

Analytical Assessment of the New Roche Cobas t 711 Fully Automated Coagulation Analyzer

Giuseppe Lippi, MD¹ Gian Luca Salvagno, MD¹ Matteo Gelati, PhD¹ Giovanni Poli, MD¹
Davide Giavarina, MD² Emmanuel J. Falavero, PhD, FFSc (RCPA)³

¹ Section of Clinical Biochemistry, Department of Neurological, Biomedical and Movement Sciences, University of Verona, Verona, Italy

² Department of Laboratory Medicine, San Bortolo Hospital, Vicenza, Italy

³ Department of Haematology, Sydney Centres for Thrombosis and Haemostasis, Institute of Clinical Pathology and Medical Research, NSW Health Pathology, Westmead Hospital, Westmead, NSW, Australia

Address for correspondence Giuseppe Lippi, MD, Section of Clinical Biochemistry, Department of Neurological, Biomedical and Movement Sciences, University Hospital of Verona, Piazzale L.A. Scuro 10, 37134–Verona, Italy (e-mail: giuseppe.lippi@univr.it).

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Abstract

This study aimed to provide a preliminary evaluation of the analytical performance of the new Roche **cobas t 711** fully automated coagulation analyzer, which uses both liquid and lyophilized reagent cassettes. The analytical assessment included analysis of imprecision and linearity of prothrombin time (PT), activated partial thromboplastin time (APTT), and fibrinogen on **cobas t 711** analyzer. Test results of 120 routine plasma samples were also compared with those obtained using two other coagulation analyzers (Instrumentation Laboratory ACL TOP 700 and Stago STA-R MAX). The accuracy, imprecision, and comparability of manual and automatic lyophilized material resuspension were also evaluated using 200 routine plasma samples. Overall, automatic resuspension was found to be more precise than, and equally accurate as, manual reconstitution, with coefficient of variations (CV%) three- to sixfold lower compared with manual reconstitution. The analytical imprecision was found to be excellent, as attested by total CV% of 0.7% for PT, 1.7 to 1.8% for APTT, and 1.9 to 3.2% for fibrinogen. Linearity was excellent over a clinically significant range of PT, APTT, and fibrinogen values, displaying correlation coefficients comprised between 0.994 and 0.999. Methods comparison studies revealed that results of PT, APTT, and fibrinogen on **cobas t 711** are globally aligned with those obtained using identical plasma samples on IL ACL TOP 700 and Stago STA-R MAX, displaying correlation coefficients of 0.97 for PT, 0.81 and 0.88 for APTT, 0.90 and 0.94 for fibrinogen, respectively. In conclusion, the results of this preliminary evaluation demonstrate that PT, APTT, and fibrinogen on **cobas t 711** coagulation analyzer displays excellent performance for routine use in clinical laboratories.

Keywords

- ▶ blood coagulation
- ▶ hemostasis
- ▶ diagnosis
- ▶ laboratory
- ▶ instrumentation
- ▶ analyzer

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Hemostasis is an intricate and multifaceted biological pathway, whose appropriate functioning is essential for survival of humans and of many other animal species.¹ Physiological hemostasis is conventionally divided into three parts: primary and secondary hemostasis, which are mainly aimed at allowing the generation of a stable blood clot once the integrity of blood vessels has been jeopardized, and which are accompanied by fibrinolysis, a biological process aimed to further control and dissolve blood clots once hemorrhage has been arrested.¹

Hemostasis disturbances can be conventionally classified as hemorrhagic, when blood coagulation cannot efficiently prevent the leakage of blood from arterial or venous vessels, or as thrombotic, when blood clot generation is disproportionate or apparently unnecessary (i.e., not associated with disruption of blood vessels integrity).² Both these conditions represent important causes of morbidity and mortality around the world.³ The current diagnostic approach to patients with hemostasis disturbances encompasses an integrated strategy, combining clinical history and physical examination, alongside results of laboratory testing.⁴ The many available hemostasis tests are usually divided into sequential priority classes, the first being represented by the so-called first-line (screening) analyses, mostly entailing prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, D-dimer, and potentially platelet function screening tests (i.e., by platelet analyzer [PFA] 100/200), followed by second-line tests, mainly aimed at identifying the underlying source of the hemorrhagic or thrombotic disease, which are then followed by third-line tests, mostly represented by molecular biology and other highly specialized analyses aimed at recognizing the precise molecular or biochemical defect.^{1,5,6}

