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ORIGINAL ARTICLE

Development of a Quality Assurance System for Hematocrit Testing by Centrifugation Using Reference Materials and Target Values

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SUMMARY

Background: **Hematocrit (Hct) testing by centrifugation is widely performed at primary care units in Thailand, known as Subdistrict Health Promotion Hospitals (SDHHs), to support early detection of anemia and reduce referral burden. However, current external quality assessment (EQA) programs rely primarily on peer-group evaluation and lack metrological traceability. This study aimed to develop and pilot an accuracy-based quality assurance (QA) system for centrifugation-based Hct testing using commutable whole-blood reference materials (RMs) with assigned target values.**
Methods: **Six levels of whole-blood RMs were produced using ISO 17034-aligned procedures and assessed for homogeneity and stability according to ISO Guide 35 and ISO 13528. Commutability was verified following CLSI EP14-A4 using Deming regression across four centrifugation systems and 24 native clinical samples. Target values were assigned by three nationally accredited laboratories. Two QA rounds were conducted among 28 medical laboratories and 269 SDHHs in Health Region 6. Laboratory performance was evaluated using percentage bias and z-scores calculated from both peer-group means and accuracy-based target values.**
Results: **All RMs met criteria for homogeneity, 120-day stability, and commutability. Chi-squared analysis demonstrated a significant association ($\chi^2 = 47.61$, $p < 0.001$) between peer-group and accuracy-based classifications when using the ± 4% criterion in Round 2 and the combined analysis, whereas no significant association was observed in Round 1. When using the ± 6% criterion, no significant association was found in either round or in the combined analysis.**
Conclusions: **This study established Thailand's first accuracy-based QA system for centrifugation-based Hct testing using commutable RMs with target values assigned by nationally accredited laboratories. The system demonstrated strong capability in detecting deviations from true target values and is well suited for scalable integration into national QA frameworks for SDHHs in Thailand.**
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KEYWORDS

hematocrit, accuracy-based quality assessment, reference materials, anemia, commutability, microhematocrit, primary care units

INTRODUCTION

Hematocrit (Hct), defined as the ratio of red blood cell volume to overall blood volume and expressed as a percentage, is a key parameter for screening and monitor-

ing anemia, polycythemia, dehydration, and acute blood loss [1]. The centrifugation-based method or microhematocrit remains widely used because it is simple, inexpensive, requires only a small specimen volume, and provides rapid results [1,2]. In Thailand, Hct testing is routinely performed not only in hospital wards and medical laboratories but also in primary healthcare settings, including more than 9,878 Subdistrict Health Promotion Hospitals (SDHHs) nationwide. SDHHs play a central role in supporting the Ministry of Public Health's policy to enable early detection and follow-up of anemia at the community level, thereby reducing patient congestion and service burdens on secondary and tertiary hospitals [3,4].

Although a clinical laboratory in network hospitals in each region actively supervises and supports the internal quality control of hematocrit testing by providing training and promoting participation in external quality assessment (EQA) programs, most existing schemes still rely on peer-group evaluation. This approach mainly reflects relative performance among participants but does not have traceable measurement trueness. Analytical errors may arise from variation in centrifuge performance, timing control, operational technique, or manual interpretation of packed cell volume results, all of which are critical contributors to measurement error. These limitations underscore the need for a more robust quality assurance framework and commutable reference materials to ensure analytical reliability and clinical comparability [5-7].

Conventional EQA schemes that rely on peer-group means lack metrological traceability and may conceal systematic bias [7,8]. Advances in accuracy-based QA supported by commutable reference materials (RMs) with target values assigned by accredited laboratories allow for more rigorous performance assessment [9,10]. Commutability means that when a reference material is tested by multiple assay methods, the pattern of results versus patient samples is equivalent. According to CLSI EP-14A [11], commutable blood materials ensure matrix equivalence to native clinical samples, which is essential for valid accuracy-based QA programs [9,10,12]. This study aimed to develop and pilot an accuracy-based QA system for Hct testing by the centrifugation method in Thailand's Health Region 6, using ISO 17034 aligned commutable reference materials with target values. The quality system was implemented across two groups of service sites: 1) laboratories with formal training in medical laboratories, and 2) non-laboratory healthcare facilities, including SDHHs.

