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Verification of the STA Compact Max Coagulation Analyser: Experience from a Malaysian Clinical Laboratory

Abstract **–** The STA Compact Max is an automated coagulation analyser designed for medium-sized laboratories. Local verification is required prior to clinical implementation to ensure accuracy and reliability. Analytical performance for Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), and International Normalized Ratio (INR) was evaluated at the Clinical Diagnostic Laboratory (CDL), Pusat Kanser Tun Abdullah Ahmad Badawi (PKTAAB). Verification parameters assessed included within-run and inter-run precision, sample and reagent carryover, method correlation with the existing STA Compact analyser, establishment of reference times, verification of manufacturer's reference intervals, and INR verification. Both PT and APTT demonstrated coefficients of variation within manufacturer claims. No significant sample or reagent carryover was observed. Correlation with the existing analyser was excellent ($r \geq 0.99$), with slopes, intercepts, and biases meeting international analytical performance specifications. Reference times were established (PT: 13.6 s; APTT: 34.5 s) and manufacturer/donor reference ranges were verified. INR verification showed agreement within ±15% of assigned values. The STA Compact Max fulfilled all verification criteria, demonstrating reliable analytical performance for PT, APTT, and INR testing. This verification supports its implementation for routine haemostasis testing and provides locally relevant evidence for clinical laboratories in Malaysia.

Keywords **–** *STA Compact Max, coagulation analyser, precision study, correlation study, INR verification*

1 INTRODUCTION

Haemostasis testing, particularly Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), and International Normalized Ratio (INR), plays a central role in the diagnosis and monitoring of coagulation disorders, guiding anticoagulant therapy, and supporting perioperative decision-making. The accuracy and reproducibility of these assays are critical, as even small analytical errors may directly impact patient safety and clinical outcomes (1).

Before a new analyser is introduced into clinical service, laboratories are required to perform method verification in accordance with international guidelines such as those from the Clinical and Laboratory Standards Institute (CLSI) and ISO 15189. Verification ensures that analytical performance such as precision, carryover, and correlation with existing methods meets defined standards and that reference intervals and INR calibration are appropriate for the local population. This step is essential for maintaining comparability of results across laboratories and ensuring reliable clinical interpretation (2-4).

Several studies have evaluated the analytical performance of automated coagulation analysers, including the STA Compact Max and other commercially available coagulation platforms from different manufacturers. Verification work comparing the STA-Compact with the Sysmex CS-2500 demonstrated excellent precision (coefficients of variation <3.5%) and strong agreement for PT/INR and APTT assays, confirming reliability across routine parameters (5). Similarly, multi-analyser comparisons involving the STA-R MAX 3 and other platforms reported satisfactory precision, linearity, and carryover, although minor variations were observed in APTT and D-dimer when samples were haemolysed, lipaemic, or frozen (6,7).

Specific studies on the STA Compact Max for chromogenic assays, particularly in monitoring direct oral anticoagulants, also demonstrated good within-laboratory precision, though reduced accuracy was noted at lower analyte concentrations (9). Additional evaluations of the STA-R MAX 3, a high-throughput instrument using the same detection principles, have confirmed robust reproducibility across PT, APTT, fibrinogen, and factor assays (8,9). Collectively, these studies establish the strong analytical performance of the STA family of analysers, but they also highlight variability between methods, populations, and pre-analytical conditions.

Local validation is particularly important in the Malaysian context, as pre-analytical factors such as sample handling practices, population-specific biological variation, and reagent lot-to-lot variability may influence coagulation assay results. Furthermore, donor profiles in Southeast Asian populations differ from those in Western reference studies, and reliance on manufacturer-provided ranges without verification may compromise clinical accuracy. By generating locally relevant verification data, laboratories can ensure that results are reliable, reproducible, and directly applicable to patient care in this setting (10). Accurate haemostasis testing is critical for patient safety, particularly in anticoagulant monitoring where small analytical deviations may lead to bleeding or thrombotic complications.

2 MATERIALS AND METHODS

2.1 Study Setting

This Verification study was conducted at the Clinical Diagnostic Laboratory (CDL), Pusat Kanser Tun Abdullah Ahmad Badawi (PKTAAB), prior to routine implementation of the STA Compact Max coagulation analyser (Diagnostica Stago, France).

This study utilised retrospective, anonymised data obtained from routine laboratory method verification conducted in accordance with MS ISO 15189 quality management requirements. In line with institutional guidelines, studies involving anonymised residual samples as part of routine laboratory quality assurance are considered minimal risk and are therefore exempt from full ethical review. Consequently, formal ethical approval was not required for this study.