Since laboratory diagnostics has now become a mainstay for the diagnostic and therapeutic approach of hemostasis disorders, the availability of rapid, accurate, precise, automated, and relatively inexpensive, laboratory tests is becoming increasingly important.^{4,7} The new generation of coagulation analyzers is designed to meet most of these essential aspects, thus encompassing fully automated functioning, cap piercing, random analysis of samples (for both routine and urgent testing), large test menus (including a vast array of clotting, chromogenic, and immunoturbidimetric assays), advanced software enabling automatic retesting or reflex testing, suitability for laboratory automation, and, with some analyzers, automatic check of sample quality.^{8–10} Therefore, the present study was aimed to perform a preliminary analytical assessment of three first-line coagulation tests (i.e., PT, APTT, and fibrinogen) on the new Roche **cobas t 711** fully automated coagulation analyzer.

Materials and Methods

Analyzer Description

The Roche **cobas t 711** analyzer (Roche Diagnostics GmbH) is a new fully automated, random continuous-access coagulation analyzer, which has broadened the hemostasis testing concept to use reagent cassettes, as characterizing other clinical chemistry and immunochemistry analyzers of the Roche cobas series. The cassettes can contain both liquid and lyophilized reagents. Regarding the latter, the instrument performs an

automatic resuspension of lyophilized material, thus potentially overcoming the inherent imprecision and potential inaccuracy of manual pipetting.¹¹ Reconstitution of reagents can be automatically scheduled, thus improving walk-away reagents management. The test menu encompasses a variety of clotting (optical clot detection), chromogenic, and immunoturbidimetric assays. The analyzer has a capacity of 225 samples and is capable of performing up to 390 tests per hour, along with automatic checking of sample tube pressure and quality, to address the presence of relevant concentrations of interfering substances such as cell-free hemoglobin, bilirubin, and lipids.¹² The analyzer has hence different capabilities to detect clotted and/or preactivated specimens. Sample pipetting is constantly monitored by pressure sensors so that pipetting will not be performed and test results will be flagged accordingly when the delta pressure is compatible with clot aspiration. When the sample is partially clotted, or serum is aspirated (even without clots), the measurements will be performed. In such cases, however, clotting will not take place in an established timeframe, and results will be then flagged. The reagents used in this study were PT, clotting assay with human recombinant thromboplastin as activator (cobas PT Rec; Roche Diagnostics GmbH), APTT, clotting assay with ellagic acid as activator (cobas aPTT; Roche Diagnostics GmbH), fibrinogen, Clauss clotting assay (cobas Fibrinogen; Roche Diagnostics GmbH; ▶ **Table 1**). The reference ranges declared by the manufacturer are comprised between 8.4 and 10.6 seconds for PT, 23.6 and 30.6 seconds for APTT, and between 1.9 and 4.1 g/L for fibrinogen, respectively.

Lyophilized Reagents Reconstitution Studies

This preliminary aspect of our study was planned to evaluate accuracy and imprecision of manual and automatic resuspension of the two methods based on cassettes containing lyophilized material (i.e., PT and fibrinogen). More specifically, 10 PT empty cassettes and 10 fibrinogen empty cassettes were weighed on a precision balance (AG135 Dual Range; Mettler Toledo; linearity range: 101–0.0001 g; imprecision: ± 0.0003 g), and were then loaded into the analyzer for automatic resuspension with distilled water (i.e., 33 mL for PT and 14.4 mL for fibrinogen, respectively, as declared by the manufacturer). Immediately after resuspension, the cassettes were unloaded, weighed on the same precision balance, and the weight difference after and before automatic resuspension was finally calculated for each cassette (1 mL of distilled water = 1 g). Successively, 10 PT empty cassettes and 10 fibrinogen empty cassettes were also weighed on a precision balance and manually resuspended by pipetting the nominal amount of distilled water, as for automatic resuspension. The cassettes were then weighed on the same precision balance and the weight difference after and before manual resuspension was finally calculated for each cassette. The ensuing analysis encompassed the calculation of accuracy (i.e., mean percent difference from nominal filling volume of the cassettes) and imprecision (i.e., coefficient of variation; CV%) for both automatic and manual resuspension.

