

Original article

External quality assessment of blood bank laboratory in Thailand, 2024-2025

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Abstract:

Introduction: Blood transfusion should not only provide the intended therapeutic benefit but also prioritize patient safety through accurate and reliable laboratory testing. **Objective:** This study aimed to evaluate the performance of analytical testing among blood bank laboratories participating in the External Quality Assessment program in Thailand. **Materials and Methods:** The Division of Proficiency Testing, Department of Medical Sciences, distributed proficiency testing materials to 1,242 member laboratories from both the public and private sectors in 2024 and 1,243 laboratories in 2025, through three testing rounds per year, totaling six rounds over the two-year study period. **Results:** For ABO blood group testing, more than 90% of laboratories achieved satisfactory performance in most rounds, except for rounds 3/2024 and 3/2025, with satisfactory performance rates of 72.3% and 77.9%, respectively. The test items distributed in these rounds were B_3 and AB_3 subgroups. For RhD testing, more than 98% of laboratories achieved satisfactory performance in most rounds, except for rounds 1/2024 and 2/2025, with satisfactory performance rates of 97.5% and 90.9%, respectively. The test items distributed in these rounds were RhD negative samples. For antibody screening and antibody identification, more than 97% of laboratories achieved satisfactory performance in most rounds, except for rounds 2/2024, 3/2024, and 1/2025, with satisfactory performance rates of 96.0%, 96.7%, and 96.5%, respectively. **Conclusion:** The findings indicate that proficiency testing materials involving complex or uncommon cases encountered in routine practice may increase the likelihood of incorrect test results. Continuous development of laboratory personnel's knowledge and technical skills is therefore essential to improve the accuracy and reliability of test results and to support safe transfusion practices and optimal patient care.

Keywords : ● ABO blood grouping ● RhD blood grouping ● Antibody screening ● Antibody identification
● External quality assessment (EOA)

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นิพนธ์ต้นฉบับ

การประเมินคุณภาพการตรวจวิเคราะห์ทางห้องปฏิบัติการธนาคารเลือดในประเทศไทย ปี พ.ศ. 2567-2568

อาริดา กล่อมเกลี้ยง ฤทัยชนก เพ็ญภู่ พิพาลิน พรหมประดิษฐ์ และ ลูติวัสส์ สุวพันธ์

กองทดสอบความชำนาญ กรมวิทยาศาสตร์การแพทย์ กระทรวงสาธารณสุข

บทคัดย่อ

บทนำ การเตรียมเลือดเพื่อให้แก่ผู้ป่วย นอกจากจะต้องก่อให้เกิดประโยชน์สูงสุดต่อผู้ป่วยแล้ว ยังต้องคำนึงถึงความปลอดภัยเป็นสำคัญ **วัตถุประสงค์** การศึกษานี้เพื่อประเมินคุณภาพการตรวจวิเคราะห์ของห้องปฏิบัติการธนาคารเลือดในประเทศไทย **วัสดุและวิธีการ** กองทดสอบความชำนาญ กรมวิทยาศาสตร์การแพทย์ ได้จัดส่งวัตถุดิบทดสอบ ให้แก่ห้องปฏิบัติการสมาชิกทั้งภาครัฐและเอกชน จำนวน 1,242 แห่ง ในปี พ.ศ. 2567 และ 1,243 แห่ง ในปี พ.ศ. 2568 จำนวน 6 รอบ **ผลการศึกษา** ผลการประเมินพบว่า การตรวจหมู่เลือดระบบ ABO ห้องปฏิบัติการส่วนใหญ่มีผลการประเมินผ่านเกณฑ์มากกว่าร้อยละ 90 ยกเว้นรอบที่ 3/2567 และ 3/2568 ซึ่งผ่านเกณฑ์ร้อยละ 72.3 และ 77.9 ตามลำดับ โดยวัตถุดิบทดสอบที่จัดส่งเป็นหมู่เลือดชนิด B₃ และ AB₃ ซึ่งเป็น subgroup สำหรับการตรวจหมู่เลือด RhD ห้องปฏิบัติการส่วนใหญ่มีผลการประเมินผ่านเกณฑ์มากกว่าร้อยละ 98 ยกเว้นรอบที่ 1/2567 และ 2/2568 ซึ่งผ่านเกณฑ์ร้อยละ 97.5 และ 90.9 ตามลำดับ โดยวัตถุดิบทดสอบที่จัดส่งเป็น Rh negative สำหรับการตรวจคัดกรองแอนติบอดี และการตรวจระบุชนิดของแอนติบอดี ห้องปฏิบัติการส่วนใหญ่มีผลการประเมินผ่านเกณฑ์มากกว่าร้อยละ 97 ยกเว้นรอบการจัดส่งที่ 2/2567, 3/2567 และ 1/2568 ซึ่งผ่านเกณฑ์ร้อยละ 96.0, 96.7 และ 96.5 **สรุป** ผลการศึกษาส่งสะท้อนให้เห็นว่า เมื่อวัตถุดิบทดสอบมีความซับซ้อนหรือเป็นกรณีพิเศษที่พบไม่บ่อยในงานประจำวัน อาจส่งผลให้ห้องปฏิบัติการรายงานผลไม่ถูกต้อง ดังนั้น จึงควรส่งเสริมการพัฒนาความรู้และทักษะของผู้ปฏิบัติงานอย่างต่อเนื่อง เพื่อเพิ่มความถูกต้องและความน่าเชื่อถือของผลการตรวจวิเคราะห์ และสนับสนุนให้ผู้ป่วยได้รับการรักษาที่ปลอดภัยและเกิดประโยชน์สูงสุด