2.2 Precision Study

Precision was evaluated using normal and pathological control plasma (STA-Coag Control N and P) for both PT and APTT assays. Each control was analysed in five replicates per day over five consecutive days. The mean, standard deviation (SD), and coefficient of variation (CV%) were calculated for both within-run and inter-run precision. Within-run precision was assessed by comparing daily replicate results against manufacturer specifications (PT: CV < 1.5% for normal, < 2.0% for pathological; APTT: CV < 1.5% for normal, < 2.0% for pathological), while inter-run precision was determined from the overall SD and CV across the five-day period, with acceptability defined as CV < 5.0% for both PT and APTT (3,8,10,11).

2.3 Sample Carryover Study

Sample carryover was evaluated using a high-APTT plasma sample (50–80 s) tested in triplicate, followed immediately by a normal plasma sample in triplicate. This sequence was repeated 10 times, and carryover was expressed as a percentage. Acceptability was defined as < 5% (3,10).

Carryover assessment was performed to evaluate the potential for contamination between consecutive samples, particularly from abnormal to normal plasma. Such contamination may result in falsely elevated or reduced coagulation values, leading to potential misinterpretation of a patient's haemostatic status. This is particularly critical in anticoagulant monitoring, where small analytical deviations may result in inappropriate dose adjustment and increased risk of bleeding or thrombosis. For example, particularly at INR 2.0 - 3.0 therapeutic range, where a 0.5 INR deviation may alter anticoagulant dosing. Therefore, minimising carryover is essential to ensure accurate and clinically reliable results.

2.4 Reagent Carryover Study

Reagent carryover was assessed by performing 10 replicate APTT tests on normal plasma, followed by alternating PT and APTT assays in 10 replicates. Precision (CV%) and mean APTT values were compared between series, with acceptability defined as CV < 1.5% and difference < 5% (3,8,10).

2.5 Correlation Study

Forty (40) patient plasma samples (20 normal, 20 pathological) were tested on both the STA Compact Max and the existing STA Compact analyser within two hours. Linear regression was performed to determine correlation coefficient (r), slope, and intercept. Bias at medical decision limits was compared with analytical performance specifications from The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Clinical Laboratory Improvement Amendments (CLIA), and Royal College of Pathologists of Australasia (RCPA) guidelines (8,10,14).

Medical decision limits (MDLs) were defined as clinically relevant concentration thresholds at which clinical decisions regarding diagnosis or treatment are made. Bias was evaluated at these MDLs to ensure that analytical performance is acceptable at decision-critical levels.

Total error (TE) was calculated using the formula:

$$TE = |Bias| + 1.65 \times CV$$

where bias represents the systematic difference between methods and CV represents the coefficient of variation. The factor 1.65 corresponds to the one-sided 95% confidence interval. Analytical performance was considered acceptable when TE was less than the allowable total error (TEa) derived from biological variation data.

2.6 Establishment of Reference Time

Reference times for PT and APTT were established from healthy donor plasma ($n \geq 20$ per assay) by calculating the geometric mean. Reference range verification was performed by testing at least 20 healthy donors; manufacturer or donor-laboratory reference intervals were accepted if ≤ 10% of values fell outside (3,8,10).

2.7 Verification of Manufacturer's Reference Range

Verification of reference ranges was performed by testing at least 20 healthy donor samples for PT and APTT and comparing the results with manufacturers or donor laboratory reference intervals. The reference ranges were accepted if no more than 2 results fell outside the specified limits.

If 3 or 4 results were outside the range, additional testing was performed using another 20 healthy donor samples. If no more than 2 results from this second set fell outside the reference intervals, the ranges were considered acceptable; otherwise, a new reference interval was established (10,15).

2.8 INR Verification

INR verification was performed using certified calibrant plasma with assigned INR values between 1.0 and 4.5, tested in duplicate over three days. Results were considered acceptable if within ±15% of assigned values (3,15,16).

2.9 Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics (IBM Corp., Armonk, NY, USA). Descriptive statistics, including mean, standard deviation (SD), and coefficient of variation (CV%), were used to assess within-run and inter-run precision. Linear regression analysis was applied to evaluate agreement between the STA Compact Max and the existing STA Compact analyser, including calculation of the correlation coefficient (r), slope, and intercept. Bias was assessed at predefined medical decision limits (MDLs), and total error (TE) was calculated to evaluate analytical performance against allowable total error (TEa) derived from biological variation data. All statistical analyses were performed in accordance with CLSI recommendations.