Two automatically resuspended PT cassettes and two automatically resuspended fibrinogen cassettes were then

Table 1 Description of analyzers, reagents, and methods used for this study

| Test | Analyzer | Reagent | Method | Reference range ^a |
|------------|--------------------------|---------------------------------------|---|------------------------------|
| PT | Roche cobas t 711 | Cobas PT Rec (Lyophilized; ISI, 0.91) | Clotting assay with human recombinant thromboplastin as activator | 8.4–10.6 s |
| PT | IL ACL TOP | HemosIL RecombiPlasTin (ISI, 0.99) | Clotting assay with human recombinant thromboplastin as activator | 9.4–12.5 s |
| PT | Stago STA-R MAX | STA-NeoPTitimal (ISI, 1.00) | Clotting assay with rabbit brain thromboplastin as activator | 11.7–15.3 s |
| APTT | Roche cobas t 711 | Cobas aPTT | Clotting assay with ellagic acid as activator | 23.6–30.6 s |
| APTT | IL ACL TOP | HemosIL SynthASil | Clotting assay with colloidal silica activator | 25.1–36.5 s |
| APTT | Stago STA-R MAX | STA-Cephascreen | Clotting assay with polyphenolic activator | 26.4–32.0 s |
| Fibrinogen | Roche cobas t 711 | Cobas Fibrinogen (Lyophilized) | Clauss clotting assay | 1.9–4.1 g/L |
| Fibrinogen | IL ACL TOP | HemosIL Fibrinogen-C XL | Clauss clotting assay | 2.4–5.0 g/L |
| Fibrinogen | Stago STA-R MAX | STA-Liquid Fib | Clauss clotting assay | 2.0–4.0 g/L |

Abbreviations: APTT, activated partial thromboplastin time; ISI, international sensitivity index; PT, prothrombin time.

^aAs quoted by manufacturers.

used for measuring PT and fibrinogen on 200 routine plasma samples, randomly selected from those referred to the local laboratory for routine coagulation testing. Test results were then compared with those obtained on the same set of plasma samples using two other manually resuspended PT and fibrinogen cassettes. Data comparison was performed using Spearman's correlation and Bland and Altman plots (mean values and 95% confidence interval [95% CI]).

Imprecision Studies

This part of our study planned to evaluate the within-run, between-run, and total imprecision of **cobas t 711** analyzer, using automatically resuspended cassettes. Two plasma pools each for PT and APTT (labeled as “low” and “high”) and three plasma pools for fibrinogen (labeled as “low,” “medium,” and “high”) were prepared from plasma samples referred to the local laboratory for routine coagulation testing. The pools were then divided into 11 matched plasma aliquots each. The first aliquot was used for within-run imprecision studies, which were carried out by performing 20 consecutive measurements on the same plasma aliquot. The remaining 10 plasma aliquots of each pool were frozen at -80°C ; one plasma aliquot of each of the seven pools was then thawed throughout each of the 10 following working days for analyzing PT, APTT, and fibrinogen. The within-run, between-run, and total imprecision were finally expressed as CV%.

Linearity Studies

This part of our study planned to evaluate the linearity of **cobas t 711** analyzer, using automatically resuspended cassettes. Two plasma pools each for PT, APTT, and fibrinogen, displaying high and low values of these tests, were prepared using plasma samples referred to the local laboratory for routine coagulation testing. The “high” and “low” plasma pools were serially mixed at fixed ratios (10 + 0, 1 + 9, 8 + 2, 7 + 3, 6 + 4, 5 + 5, 4 + 6, 3 + 7, 2 + 8, 1 + 9, 0 + 10), to obtain scalar values of all tests

covering the most clinically significant ranges. The resulting dilutions were then tested in duplicate on **cobas t 711** analyzer; the mean values of the duplicate tests were calculated and the linearity of PT, APTT, and fibrinogen were finally assessed with Pearson's correlation, by plotting theoretical versus measured values.

