland-Altman fark grafiği.

Table 3 presents the results of the Passing-Bablok regression analysis and Figure 2 displays the Passing-Bablok regression plots, showing the degree of agreement between the Sysmex CS-5100 and ACL Top 700 analyzers. Excellent correlations were observed for all parameters, with the highest coefficients seen in PT and INR followed closely by fibrinogen and aPTT. D-dimer also demonstrated strong correlation, despite a markedly different slope. Specifically, the slope for D-dimer, indicating a significant proportional bias. PT also showed both constant and proportional bias, as reflected in its intercept, which deviated from the ideal values. Conversely, INR, aPTT, and fibrinogen showed intercepts including zero and slopes approaching one, suggesting minimal systematic error. These findings confirm strong agreement between platforms for most parameters, while reinforcing the need for cautious interpretation of PT and D-dimer due to significant proportional deviations.

Figure 2 displays the Passing-Bablok regression plots. The correlation coefficients (Spearman's rho) for PT, INR, and fibrinogen, indicating strong agreement. The coefficients for aPTT and D-dimer were lower, reflecting the variability noted in Bland-Altman plots. The 95% confidence intervals for the intercept included zero for all parameters, while the slope confidence intervals included one for aPTT and fibrinogen only. Notably, the slope for D-dimer was substantially greater than one, confirming the presence of a proportional bias.

Taken together, these results indicate that while PT, INR, aPTT, and fibrinogen measurements are comparable between analyzers, D-dimer results differ significantly, likely due to differences in reagent kits and analytical methodologies. No diagnostic discrepancies were observed based on clinical cutoffs, but the proportional differences should be considered when interpreting D-dimer values across platforms.

Table 3. Passing-Bablok regression analysis.
Tablo 3. Passing-Bablok regresyon analizi.

	n	Range	Median (2,5–97,5 percentile)	Intercept (95% CI)	Slope (95% CI)	r
PT (s)	106	9,5-79,8	13,8 (10,4 - 61,6)	**1,76 (1,08 - 2,34)**	**0,83 (0,78 - 0,89)**	0,987
INR	104	0,83-7,08	1,2 (0,88 - 5,47)	0,06 (-0,011 - 0,1)	**0,88 (0,84 - 0,95)**	0,989
aPTT (s)	105	18-80,4	34,43 (25,1 – 63,7)	-2,52 (-6,1 - 1,3)	0,9 (0,78 - 1,01)	0,926
Fibrinogen (mg/dL)	80	136-895	331 (183,9 – 806,3)	-5,06 (-23,4 - 10,8)	0,98 (0,94 - 1,06)	0,982
D-Dimer (µg/L)	71	88-3070	198 (91,8 – 2144,5)	-17,32 (-46,12 - 16,59)	**2,68 (2,42 - 2,87)**	0,940

PT: prothrombin time, INR: international normalized ratio, aPTT: activated partial thromboplastin time, n: number of samples, r: correlation coefficient. Range of results are shown according to ACL TOP 500. Bold characters indicate cases where the confidence intervals for the intercept and slope do not include zero and one, respectively.