3 RESULTS

3.1 Within Run Precision Study

The within run precision study's results of PT and APTT for STA Compact Max were shown in Table 1 and Table 2. Both PT and APTT demonstrated excellent precision, with CV% values consistently below manufacturer-defined limits for within-run conditions, indicating stable analytical performance across normal and pathological samples.

Table 1. Within-run precision results for PT and APTT (normal control plasma)

Parameter	Mean (s)	SD	CV (%)	Manufacturer limit
PT	14.12	0.15	1.04	CV < 1.5%
APTT	32.48	0.33	1.01	CV < 1.5%

Table 2. Within-run precision results for PT and APTT (pathological control plasma)

Parameter	Mean (s)	SD	CV (%)	Manufacturer limit
PT	26.21	0.28	1.07	CV < 2.0%
APTT	53.62	0.49	0.92	CV < 2.0%

3.2 Inter Run Precision Study

PT and APTT demonstrated excellent inter-run precision, with CV% values consistently below predefined acceptance limits, confirming stable and reproducible analytical performance across multiple runs (Tables 3–4).

Table 3. Inter-run precision results for PT and APTT (normal control plasma)

Parameter	Mean (s)	SD	CV (%)	Manufacturer limit
PT	14.12	0.16	1.15	CV < 5.0%
APTT	32.48	0.32	0.99	CV < 5.0%

Table 4. Inter-run precision results for PT and APTT (pathological control plasma)

Parameter	Mean (s)	SD	CV (%)	Manufacturer limit
PT	26.21	0.46	1.77	CV < 5.0%
APTT	53.62	0.56	1.05	CV < 5.0%

Overall, precision performance met all predefined analytical criteria for both within-run and inter-run conditions.

3.3 Sample Carryover Study

The carryover effect from abnormal to normal plasma in the STA Compact Max was negligible (<5%), indicating no clinically significant sample-to-sample contamination that could affect patient results (Table 5).

Table 5. Sample carry over performance

Transition	Carryover (%)	Limit (%)
Abnormal → Normal	0.00	< 5.0

3.4 Reagent Carryover Study

The CV% of the test parameters (PT and APTT) passed the manufacturer's precision limit. The difference between mean of APTT single series and mean of APTT in test profile (0.50%) was less than manufacturer's acceptance criteria of 5% as shown in Table 6.

This proved that there is minimal reagent carryover, with consistent APTT values observed between single and mixed assay sequences, indicating low risk of analytical interference in STA Compact Max.

Table 6. Reagent carry-over performance

Series	Mean APTT (s)	SD	CV (%)	Mean difference (%)	Limit
Single APTT series	34.21	0.18	0.52	–	CV < 1.5%
Mixed PT/APTT series	34.04	0.38	1.12	0.5	Difference < 5%

3.5 Correlation Study

Generally, STA Compact Max demonstrated excellent agreement, with correlation coefficients of 1.00 and minimal bias across clinically relevant ranges with existing STA Compact for PT and APTT assays. The results were shown in Table 7.

Table 7. Correlation of STA Compact Max vs STA Compact

Parameter	n	r	Slope	Intercept	Mean Bias (%)
PT (s)	40	1.00	0.98	0.63	–0.94
PT INR	40	1.00	0.97	0.05	–1.12
APTT (s)	40	1.00	0.97	–0.04	–2.80

3.6 Establishment of Reference Time

PT and APTT reference times were established using 26 and 20 healthy donor samples, respectively, on the STA Compact Max. The mean reference times were 13.6 seconds for PT and 34.5 seconds for APTT. These values fall within the verified reference intervals of 11.7–15.3 seconds for PT and 30.3–46.5 seconds for APTT, as shown in Table 8.