Methods Comparison Studies

This part of our study planned to evaluate the comparability of PT, APTT, and fibrinogen test results obtained using **cobas t 711** analyzer versus those measured in paired plasma samples with Instrumentation Laboratory ACL TOP 700 (Instrumentation Laboratory [IL]) and Stago STA-R MAX (Diagnostica Stago SAS), as otherwise representing established coagulation systems. For this purpose, 120 routine plasma samples were randomly selected (40 from outpatients, 30 from emergency department patients, and 40 from patients on warfarin therapy) and divided in three identical aliquots, which were frozen at -80°C until measurement. All the three aliquots of each plasma sample were then thawed during the same day; the first aliquot was tested on **cobas t 711** analyzer, the second on IL ACL TOP 700, and the third on STA-R MAX (description of reagents is provided in ►Table 1). Comparison of data generated by the three different coagulation analyzers was performed using Spearman's correlation and Passing and Bablok regression analysis.

Sample Collection and Ethical Committee Approval

All the samples used in this study were collected by straight needle venipuncture, directly into evacuated blood tubes containing 0.105 mmol/L buffered sodium citrate (Vacutest Kima). The plasma was separated by centrifugation at $1,300 \times g$ for 15 minutes at room temperature. The entire study was based on preexisting and anonymized samples referred to the local laboratory for routine coagulation

Table 2 Accuracy and imprecision of manual and automatic lyophilized cassettes resuspension on Roche cobas t 711 analyzer (1 mL of distilled water = 1 g)

| Test | Theoretical filling weight ^a | Automatic resuspension | | | Manual resuspension | | |
|------------|---|-----------------------------|-------|---|-----------------------------|-------|---|
| | | Filling weight ^b | CV% | Difference vs. theoretical filling weight | Filling weight ^b | CV% | Difference vs. theoretical filling weight |
| PT | 33 g | 32.86 ± 0.01 g | 0.04% | -0.4 ± 0.1% | 33.12 ± 0.09 g | 0.27% | 0.4 ± 0.3% |
| Fibrinogen | 14.4 g | 14.32 ± 0.01 g | 0.09% | -0.6 ± 0.1% | 14.47 ± 0.04 g | 0.26% | 0.5 ± 0.3% |

Abbreviations: APTT, activated partial thromboplastin time; CV%, coefficient of variation; PT, prothrombin time.

Notes: Data are calculated on 10 cassettes each of both PT and fibrinogen reagents. Source: Data are shown as mean ± standard deviation (SD).

^aAs declared by the manufacturer.

^bWeight difference of the cassettes after and before resuspension.

testing, and representing excess material otherwise destined for discarding, so that patient-informed consent was unnecessary. Test results obtained in this study were used only for this analytical evaluation and were not reported. The study was approved by the local ethical committee (University Hospital of Verona, Protocol n. 971CESC; July 7, 2016).

Results

Lyophilized Reagents Reconstitution Studies

The results of reagent reconstitution studies for PT and fibrinogen cassettes are shown in ►Table 2. As predictable, the precision of the automatic resuspension was consistently better than that of manual resuspension for both PT (respective imprecision 0.04 vs. 0.27%; $p < 0.001$) and fibrinogen (0.09 vs. 0.26%; $p < 0.001$) cassettes. The difference between theoretical and measured filling volume was comparable for both PT (automatic: $-0.4 \pm 0.1\%$; manual: $0.4 \pm 0.3\%$) and fibrinogen (automatic: $-0.6 \pm 0.1\%$; manual: $0.5 \pm 0.3\%$) cassettes. The difference of values obtained measuring 200 routine plasma samples with automatically or reconstituted reagent cassettes was neither statistically nor clinically significant for both PT ($r = 0.989$ and $p < 0.001$; mean bias, -0.4% and 95% CI: -0.8% to -0.0% ; $p = 0.05$) and fibrinogen

($r = 0.985$ and $p < 0.001$; mean bias: -0.8% and 95% CI: -2.8 to 1.1% ; $p = 0.408$).

Imprecision Studies

The results of imprecision studies are shown in ►Table 3. Briefly, within-run ($n = 20$), between-run ($n = 10$), and total imprecision were 0.4 to 0.5%, 0.5 to 0.6%, and 0.7% for PT; 0.6 to 0.8%, 1.5 to 1.7%, and 1.7 to 1.8% for APTT; 0.8 to 1.7%, 1.7 to 2.7%, and 1.9 to 3.2% for fibrinogen, respectively.