MATERIALS AND METHODS

This study utilized reference materials for hematocrit (Hct) in blood materials to develop an accuracy-based quality assurance system for centrifugation-based Hct measurement in 28 medical laboratories (MLs) and 269 SDHHs within Thailand's Health Region 6. We conducted a survey to assess the use of hematocrit centrifuges, operational problems, quality control practices, and participation EQA programs using a structured questionnaire. This study was conducted in accordance with the Declaration of Helsinki and was approved by the Buddhasothorn Hospital Institutional Review Board (BSH-IRB No. 010/2568; approved on June 6, 2025).

Preparation of reference materials

Six blood RMs for Hct were prepared by We Med Lab Center Company at Naresuan University, Thailand under ISO 17034 [6] with aligned procedures and dispensed into 0.5 mL sealed vials. Aliquots were used for homogeneity, stability, and commutability assessments.

Homogeneity assessment

Ten vials of each six RMs were randomly selected from total 500 vials of each number. Hematocrit was measured in duplicate using a validated centrifugation method. Between-unit homogeneity was evaluated using one-way ANOVA and generated $F_{calculate}$ and $F_{critical}$. Acceptance required $F_{calculate} \leq F_{critical}$ according to ISO Guide 35 [13]. The statistical assessment of homogeneity according to ISO 13528 [14] was performed using the same data set, applying the acceptance criterion $ss \leq 0.3\ \sigma pt$.

Stability studies

For each storage condition, four vials from each of the six reference materials (RMs) were randomly selected. Hematocrit values were measured using a validated centrifugation-based method, with two replicate measurements per vial.

Short-term stability [13] was evaluated at room temperature (25 ± 5°C) and 37 ± 1°C (simulation conditions) on Days 0, 3, and 7. Paired *t*-tests were performed to compare mean values across time points, where $p > 0.05$ indicates no significant degradation.

Long-term stability [13] was assessed over 120 days using regression analysis. The LINEST function was applied to determine the slope of between-unit variation over time. The T-calculated value represents the observed test statistic derived from the regression slope, while the T-critical value corresponds to the theoretical threshold based on a two-tailed t distribution at $\alpha = 0.05$. Long-term stability is confirmed when |T-calculated| < T-critical, indicating no statistically significant trend over time. Stability was also assessed using ISO 13528 [14].

Commutability evaluation

Three RMs, low, medium, and high, together with 24 EDTA blood patient specimens (native samples) were measured in triplicate using four validated centrifugation-based methods across four clinical laboratories in Health Region 6. Commutability was assessed using Deming regression analysis following CLSI EP14-A4 [11], with statistical significance set at $p < 0.05$.

Table 1. Homogeneity of hematocrit in 6 reference materials.

Lot. No.	Mean Hct (%)	ISO Guide 35		Interpretation	ISO 13528		Interpretation
		F_{cal}	$F_{critical}$		s_s	$0.3\ \sigma_{pt}$	
RM-Hct68-02007	26	2.44	3.02	sufficient	0.27	0.37	adequately
RM-Hct68-02008	33	0.89	3.02	sufficient	0.00	0.45	adequately
RM-Hct68-02009	34	1.04	3.02	sufficient	0.07	0.45	adequately
RM-Hct68-02010	42	0.89	3.02	sufficient	0.00	0.51	adequately
RM-Hct68-02011	44	1.22	3.02	sufficient	0.15	0.56	adequately
RM-Hct68-02012	50	2.44	3.02	sufficient	0.27	0.63	adequately

σ_{pt} standard deviation for proficiency assessment, Ss between sample standard deviation.

Table 2. Stability of hematocrit in 6 reference materials.