Table 8. Reference times established for PT and APTT

Test	Reagent (lot)	n	Reference time (s)
PT	STA-NeoPTimal (270856)	26	13.6
APTT	STA-PTT A (271377)	20	34.5

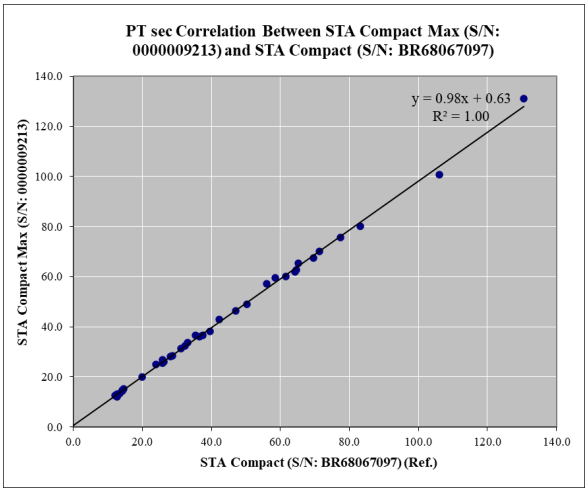

Figure 1. Correlation of PT results between STA Compact Max and STA Compact**.** *Linear regression demonstrated excellent correlation (r = 1.00)*

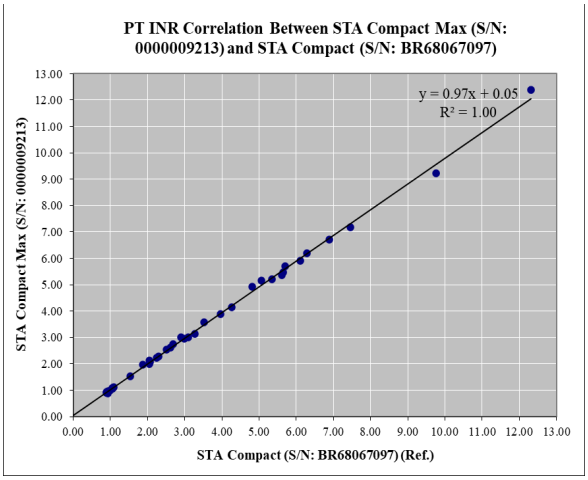

Figure 2. Correlation of PT INR results between STA Compact Max and STA Compact. *Linear regression demonstrated excellent correlation (r = 1.00)*

3.7 Verification of Manufacturer's Reference Range

No more than 10% of test subjects for PT, PT INR, and APTT fell outside the respective reference intervals when assessed on the STA Compact Max (Table 9). Specifically, results for PT and PT-INR were within the manufacturer's reference ranges, while APTT results were within the reference range established by Hospital Pakar Kanak-Kanak, Universiti Kebangsaan Malaysia (HPKK UKM). These findings confirm that the reference intervals are applicable for use on the STA Compact Max at the Clinical Diagnostic Laboratory, PKTAAB.

3.8 International Normalized Ratios (INR) Verification

Since the percentage difference of local generated INR versus assigned INR was less than 15% (Table 10), the manufacturer International Sensitivity Index (ISI) value (1.11) and lab established Mean Normal Prothrombin Time (MNPT) (13.6 sec) for STA-NeoPTimal between locally generated INR and assigned INR values are acceptable for use on STA Compact Max at CDL, PKTAAB. Overall, all analytical performance parameters met predefined acceptance criteria, supporting the reliability of the analyser for routine clinical use.

Table 9. Verification of Reference Range

Parameter	n	Reference range	% outside range	Acceptability
PT (s)	26	11.7–15.3	0.0	≤ 10%
PT INR	26	0.80–1.20	0.0	≤ 10%
APTT (s)	20	30.3–46.5	0.0	≤ 10%

Table 10. INR verification using certified plasma calibrants

Calibrant	Local INR	Assigned INR	% Difference	Limit
A	1.04	1.04	+0.35	≤ 15%
B	2.44	2.44	+0.15	≤ 15%
C	4.00	4.06	–1.40	≤ 15%
D	5.93	6.23	–4.77	≤ 15%

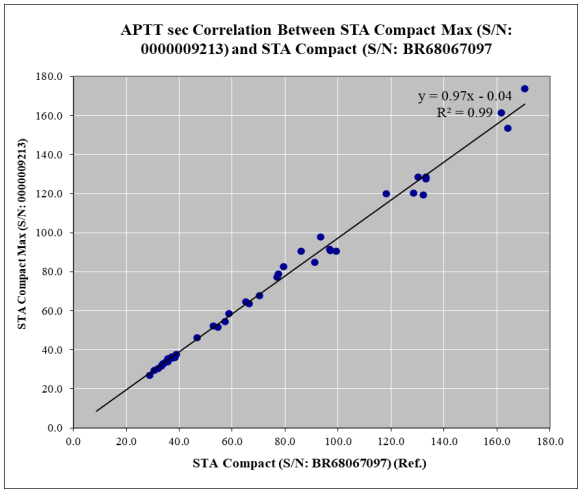

Figure 3. Correlation of APTT results between STA Compact Max and STA Compact. *Linear regression demonstrated excellent correlation (r = 1.00)*