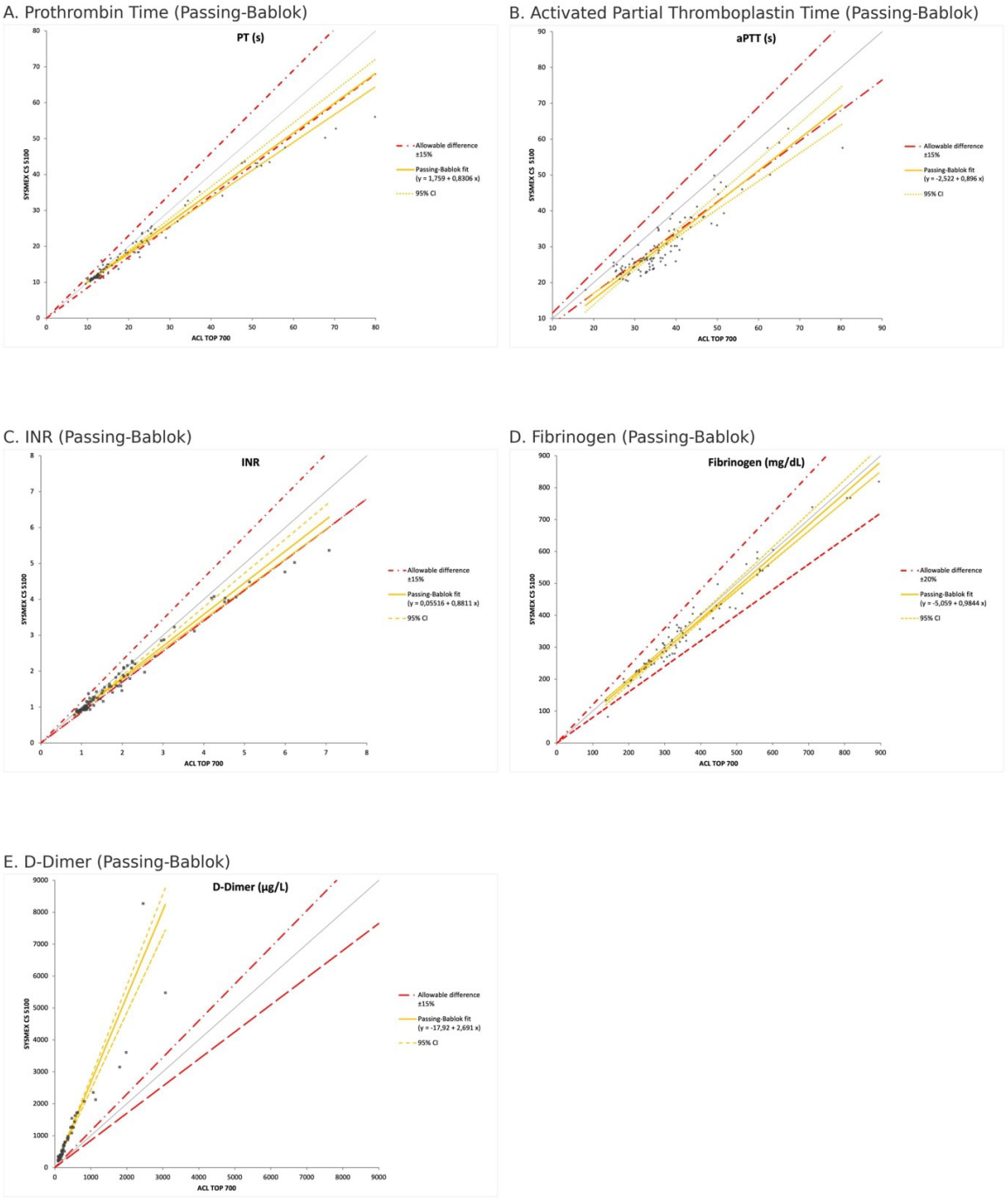

Figure 2. Method Comparison analysis: Passing-Bablok regression analysis.
Şekil 2. Metod karşılaştırma analizi: Passing-Bablok regresyon analizi.

DISCUSSION

This study aimed to assess the analytical performance of routine coagulation parameters—including PT, INR, aPTT, fibrinogen, and D-dimer—using the Sysmex CS-5100 analyzer and to compare these results with those from the ACL Top 700. Precision, accuracy, and method comparison analyses were conducted in accordance with

CLSI guidelines and evaluated using biological variation criteria.

When interpreting the overall analytical performance of the Sysmex CS-5100, it is important to consider the combined outcomes of precision, bias, and total error analyses. The analyzer demonstrated excellent within- and between-day imprecision for all test parameters, consistently meeting both minimum and desirable biological variation thresholds. Most bias and total error values also complied with Ricos criteria (7). But some deviations were observed in the bias and total error values for PT, fibrinogen, and INR. Specifically, the bias values for INR at the normal control level and fibrinogen at the pathological level did not meet the desirable Ricos thresholds; however, their total error values remained within acceptable limits, indicating no significant impact on clinical interpretation. The PT results, at the pathological control level, failed to meet the minimum Ricos specifications for both bias and total error. This contrasts with the findings of Geens et al., who demonstrated that both bias and total error satisfied the Ricos criteria when using the Dade Innovin (PT) kit on the same autoanalyzer (10). Further analysis using the Bland–Altman plot for PT shows that dispersion widens in the negative direction as PT increases (Figure 1). This suggests that the elevated absolute values of bias and total error observed with pathological control materials are not random but rather reflect a systematic source of error. This interpretation is supported by the fact that precision met the acceptance thresholds. In a related observation, a review of the external quality control results (RIQAS Cycle 15, Coagulation Program) determined that, while the overall results were distributed within the ± 1standard deviation range, the specific PT results for external quality control samples (ranging between 10.9-15.2 s) remained within the normal reference range, and no prolonged results were obtained.

We also note that converting PT seconds to INR substantially attenuates the proportional deviations seen at prolonged clotting times, thereby improving comparability between different measurement methods (11). In routine clinical care, particularly for monitoring vitamin K antagonist therapy, clinical decisions are primarily based on the INR value rather than the raw PT in seconds. Nevertheless, markedly prolonged PT values may still be encountered (e.g., at the high end of the range or in the presence of analytical interferences/flags), and these deviations may not be fully captured by a near-therapeutic INR. Consequently, clinicians should be explicitly alerted when the PT result is unusually high, allowing the results to be interpreted within the appropriate clinical and preanalytical context.