Short-term stability					
Lot. No.	Day	25 ± 5°C	37 ± 1°C	p	ISO 13528 ≤ 0.3 σPT
RM-Hct68-02007	0	27	27	1.000	sufficient
	3	28	29	0.500	
	7	28	28	1.000	
RM-Hct68-02008	0	33	34	0.500	sufficient
	3	34	34	1.000	
	7	34	35	0.500	
RM-Hct68-02009	0	34	35	0.500	sufficient
	3	35	35	1.000	
	7	35	35	0.500	
RM-Hct68-02010	0	42	43	0.500	sufficient
	3	43	43	1.000	
	7	42	43	0.500	
RM-Hct68-02011	0	44	45	0.500	sufficient
	3	45	45	0.500	
	7	45	45	0.500	
RM-Hct68-02012	0	50	50	0.500	sufficient
	3	50	50	0.500	
	7	50	50	0.500	
Long term stability at 30 ± 2°C (Min 27, Max 32), RH: 66 ± 4%, Min 57, Max 71)					
Lot. No.	Day	Mean Hct (%)	$T_{calculate}$	$T_{critical}$	Interpretation
RM-Hct68-02007	120	27	1.324	2.024	sufficient
RM-Hct68-02008	120	33	1.313	2.024	sufficient
RM-Hct68-02009	120	34	1.227	2.024	sufficient
RM-Hct68-02010	120	42	0.369	2.024	sufficient
RM-Hct68-02011	120	44	1.577	2.024	sufficient
RM-Hct68-02012	120	50	0.104	2.024	sufficient

RH Relative Humidity.

Table 3. Commutability evaluation of 3 RMs for hematocrit testing by centrifugation across four hematocrit centrifuges from four medical laboratories.

Method B (Y-axis)	Lot No.	Method A (X -axis)			
		LAB 1 BOECO	LAB 2 Hettich	LAB 3 DLAB	LAB 4 iFuge
LAB 1 BOECO	RM-Hct68-02007	not evaluated	C	C	C
	RM-Hct68-02009		C	C	C
	RM-Hct68-02010		C	C	C
LAB 2 Hettich	RM-Hct68-02007	C	not evaluated	C	C
	RM-Hct68-02009	C		C	C
	RM-Hct68-02010	C		C	C
LAB 3 DLAB	RM-Hct68-02007	C	C	not evaluated	C
	RM-Hct68-02009	C	C		C
	RM-Hct68-02010	C	C		C
LAB 4 iFuge	RM-Hct68-02007	C	C	C	not evaluated
	RM-Hct68-02009	C	C	C	
	RM-Hct68-02010	C	C	C	

C Commutable, the average measurement result of the reference material from each measurement procedure falls within the 95% prediction interval (PI), indicating that the material demonstrates commutability, BOECO BOECO Boeckel + Co Model H-240 (Hamburg, Germany), Hettich Hettich Model Haematokrit 200 (Tuttlingen, Germany), DLAB DLAB Model DLAB Centrifuge, Scientific Co., Ltd (Beijing, China), iFuge, iFuge HCT, Neuation Technologies Pvt. Ltd. (Gujarat, India).

Target value assignment

Three central laboratories measured the RMs under standardized procedures. Assigned target values and associated uncertainties were calculated using robust statistics (e.g., weighted mean/median) in accordance with ISO Guide 35 [13].

Performance evaluations

Twenty-eight medical laboratories and 269 SDHHs across Health Region 6 were voluntarily enrolled and received three blinded samples per round for two testing rounds. The two rounds were conducted in accordance with ISO/IEC 17043 [15] by Naresuan University, with three samples distributed in each round. All six samples were shipped simultaneously to participants along with written instructions specifying: 1) the required analytical method, 2) the deadlines for result submission and the closing dates for Rounds 1 and 2, and 3) guidance for sample storage if immediate analysis was not possible. After completing the measurements, participants were instructed to submit their results exclusively through the online platform within 14 days.

Accuracy was evaluated as percentage deviation from assigned targets and by z-scores (Satisfactory: $|z| \leq 2$; Questionable: $2 < |z| < 3$; Unsatisfactory: $|z| \geq 3$) using the equation $x_i - x_{pt}/\sigma_{pt}$ (x_i: participant's result; x_{pt}: assigned value; σ_{pt}: standard deviation for proficiency assessment). An allowable total error of ± 6% [16] around the target value was used for acceptance or unacceptance classifications.