4 DISCUSSION

This study demonstrates that the STA Compact Max provides reliable and clinically acceptable analytical performance across key coagulation parameters, including PT, APTT, and INR. The analyser exhibited excellent precision, negligible carryover, and strong agreement with the existing STA Compact, with correlation coefficients ≥0.99 and minimal bias across clinically relevant ranges. Importantly, analytical performance evaluated at medical decision limits met specifications defined by biological variation, and total error values were within allowable thresholds. Verification of reference intervals and accurate INR calibration further support its clinical applicability. Collectively, these findings reduce the risk of clinically significant misinterpretation and support continuity of care, particularly in anticoagulant monitoring where analytical accuracy is critical for patient safety.

This study not only evaluates analytical performance but also emphasises the clinical relevance of the findings, particularly in reducing the risk of misinterpretation and supporting safe clinical decision-making.

The demonstrated analytical performance supports reliable clinical interpretation of coagulation results, thereby reducing analytical uncertainty and the risk of diagnostic misclassification. This is particularly important in anticoagulant monitoring, where inaccurate results may lead to inappropriate dose adjustment and increased risk of bleeding or thrombotic complications.

By providing analytically robust and reproducible results, the STA Compact Max supports safer clinical decision-making and enhances patient outcomes. In addition, the strong agreement between analysers ensures continuity of care by maintaining consistency in patient monitoring across different testing platforms

4.1 Precision and Carryover study

The STA Compact Max (S/N: 0000009213) demonstrated good performance in both precision and carryover testing. The CV% of PT and APTT were within manufacturer limits for within-run and inter-run precision, indicating consistent results for both normal and abnormal samples. Sample carryover for APTT was below the 5% acceptance limit, demonstrating no significant cross-contamination between abnormal and normal samples. Reagent carryover was negligible, with APTT values remaining consistent across single and mixed series, confirming minimal contamination risk between assays. High analytical precision ensures consistent and reproducible results, minimising variability that could affect clinical interpretation and patient management, while minimal carryover further reduces the risk of sample-to-sample contamination and subsequent erroneous clinical decisions.

4.2 Correlation Study

A total of 40 patient samples covering the reportable range were analysed on both the STA Compact Max and the existing STA Compact. The new analyser demonstrated excellent agreement for PT, PT-INR, and APTT, with correlation coefficients ≥ 0.99 and slopes and intercepts close to identity. Mean biases at medical decision limits were within the analytical performance specifications defined by the EFLM biological variation database (Table 11), and total error calculations met allowable error thresholds (Table 12). These findings are consistent with previous validation studies of coagulation analysers, including the evaluation by Kim et al. (18,19), which reported high precision and strong inter-instrument agreement across multiple platforms. Such concordance ensures continuity of patient monitoring when laboratories transition between analysers. The strong agreement between analysers ensures continuity of patient monitoring, particularly in anticoagulant therapy, where inconsistent results may lead to inappropriate dose adjustment and increased risk of bleeding or thrombosis.

Table 11. The biases at medical decision levels for STA Compact Max vs STA Compact

Parameter	MDL	Bias	% Bias	Acceptable Limit
PT sec	14.0	0.28	2.01	2.10%
	16.0	0.23	1.45	
	30.0	-0.12	-0.39	
PT INR	1.50	0.01	0.77	2.00%
	2.00	0.00	-0.07	
	2.50	-0.01	-0.57	
	3.00	-0.03	-0.90	
	3.50	-0.04	-1.14	
	4.50	-0.07	-1.46	
APTT sec	35.0	-0.99	-2.83	2.90%
	45.0	-1.26	-2.80	
	90.0	-2.48	-2.76	

APS: Analytical performance specification, EFLM: European Federation of Clinical Chemistry and Laboratory Medicine, BV: biological variation, MDL: Medical Decision Limit

Table 12. The total calculated error at medical decision levels for STA Compact Max vs STA Compact

Parameter	MDL	TEc	TEa
PT sec	14.0	3.91	5.40%
	16.0	3.35	
	30.0	2.52	
APTT sec	14.0	3.91	2.10%
	16.0	3.35	
	30.0	2.52	

MDL: Medical Decision Limit, TEc: Calculated Total Error, TEa: Allowable Total Error

4.3 Establishment of Reference Time

Variability in thromboplastin sensitivity across PT reagents can lead to inter-laboratory differences in clotting times, which the WHO addressed by introducing the INR system in 1983 to standardise results for anticoagulant monitoring. According to CLSI H54-A, laboratories should verify INR using instrument-specific ISI values. For STA-NeoPTimal, ISI is reagent- and instrument-specific, determined against international reference plasma, and does not require independent verification (3).