Linearity Studies

The linearity studies showed excellent performance of the three reagents tested, over a clinically significant range of PT, APTT, and fibrinogen values. More specifically, PT was found to be highly linear ($r = 0.992$; $p < 0.001$) between 7.6 and 47.3 seconds, APTT ($r = 0.984$; $p < 0.001$) between 24.5 and 131.7 seconds, and fibrinogen ($r = 0.999$; $p < 0.001$) between 0.08 and 7.48 g/L.

Methods Comparison Studies

The results of the method comparison studies are shown in ►Table 4 and ►Fig. 1. The correlations of values ($n = 120$) between cobas t 711 and ACL TOP or STA-R MAX were 0.97 for PT, 0.88 and 0.81 for APTT, and 0.97 for fibrinogen,

Table 3 Results of imprecision studies on Roche cobas t 711 analyzer

| Test | Within run ($n = 20$) | | Between run ($n = 10$) | | Total CV% |
|------------------|-------------------------|------|--------------------------|------|-----------|
| | Values (mean ± SD) | CV% | Values (mean ± SD) | CV% | |
| PT (s) | | | | | |
| Low | 7.99 ± 0.03 | 0.4% | 7.97 ± 0.05 | 0.6% | 0.7% |
| High | 28.34 ± 0.14 | 0.5% | 27.82 ± 0.13 | 0.5% | 0.7% |
| APTT (s) | | | | | |
| Low | 27.07 ± 0.16 | 0.6% | 25.77 ± 0.43 | 1.7% | 1.8% |
| High | 43.36 ± 0.33 | 0.8% | 40.85 ± 0.63 | 1.5% | 1.7% |
| Fibrinogen (g/L) | | | | | |
| Low | 1.22 ± 0.01 | 0.8% | 1.21 ± 0.02 | 1.7% | 1.9% |
| Medium | 2.54 ± 0.04 | 1.7% | 2.56 ± 0.05 | 2.0% | 2.6% |
| High | 6.01 ± 0.10 | 1.7% | 6.06 ± 0.16 | 2.7% | 3.2% |

Abbreviations: APTT, activated partial thromboplastin time; CV%, coefficient of variation; PT, prothrombin time; SD, standard deviation.

Table 4 Results of methods comparison studies

| Test | Cobas t 711 vs. ACL TOP | Cobas t 711 vs. STA-R MAX | ACL TOP vs. STA-R MAX |
|------------|--|---|---|
| PT | $y = 0.78x - 0.51$ $r = 0.97$ (95% CI, 0.96–0.98; $p < 0.001$) | $y = 0.61x + 0.12$ $r = 0.97$ (95% CI, 0.95–0.98; $p < 0.001$) | $y = 1.25x - 0.54$ $r = 0.98$ (95% CI, 0.97–0.98; $p < 0.001$) |
| APTT | $y = 1.47x - 13.39$ $r = 0.88$ (95% CI, 0.83–0.91; $p < 0.001$) | $y = 1.03x - 2.84$ $r = 0.81$ (95% CI, 0.74–0.87; $p < 0.001$) | $y = 0.97x + 2.75$ $r = 0.74$ (95% CI, 0.65–0.81; $p < 0.001$) |
| Fibrinogen | $y = 0.90x + 0.39$ $r = 0.97$ (95% CI, 0.96–0.98; $p < 0.001$) | $y = 0.94x + 0.02$ $r = 0.97$ (95% CI, 0.96–0.98; $p < 0.001$) | $y = 0.96x + 0.38$ $r = 0.95$ (95% CI, 0.93–0.97; $p < 0.001$) |

Abbreviations: 95% CI, 95% confidence interval; APTT, activated partial thromboplastin time; PT, prothrombin time.