A chi-squared test was conducted to examine the associations between satisfactory performance and evaluation methods.

The homogeneity of Hct values in the six RMs is shown in Table 1. Short- and long-term stability testing results are shown in Table 2, demonstrating that all six RMs remained stable for 120 days. Temperature and humidity during express and simulated transport of the blood materials prior to distribution to medical laboratories and SDHHs in Health Region 6 are presented in Table S1. The predicted shelf-life profiles of the reference materials, assessed according to ISO Guide 35, demonstrated the stability of packed red cell volume in RM-Hct68-02007 and RM-Hct68-02010, as shown in Figure S1. According to Table 3, the three RMs were commutable based on CLSI EP14-A4 [11] requirements, with measurement results falling within the 95% prediction interval derived from native clinical-blood samples (Figure 1). Performances of Hct by centrifuge methods assessment using z-scores and biases calculated form peer group assignment and target values are shown in Table 4.

DISCUSSION

This study is the first in Thailand to establish an accuracy-based quality assurance system for hematocrit testing by centrifugation using commutable blood reference materials (RMs) with target values assigned by three accredited laboratories, rather than relying on peer-group means. The commutable blood RMs were produced through collaboration between Naresuan University and We Med Lab Center Co., Ltd., following

Table 4. Hematocrit by centrifuge methods assessment using z-scores and biases calculated from peer group assignment and target values.

Type of Facility	Sample Code	Satis-factory (|z| ≤ 2) (%)	Ques-tionable (2 < |z| < 3) (%)	Unsatis-factory (|z| ≥ 3) (%)	Accept-able Bias ≤ 4% (%)	Unac-ceptable Bias > 4% (%)	Accept-able Bias ≤ 6% (%)	Unac-ceptable Bias > 6% (%)	Accept-able Bias ≤ 10% (%)	Unac-ceptable Bias > 10% (%)	Not evalu-ated %
		Peer group	Peer group	Peer group	Target value	Target value	Target value	Target value	Target value	Target value	
		Round 1									
All (n = 294)	PT-1	54	12	34	44	56	44	56	56	44	0
	PT-2	64	11	25	38	62	38	62	67	33	0
	PT-3	59	11	30	32	68	32	68	62	37	0
ML (n = 26)	PT-1	77	11	12	69	31	69	31	77	23	0
	PT-2	88	4	8	54	46	54	46	92	8	0
	PT-3	77	15	8	31	69	31	69	85	15	0
SD HH (n =268)	PT-1	53	12	35	41	59	41	59	54	46	0
	PT-2	67	7	26	37	63	37	63	65	35	0
	PT-3	46	22	32	32	68	32	68	60	40	0
		Round 2									
All (n = 297)	PT-4	31	23	45	23	76	34	65	48	51	1
	PT-5	41	18	40	20	79	32	67	53	46	1
	PT-6	41	17	41	23	76	31	68	48	51	1
ML (n = 28)	PT-4	39	25	36	46	54	54	46	61	39	0
	PT-5	64	18	18	36	64	50	50	75	25	0
	PT-6	71	11	18	46	54	54	46	75	25	0
SD HH (n = 269)	PT-4	33	27	39	21	78	32	67	47	52	1
	PT-5	43	17	39	18	81	30	69	51	49	1
	PT-6	36	19	44	20	79	28	71	45	54	1

ML Medical laboratories, SDHH Subdistrict Health Promotion Hospitals, PT-1 Hct68-02007, PT-2 Hct68-02008, PT-3 Hct68-02009, PT-4 Hct68-02010, PT-5 Hct68-02011, PT-6, Hct68-02012, Chi-squared analysis demonstrated a significant association between peer-group and accuracy-based classifications when using the ± 4% criterion in Round 2 and the combined analysis, whereas no significant association was observed in Round 1. When using the ± 6% criterion, no significant association was found in either round or in the combined analysis.