In this study, 26 healthy donor samples were used to establish the MNPT for STA-NeoPTimal on the STA Compact Max, yielding a reference time of 13.6 seconds. INR verification confirmed accuracy within CLSI limits, supporting reliable monitoring of patients on warfarin therapy, for which INR is specifically standardised.

Similarly, APTT reference intervals vary depending on reagent sensitivity to intrinsic factors, heparin, and lupus anticoagulant. Using 20 healthy donors, the APTT reference time for STA-PTT was established at 34.5 seconds, corresponding to a verified reference interval of 30.3 – 46.5 seconds for the local population. This aligns with manufacturer claims and provides locally verified values for routine diagnostic use (10,15).

4.4 Verification of Manufacturer's Reference Range

According to CLSI guideline C28-A2, at least 120 healthy subjects are recommended for establishing reference ranges (15). When such numbers are impractical, reference interval transference may be verified with a minimum of 20 healthy subjects, provided that no more than 10% of results fall outside the proposed range.

In this study, 26 healthy donor samples were used to verify the manufacturer's PT and PT-INR reference ranges, and 20 donors were used to verify the APTT reference range established at HPKK UKM (n=132 donors). In both cases, fewer than 10% of donor results fell outside the respective ranges (Table 12), fulfilling CLSI acceptance criteria (15). Therefore, the manufacturer's PT and PT-INR reference ranges and HPKK UKM's APTT reference range were considered valid for use on the STA Compact Max in CDL, PKTAAB (10,15). The final reference intervals adopted are summarised in Table 13.

Table 13. STA Compact Max: Reference Range

Parameter	Reference Range
PT sec	11.7 – 15.3 sec
PT INR	0.80 – 1.20 INR
APTT sec	30.3 – 46.5 sec

4.5 INR Verification

Local INR verification is essential to ensure patient safety in anticoagulant monitoring, particularly given the narrow therapeutic range of vitamin K antagonists. According to CLSI H54-A, verification should be undertaken when changing PT reagents, reagent lots, or instruments, and at least annually in routine practice (3). Although Stago provides instrument-specific ISI values, local verification remains recommended to confirm consistency under real laboratory conditions (3).

In this study, INR verification was performed using AK Calibrant plasma on STA-NeoPTimal. All four calibrant levels fell within ±15% of the assigned INR values, fulfilling CLSI acceptance criteria. These findings validate the use of the manufacturer's ISI value (1.11) with the locally established MNPT (13.6 s), confirming the reliability of PT/INR reporting on the STA Compact Max in our setting.

Accurate INR verification is essential for safe anticoagulant management, as small analytical deviations may result in inappropriate dosing and increased risk of bleeding or thrombotic complications.

4.6 Limitations

This verification was conducted in a single laboratory with a relatively small number of healthy donors for reference interval verification, which may limit generalisability. Only PT, APTT, and INR were validated; other haemostasis parameters such as fibrinogen, D-dimer, and factor assays were not included. Multi-centre

studies with larger sample sizes and additional parameters would strengthen the evidence.

Overall, these findings are clinically relevant as they reduce analytical uncertainty, support accurate interpretation of coagulation results, and minimise the risk of inappropriate clinical decisions, thereby enhancing patient safety and continuity of care. No Direct Oral Anticoagulant (DOAC) interference evaluation, No pre-analytical variability control and No Lot-to-Lot variability.

5 CONCLUSION

This study demonstrated that the STA Compact Max analyser meets international validation standards, showing excellent precision, no significant carryover, strong agreement with an existing analyser, and verified reference intervals and INR calibration. These findings confirm its reliability for routine haemostasis testing under Malaysian laboratory conditions. The verification provides locally generated evidence to support safe implementation of the analyser in clinical practice. This verification supports not only analytical performance but also safe clinical decision-making and continuity of patient care.

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AUTHORSHIP CLARIFICATION

All authors meet the ICMJE criteria for authorship and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

All authors have read and approved the final manuscript and consent to its publication in this journal.

CONFLICTS OF INTEREST

The authors declare that they have no conflict of interest.

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