คำสำคัญ : ● การตรวจหมู่เลือด ABO ● การตรวจหมู่เลือด RhD ● การตรวจกรองแอนติบอดี ● การแยกชนิดของแอนติบอดี
● การประเมินคุณภาพการตรวจวิเคราะห์

วารสารโลหิตวิทยาและเวชศาสตร์บริการโลหิต. 2569;36:263-71.

Introduction

Safe blood transfusion is an essential part of patient care. In addition to ensuring the intended therapeutic benefit, blood transfusion requires careful measures to minimize the risk of adverse transfusion reactions. Therefore, ensuring blood compatibility is a fundamental responsibility of blood bank laboratories and requires accurate and standardized pre-transfusion testing.^{1,2} This testing includes ABO and RhD blood grouping, antibody screening, and antibody identification for samples with positive screening. Identification of the corresponding red blood cell antigen is required to confirm antibody specificity before compatibility testing (crossmatching) is performed. Patients should receive ABO-compatible, antigen-negative red blood cell units that are compatible by crossmatch, thereby reducing the risk of hemolytic transfusion reactions and subsequent alloimmunization.³

Because each step of the transfusion testing process can affect patient safety, maintaining high laboratory quality is essential. External Quality Assessment (EOA) is an important component of laboratory quality assurance. It provides an independent evaluation of laboratory performance and assesses the accuracy, reliability, and consistency of test results. High-quality laboratory performance supports accurate transfusion testing, appropriate blood selection, and safe patient management.^{4,5}

The Department of Medical Sciences (DMSc), through the Division of Proficiency Testing, has continuously provided an EOA program for blood bank laboratories in Thailand.^{6,7} The program includes ABO blood grouping, RhD blood grouping, antibody screening, antibody identification, compatibility testing, and the direct antiglobulin test (DAT). In 2002, the DMSc became the first organization in Southeast Asia to receive accreditation for blood bank EOA under the international standard ILAC-G13:2000 from the National Association of Testing Authorities (NATA), Australia. The program is currently accredited to ISO/IEC 17043:2023 by the Bureau of Laboratory Accreditation, Department of Science Service

Given the importance of EOA in ensuring the quality and reliability of blood bank laboratory testing, together with the established capacity and expertise of the DMSc in providing an accredited blood bank EOA program, continuous evaluation of program performance is essential. Assessment of laboratory performance across different testing areas and laboratory settings provides an opportunity to identify strengths, detect areas of suboptimal performance, and guide targeted quality improvement. Therefore, this study aimed to evaluate the performance of blood bank laboratories participating in the national EOA program in Thailand during 2024-2025.