Table 5. Associations of satisfactory performance between peer-group z-scores and accuracy-based target values using ± 4% and ± 6% decision criteria across Rounds 1 and 2.

Accuracy Criterion	Round	χ^2 (df = 1)	p	Interpretation
± 4%	round 1	0.078	0.78	not significant
± 4%	round 2	47.61	< 0.001	significant
± 4%	combined (R1 + R2)	32.47	< 0.001	significant
± 6%	round 1	0.078	0.78	not significant
± 6%	round 2	0.246	0.62	not significant
± 6%	combined (R1 + R2)	0.187	0.66	not significant

R1 Round 1, R2 Round 2.

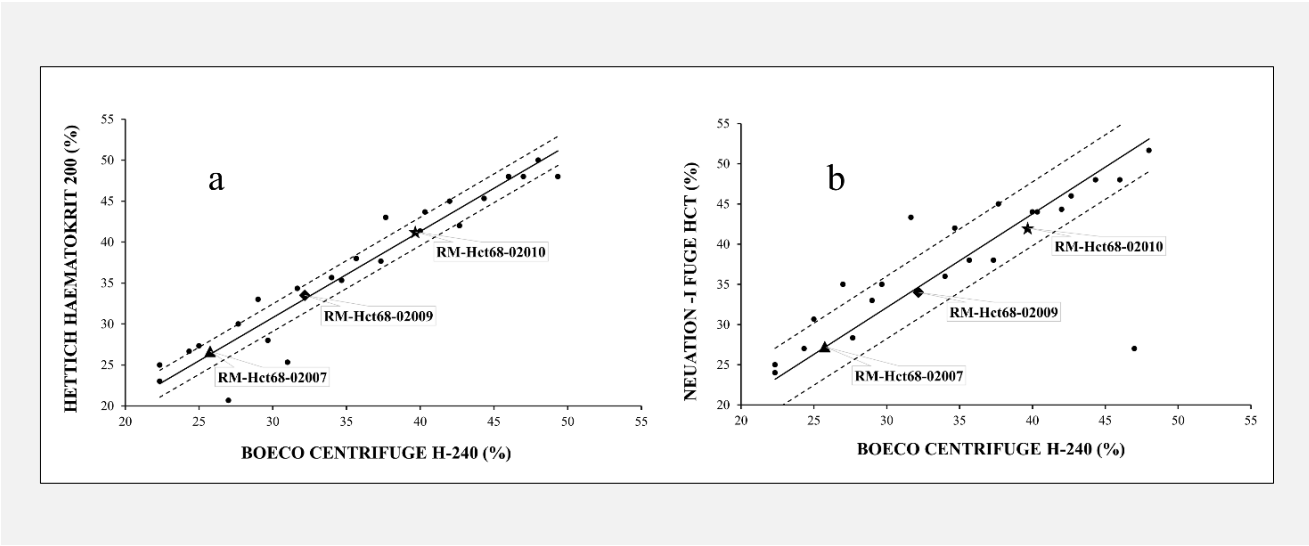

Figure 1. Deming regression analysis comparing the values of reference materials between two laboratories using three reference materials (▲ RM-Hct68-02007, ◆ RM-Hct68-02009, ★ RM-Hct68-02010) and 24 patient samples (●) for hematocrit measurement (Lab1, Lab2, Lab4) illustrate pairwise comparisons: Lab1 vs. Lab2 (a), Lab1 vs. Lab4 (b). Linear PI Upper limit and PI Lower limit (- - - -), Linear X barPC - Y predicted (——).

production processes certified under ISO 13485 [17] and aligned with ISO 17034 requirements. In this study, the proportion of satisfactory results was lower when performance was evaluated against accuracy-based target values compared with peer-group z-scores. This finding indicates that peer-group assessment can mask systematic bias, consistent with previous reports showing that non-traceable EQA schemes may overestimate laboratory performance [7-9,18-20].