The method comparison analysis revealed strong agreement between the two analyzers for PT, INR, aPTT, and fibrinogen. This was supported by high correlation coefficients, regression slopes close to 1, and Bland-Altman plots showing minimal bias within acceptable limits. Notably, the INR results were particularly robust, with minimal total error and near-perfect alignment between devices. These results affirm the suitability of the Sysmex CS-5100 for clinical use in measuring these parameters.

However, significant discrepancies were identified in the D-dimer results. The Sysmex CS-5100 consistently reported lower values than the ACL Top 700, particularly at higher concentrations. The Bland-Altman plot (Figure 1) showed a proportional bias that increased with D-dimer concentration. This finding was corroborated by the Passing-Bablok regression analysis (Figure 2), which showed a slope significantly deviating from unity (2.69), indicative of a proportional systematic difference.

Consistent with our findings, D-dimer values tended to be higher on the Sysmex platform than on the comparator system. In the CN-6000 vs. STA-R Max study, the regression slope for D-dimer was >1 (1.17), indicating higher readings on CN-6000 across the range (12). Similarly, another CN-6000 vs. STA-R comparison reported a D-dimer slope

above 1 (1.10–1.21), again pointing to slightly higher Sysmex results despite good overall agreement (13).

We attribute this variation primarily to the different D-dimer reagents used by each analyzer: the Sysmex CS-5100 utilizes the INNOVANCE® D-Dimer assay (cutoff <550 μg/L), while the ACL Top 700 uses the D-Dimer HS 500 assay (cutoff <230 μg/L). External quality control (EQC) data (RIQAS Cycle 15 & 16, Coagulation Program) over one year showed consistent performance of the INNOVANCE® assay on the CS-5100, with results remaining within ±0.5 SD of the peer group mean. Conversely, EQC participants using the HS-500 reagent reported generally lower values, aligning with our observations. These findings emphasize the need for caution when comparing D-dimer results between platforms using different assays, even when both fall within clinically accepted ranges.

Importantly, when we applied the manufacturer-recommended cutoffs to the D-dimer results from both analyzers, no diagnostic discrepancies were observed in any of the 71 patient samples. This suggests that despite numerical differences, clinical interpretation remained consistent between the platforms.

Beyond our head-to-head comparison, current literature supports three themes. First, CS-series analyzers (including CS-5100) continue to demonstrate imprecision comfortably within biological-variation targets in routine use, aligning with our precision estimates (10,14). Second, high throughput and robust analytical concordance between the CS-5100 and ACL Top systems, supporting the platform's clinical applicability (14). Third, inter-assay variability for D-dimer remains clinically relevant: contemporary studies comparing multiple D-dimer assays (including HemosIL HS/HS-500 and Innovance families) show different specificity profiles and demonstrate that harmonization or unified calibration can improve cross-system consistency (12,13,15). These points collectively support our interpretation that the PT and especially D-dimer differences we observed are primarily assay-driven and should be managed with analyzer-specific cutoffs and, where feasible, local verification or calibration alignment.

A major strength of this study is the inclusion of a relatively high number of patient samples for method comparison, which enhances the generalizability of the findings, particularly in a real-world clinical laboratory setting. In addition, the study also has limitations. This was a single-center evaluation and done without subgroup analyses across clinically distinct populations (e.g., oncology, pregnancy, renal impairment). We did not assess turnaround time, reagent consumption, or cost-effectiveness, nor did we perform external validation across multiple sites. Future work should include multi-center cohorts, analyzer-specific reference interval verification in special populations, and participation in harmonization initiatives for D-dimer calibration. In this study, the analytical performance of the Sysmex CS-5100 coagulation analyzer was evaluated and compared with the ACL Top 700 across key preliminary coagulation tests, including PT, INR, aPTT, fibrinogen, and D-dimer. The Sysmex CS-5100 demonstrated excellent precision and strong agreement with the ACL Top 700 for most parameters, supporting its reliability and suitability for routine clinical use.

While measurements of PT, INR, aPTT, and fibrinogen were consistent between the two analyzers, significant proportional differences were observed in D-dimer results, with the Sysmex CS-5100 consistently yielding lower values. These discrepancies were attributed to differences in assay design and calibration standards between reagent kits. Nonetheless, no diagnostic misclassifications occurred when analyzer-specific reference ranges were applied, reaffirming the clinical acceptability of both systems.

Overall, the Sysmex CS-5100 offers a robust and efficient alternative to the ACL Top 700 for coagulation testing in high-volume laboratory settings. However, assay-specific standardization—particularly for D-dimer—is essential to ensure cross-platform harmonization and accurate interpretation of patient results.

Conflict of Interest

The authors declare no conflict of interest.

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