Materials and Methods

Test materials

Test materials were prepared from donor red cells and serum obtained from the National Blood Centre, Thai Red Cross Society.⁸ The EOA program was conducted three times annually, with two test panels distributed in each round. Panel 1 contained four specimens, including two tubes of 8-10% red blood cell suspensions in Alsever's solution and two serum samples for ABO and RhD blood grouping. Panel 2 consisted of three serum samples for antibody screening and antibody identification. All test materials were evaluated for homogeneity and stability before distribution. The characteristics of the test materials are summarized in Table 1.

Participating laboratories

Participating laboratories were those enrolled in the Blood Bank External Quality Assessment (EOA) Program during fiscal years 2024 and 2025. Laboratories were classified according to hospital type as follows: regional hospital laboratories (PHRH); provincial hospital laboratories (PHGH); community hospital laboratories (PHCH); laboratories under the Ministry of Public Health but outside the Office of the Permanent Secretary (PNPS); government laboratories outside the Ministry of Public Health (GNPH); and private sector laboratories (NGPH). The number of participating laboratories in each category is presented in Table 2.

Table 1 Characteristics of proficiency testing items (panel 1 and 2) distributed in fiscal years 2024 and 2025

Distribution round	Characteristics of proficiency test items		
	ABO blood grouping	RhD blood grouping	Antibody screening/identification
1/2024	B	Positive	Negative
	B	Negative	Anti-E
			Negative
2/2024	AB	Positive	Anti-E, Anti-Mi ^a
	O	Positive	Negative
			Negative
3/2024	B ₃	Positive	Negative
	O	Positive	Anti-E, Anti-Mi ^a
			Negative
1/2025	A	Positive	Anti-E, Anti-Mi ^a
	A	Positive	Negative
			Negative
2/2025	O	Negative	Negative
	B	Positive	Anti-E
			Negative
3/2025	O	Positive	Negative
	AB ₃	Positive	Anti-Mi ^a
			Negative

Panel 1 : 2 red cells samples for ABO (cell grouping) and RhD typing
2 serum samples for ABO (serum grouping)
Panel 2 : 3 serum samples for antibody screening / identification

Table 2 Number of laboratories enrolled in external quality assessment in fiscal years 2024 and 2025

Laboratory	ABO blood group		RhD blood group		Antibody screening		Antibody identification	
	2024	2025	2024	2025	2024	2025	2024	2025
PHRH	27	33	27	33	26	32	26	32
PHGH	64	58	64	58	63	57	63	57
PHCH	681	687	681	687	323	357	323	357
PNPS	27	30	27	30	21	24	21	24
GNPH	98	93	98	93	69	71	69	71
NGPH	345	342	345	342	203	211	203	211
Total	1,242	1,243	1,242	1,243	705	752	705	752

PHRH = regional hospital laboratories; PHGH = provincial hospital laboratories; PHCH = community hospital laboratories;
PNPS = laboratories under the Ministry of Public Health but outside the Office of the Permanent Secretary;
GNPH = government laboratories outside the Ministry of Public Health; NGPH = private sector laboratories

Data analysis

Results submitted by participating laboratories were collected and analyzed. The target value for each test item was determined based on the consensus mode of the participants results. The consensus mode was calculated from the results reported by all participating laboratories. The consensus result was accepted as the assigned value when it was reported by at least 80% of all participating laboratories with valid results.

Performance evaluation

For ABO blood grouping and RhD blood grouping, laboratory performance was assessed in three areas: (1) testing methodology, (2) agglutination grading, and (3) final interpretation of blood group results. The total score for each test item was converted to a standardized score, with a maximum score of 4.0.

For antibody screening and antibody identification, performance was evaluated based on the accuracy of the final interpretation. The total score was similarly converted to a standardized score, with a maximum score of 4.0. The standardized score was calculated as follows:

$$\text{Standard score} = \frac{(\text{Total score obtained}) \times 4.0}{\text{Full score}}$$

Performance criteria

A standardized score of ≥ 3.5 was considered acceptable and indicative of satisfactory laboratory performance. Laboratory performance was classified into three categories according to the standardized score: Excellent (standardized score = 4.0), Good (standardized score 3.5 to < 4.0), and Unsatisfactory (standardized score < 3.5). For this study, laboratories with a standardized score of ≥ 3.5 were considered to have passed the EQA assessment, whereas those with a score < 3.5 were considered to have failed the assessment.