The use of commutable RMs enabled fair comparison across medical laboratories (MLs) and SDHHs, despite variability in operator skill, centrifuge models, and technical conditions. This characteristic is essential for future national QA expansion because ISO 15189:2022 requires participation in EQA programs that are metrologically traceable and clinically comparable [8,10].

The performance acceptance limit applied in this study (± 6%) aligns with current CLIA criteria [16]; however, CLIA 2025 will tighten the allowable hematocrit error to ± 4% [21]. To support early implementation in resource-limited networks, an additional ± 10% acceptance criterion is proposed for initial accuracy-based evaluation, as it may offer a more feasible threshold during the transition period for some SDHH networks. Accuracy-based evaluation therefore provides a preparedness pathway for laboratories and primary-care units to progressively meet these more stringent regulatory requirements.

Table 5 demonstrates how different decision criteria (± 4% vs. ± 6%) influence the agreement between peer-group evaluation and accuracy-based performance assessment. The results show that the choice of accep-

tance limits has a substantial impact on detection of analytical bias and classification of laboratory performance.

Using the ± 4% criterion, a significant association was found between the two evaluation methods in Round 2 and in the combined analysis, indicating that the accuracy-based criterion identified performance deficiencies not captured by peer-group z-scores. This divergence suggests that peer-group evaluation may overestimate performance, particularly when systematic biases are shared across participants. The non-significant finding in Round 1 may reflect narrower performance variation or smaller detectable bias during that round, emphasizing that accuracy-based evaluation is more sensitive under conditions where analytical errors are more pronounced.

In contrast, the ± 6% criterion produced no significant associations in either individual round or the combined dataset. This indicates that the wider tolerance band reduces the ability of accuracy-based assessment to distinguish true analytical bias from acceptable variation. As a result, classifications based on ± 6% become more similar to peer-group results, diminishing the added value of accuracy-based evaluation in identifying underperforming sites. The lack of significant differences at ± 6% suggests that this threshold may be insufficiently stringent for identifying clinically relevant deviations, particularly for decentralized facilities such as SDHHs. Overall, these findings reinforce that the stringency of the decision criterion is critical when implementing accuracy-based quality assurance. A tighter limit such as ± 4% increases the discriminatory power of accuracy-based evaluation and better reflects current regulatory expectations, whereas a broader limit such as ± 6% may be useful only as a transitional threshold for laboratories beginning to adopt accuracy-based performance monitoring.

Lower accuracy among SDHHs compared with medical laboratories also highlights underlying gaps in calibration, operator training, and handling of blood-based QC materials. Because the centrifugation-based Hct testing remains highly manual, errors may arise from incorrect centrifuge speed calibration, inconsistent timing, or visual misreading of packed cell volume [2,5]. The system developed in this study enables objective identification of such issues and supports targeted corrective actions.

The RMs used in this study demonstrated adequate homogeneity, 120-day stability, and commutability according to CLSI EP14-A4, confirming their suitability for accuracy-based proficiency testing [11-14]. Their production under ISO-17034-aligned processes and an ISO 13485 quality management framework further supports long-term scalability and sustainability [6,17]. Collectively, these findings demonstrate the feasibility of implementing a national accuracy-based QA model for basic hematology and related laboratory testing in SDHHs across Thailand. This model is consistent with international recommendations from the IFCC and CLSI, which emphasize the importance of commutable materials as a foundation for harmonization of hematologic measurements across instruments, facilities, and levels of care [10,12]. The accuracy-based QA system is scalable for implementation in other health regions and can be adapted to other laboratory tests in SDHHs.

CONCLUSION

This study established Thailand's first accuracy-based QA system for centrifugation-based hematocrit testing using commutable reference materials. Assigning target values from commutable RMs enables fair and comparable evaluation across participants, including both laboratory and non-laboratory personnel using different centrifuge models. The system demonstrated strong capability in detecting deviations from true target values and is well suited for scalable integration into national QA frameworks for SDHHs in Thailand.

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This article used generative AI (ChatGPT 5.1) solely for grammar editing and language polishing. All scientific content, interpretations, and conclusions were created entirely by the authors.

Declaration of Interest:
No conflicts of interest.

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