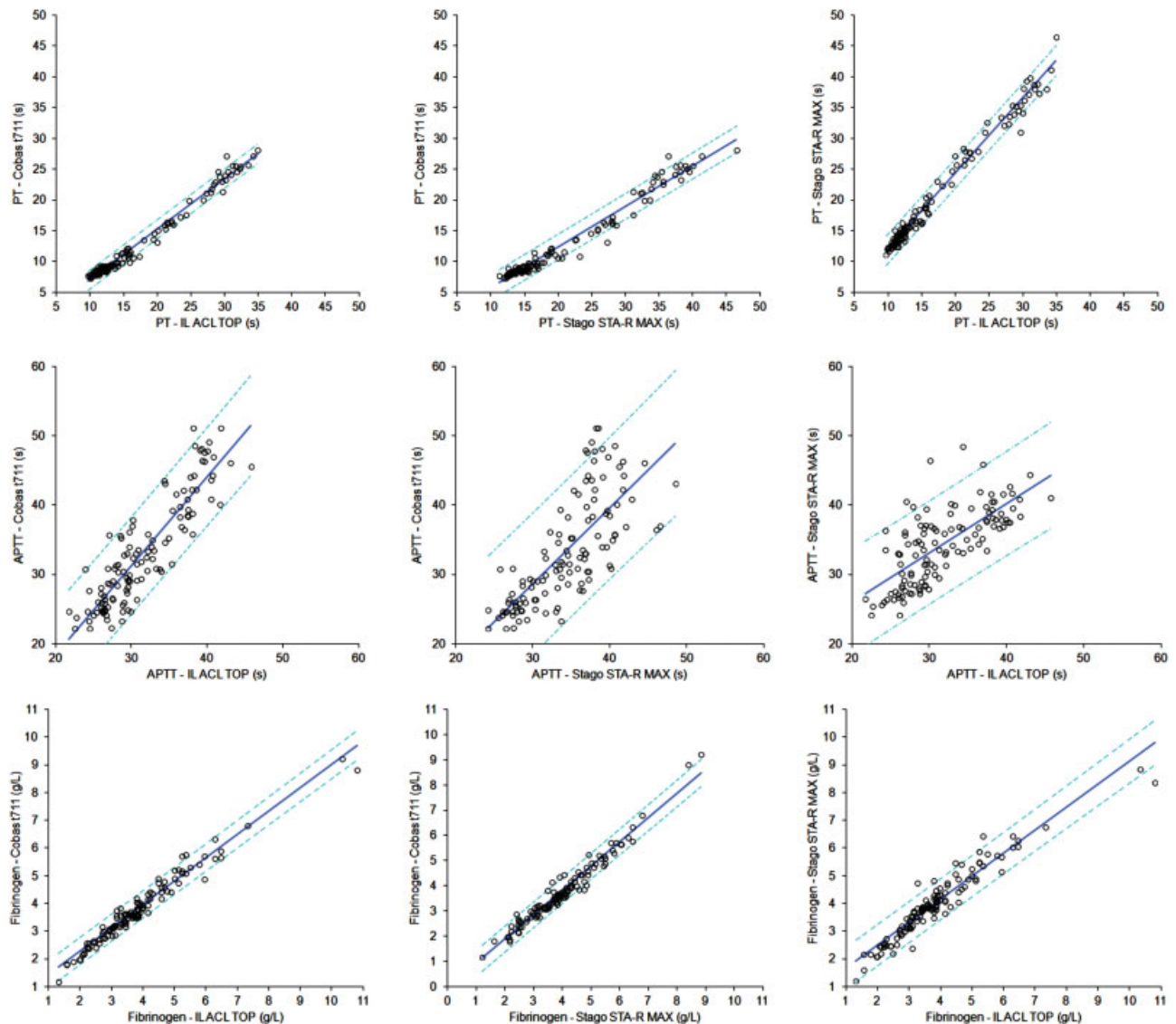


Fig. 1 Results of method comparison studies. The dotted lines are drawn at the 95% prediction interval. APTT, activated partial thromboplastin time; PT, prothrombin time.

respectively. In general, these correlations were similar or even better than those between ACL TOP and STA-R MAX (—Table 4). Due to the use of different reference values (and reagents) of both PT and APTT across the three analyzers, a substantial difference of absolute values was unsurprisingly

observed for these tests, especially for PT (i.e., slopes comprised between 0.61 and 1.25, intercepts between -0.54 and 0.12), while a much better agreement was observed for fibrinogen (slopes comprised between 0.90 and 0.96, intercepts between 0.0 and 0.39).