The results of the EQA assessment were summarized in tables and reported as the pass rate (%), calculated as the proportion of participating laboratories that achieved a standardized score of ≥ 3.5 among all laboratories submitting valid results for each testing area and EQA round.

Results

ABO blood grouping

Overall performance for ABO blood grouping was satisfactory with pass rates exceeding 90.0% in most distribution rounds. However, a marked decline in overall pass rates was observed in round 3/2024 (72.3%) and round 3/2025 (77.9%). This reduction in accuracy was most prominent among community hospital laboratories (PHCH; 59.5% in 2024 and 65.8% in 2025) and private sector laboratories (NGPH; 58.8% in 2024 and 70.5% in 2025). Regional hospital laboratories (PHRH) maintained the highest pass rates throughout all rounds (87.9-100.0%). Detailed results are presented in Table 3.

RhD blood grouping

Participating laboratories demonstrated consistently high accuracy for RhD blood grouping, with overall passing rates exceeding 98.0% in four out of six distributions. Lower overall pass rates were recorded in round 1/2024 (97.5%) and round 2/2025 (90.9%). During round 2/2025, PHCH laboratories recorded the lowest pass rate at 76.7%, whereas PHRH laboratories achieved a 100.0% pass rate across all six distributions. Detailed performance by laboratory type is shown in Table 4.

Antibody screening

Performance in unexpected antibody screening remained high and stable throughout the two-year period, with overall pass rates ranging between 96.4% and 97.1% across all distributions. PHRH and GNPH laboratories consistently achieved high passing rates (98.4-100.0%), while PHCH laboratories-maintained pass rates ranging from 90.5% to 93.9%. The data are summarized in Table 5.

Antibody identification

Overall pass rates for antibody identification exceeded 97.0% in most distributions, reaching 100.0% in round 1/2024 and round 2/2025. Slight decreases in overall performance were observed in round 2/2024 (96.0%), round 3/2024 (96.7%), and round 1/2025 (96.5%). PHRH laboratories achieved a 100.0% pass rate in every testing round. The complete performance data are presented in Table 6.

Table 3 Average percentage of laboratories achieving passing scores for ABO blood group testing in fiscal years 2024 and 2025

Laboratory	Distribution round					
	1/2024	2/2024	3/2024	1/2025	2/2025	3/2025
PHRH	100.0	100.0	92.3	97.0	97.0	87.9
PHGH	98.4	100.0	80.7	96.6	96.5	87.7
PHCH	89.1	89.9	59.5	88.7	89.8	65.8
PNPS	100.0	100.0	66.7	96.7	96.7	73.3
GNPH	94.6	91.5	75.8	95.6	96.6	82.0
NGPH	93.7	94.6	58.8	91.3	94.4	70.5
Total	96.0	96.0	72.3	94.3	95.2	77.9

PHRH = regional hospital laboratories; PHGH = provincial hospital laboratories; PHCH = community hospital laboratories; PNPS = laboratories under the Ministry of Public Health but outside the Office of the Permanent Secretary; GNPH = government laboratories outside the Ministry of Public Health; NGPH = private sector laboratories

Table 4 Average percentage of laboratories achieving passing scores for RhD blood group testing in fiscal years 2024 and 2025

Laboratory	Distribution round					
	1/2024	2/2024	3/2024	1/2025	2/2025	3/2025
PHRH	100.00	100.00	100.00	100.00	100.00	100.00
PHGH	98.40	100.00	98.40	100.00	98.30	98.30
PHCH	95.60	95.70	95.30	95.90	76.70	96.10
PNPS	96.30	100.00	100.00	100.00	93.30	96.70
GNPH	98.90	100.00	97.80	97.70	92.90	100.00
NGPH	95.80	96.70	96.60	97.00	84.20	96.60
Total	97.5	98.7	98.0	98.4	90.9	98.0

PHRH = regional hospital laboratories; PHGH = provincial hospital laboratories; PHCH = community hospital laboratories; PNPS = laboratories under the Ministry of Public Health but outside the Office of the Permanent Secretary; GNPH = government laboratories outside the Ministry of Public Health; NGPH = private sector laboratories

Table 5 Average percentage of laboratories achieving passing scores for antibody screening test in fiscal years 2024 and 2025

