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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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Supplementary Data

Table S1. Temperature and humidity in express and simulated transport conditions of PT materials before distribution to medical laboratories and SDHHs in Health Region 6.

Parameter	Express Transport Temperature (°C)	Express Transport Humidity (%)	Simulated PT Transport Temperature (°C)	Simulated PT Transport Humidity (%)
Mean	30	66	31	65
SD	2.0	4.0	3.0	4.0
% CV	6.0	7.0	9.4	6.5
Max	34	71	35	70
Min	27	57	24	52

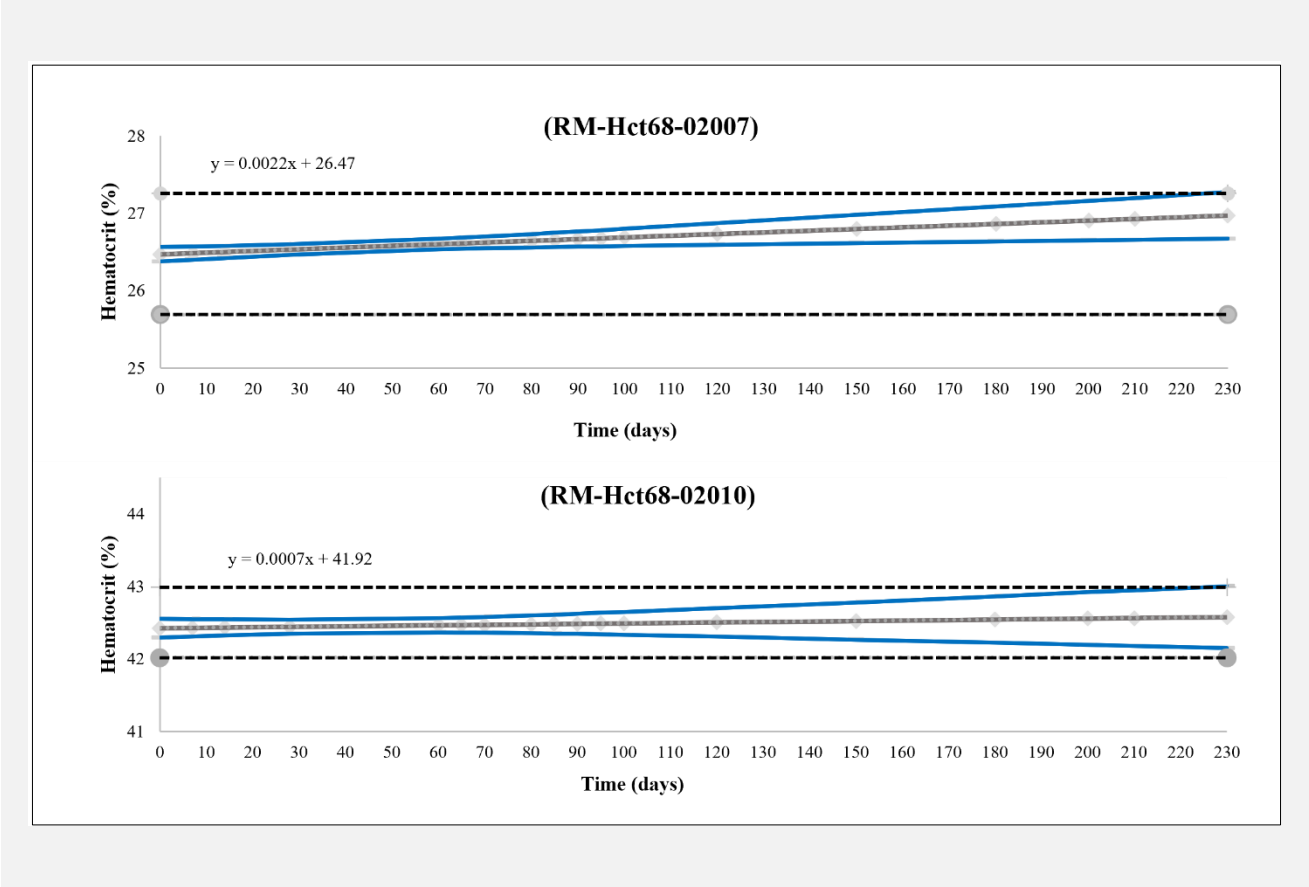

Figure S1. Predicted shelf-life profile of the reference materials by ISO Guide 35, demonstrating the stability of packed red cell volume in RM-Hct68-02007 and RM-Hct68-02010. Linear PI Upper limit and PI Lower limit (- - - -), Average (——), Regression line (——).