Discussion

The availability of fully automated, rapid, accurate, precise, and versatile laboratory instrumentation has now become increasingly important for the efficient diagnostics of hemostasis disorders. Compared with the many other marketed coagulation analyzers, **cobas t 711** analyzer presents several interesting features, such as full compatibility with total laboratory automation and, especially, availability of lyophilized reagents in barcoded cassettes, which can be automatically resuspended by the analyzer itself. This represents several interesting advantages for the total quality of hemostasis testing, as it ensures high on-board reagent capacity, up to 24 months unopened and up to 2 weeks on-board stability of reagents; eliminates the inherent risk of manual lyophilized reagent reconstitution; and improves walkaway time. Inside the analyzer, the reagents are kept in a specific area, and are then automatically moved to the disposal section once needed. This theoretical advantage seems to be coupled with excellent analytical performance, at least for the three reagents/tests that we have assessed in this analytical evaluation.

Overall, our data demonstrate that automatic resuspension is indeed more precise than, and equally accurate as, manual reconstitution, as shown in ▶Table 2. Notably, the imprecision of automatic resuspension of lyophilized reagents was three- to sixfold lower than manual reconstitution. Albeit this finding is somehow predictable, due to the virtually unavoidable intra- and, especially, interoperator imprecision of manual pipetting;¹¹ our results clearly show that automatic resuspension would help improve consistency and comparability of values generated after replacing empty vials of lyophilized reagents of the same lot. Overall, the analytical imprecision of **cobas t 711** was also found to be optimally low, as attested by total CV% of 0.7% for PT, 1.7 to 1.8% for APTT, and 1.9 to 3.2% for fibrinogen, respectively (▶Table 3). These data are aligned with, or even better than, those of other commercial coagulation analyzers. For example, earlier published studies reported that between-run imprecision was comprised between 3.0 and 3.1% for PT, 2.7 to 3.3% for APTT, and 3.4 to 6.5% for fibrinogen on ACL TOP,¹³ and total imprecision was comprised between 1.7 and 2.7% for PT, 0.9 and 2.2% for APTT, and 1.8 to 3.8% for fibrinogen on Stago STA.¹⁴ Nevertheless, linearity of **cobas t 711** was excellent over clinically relevant ranges of PT, APTT, and fibrinogen values, displaying correlation coefficients comprised between 0.994 and 0.999. It is noted that linearity is not usually required in clinical laboratories for validating clotting-time assays. Methods comparison studies revealed that results of PT, APTT, and fibrinogen on **cobas t 711** were globally aligned with those obtained using identical plasma samples on IL ACL TOP 700 and Stago STA-R MAX (▶Table 4), with correlation coefficients always greater than 0.81. Predictably, better correlation coefficients were indeed observed for PT (i.e., 0.97) and fibrinogen (i.e., 0.90 and 0.94), while the correlation of APTT values with those obtained on the other two analyzers was less satisfactory (i.e., 0.81 and 0.88), though it was still better than that

between IL ACLTOP and Stago STA-R MAX. These findings are not really surprising, as the APTT reagents of the three manufacturers are based on different contact activators (i. e., ellagic acid for Roche, colloidal silica for IL, and polyphenols for Stago; ▶Table 1), thus mirroring recent evidence showing that harmonization in hemostasis testing is still an unmet target, even for longstanding and widely used tests such as the APTT.^{15–17} The bias may also be explained by differences in the phospholipid sources and/or concentration of different APTT reagents, the use of different mathematical algorithms for detection of clot endpoint, the use of different detection methods between Stago (mechanical endpoint) and IL ACL TOP and **cobas t 711** (both optical endpoints), as well as by the possibility that some specimens might have had lupus anticoagulant activity, with different potential sensitivity among the three APTT reagents. Further study could hence be conducted to assess other aspects of this new analyzer, including normal reference ranges and heparin therapeutic range, sensitivity to factor deficiencies and lupus anticoagulants, responsiveness to nonheparin anticoagulants, along with instruments comparability for APTT values greater than 60 seconds.

In conclusion, the results of this preliminary evaluation of PT, APTT, and fibrinogen reagents on **cobas t 711** analyzer demonstrate that this innovative coagulation instrumentation displays excellent performance for routine use in clinical laboratories.

Conflicts of Interest

None.

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