Laboratory	Distribution round					
	1/2024	2/2024	3/2024	1/2025	2/2025	3/2025
PHRH	100.00	100.00	100.00	100.00	100.00	100.00
PHGH	98.40	98.40	98.40	100.00	98.20	98.20
PHCH	90.50	92.90	93.90	93.10	91.00	92.40
PNPS	95.00	100.00	95.20	91.70	95.80	95.80
GNPH	100.00	100.00	97.10	98.60	100.00	100.00
NGPH	96.00	91.40	97.90	95.20	97.60	95.10
Total	96.7	97.1	97.1	96.4	97.1	96.9

PHRH = regional hospital laboratories; PHGH = provincial hospital laboratories; PHCH = community hospital laboratories; PNPS = laboratories under the Ministry of Public Health but outside the Office of the Permanent Secretary; GNPH = government laboratories outside the Ministry of Public Health; NGPH = private sector laboratories

Table 6 Average percentage of laboratories achieving passing scores for antibody identification in fiscal years 2024 and 2025

Laboratory	Distribution round					
	1/2024	2/2024	3/2024	1/2025	2/2025	3/2025
PHRH	100.00	100.00	100.00	100.00	100.00	100.00
PHGH	100.00	94.80	90.90	100.00	100.00	100.00
PHCH	100.00	88.20	94.90	100.00	100.00	94.40
PNPS	100.00	100.00	100.00	100.00	100.00	93.30
GNPH	100.00	98.10	94.40	96.40	100.00	100.00
NGPH	100.00	94.70	100.00	82.50	100.00	97.60
Total	100.0	96.0	96.7	96.5	100.0	97.6

PHRH = regional hospital laboratories; PHGH = provincial hospital laboratories; PHCH = community hospital laboratories;

PNPS = laboratories under the Ministry of Public Health but outside the Office of the Permanent Secretary;

GNPH = government laboratories outside the Ministry of Public Health; NGPH = private sector laboratories

Discussion

The overall performance of participating laboratories for ABO blood grouping was satisfactory during fiscal years 2024-2025. In fiscal year 2024, the overall pass rate was 96.0% for the first and second distributions but decreased markedly to 72.3% in the third distribution. The decline was particularly evident among community hospitals (PHCH) and private laboratories (NGPH), where pass rates fell below 60.0%. A similar trend was observed in fiscal year 2025, with overall pass rates of 94.3% and 95.2% in the first and second distributions, respectively, followed by a decrease to 77.9% in the third distribution. The test materials distributed in the third round of both fiscal years contained B₃ and AB₃ blood groups, which are rare subgroups of B and AB. These subgroups may produce weak or mixed-field agglutination reactions with anti-B reagents, making blood group interpretation more challenging. Accurate identification requires both forward (cell) grouping and reverse (serum) grouping using the tube technique. When discrepant results are observed, further investigation is necessary to resolve the ABO discrepancy and establish the correct blood group. These findings suggest that uncommon blood group variants remain a major challenge for routine laboratory practice and highlight the importance of continuous training in the recognition and investigation of

ABO discrepancies. Mixed-field agglutination is readily recognized by experienced personnel using column agglutination techniques based on its characteristic reaction pattern. It can also be detected using the conventional tube test, with microscopic examination of the red cell suspension aiding recognition of the mixed-field reaction.⁹ Therefore, adequate proficiency in serologic testing and interpretation, together with strict adherence to standard blood grouping procedures, may help prevent errors in identifying mixed-field agglutination. When the ABO testing performance in this study was compared with that reported in other studies, particularly the study by S. Bejrachandra¹⁰, the accuracy of ABO reporting in that study ranged from 93.3% to 99.7%. This finding was consistent with the present study, in which most participating laboratories demonstrated satisfactory performance.

For RhD blood grouping, laboratory performance remained consistently high throughout the study period, with pass rates exceeding 98% in most distributions. Lower pass rates were observed only in distribution 1/2024 (97.5%) and distribution 2/2025 (90.9%). In both rounds, the test materials represented RhD negative samples, which are uncommon in the Thai population, with an estimated prevalence of approximately 0.3%.¹¹ Because the Rh blood group system is the second most

clinically significant blood group system after ABO, laboratories should carefully investigate samples with initially negative RhD results using the indirect antiglobulin test (IAT) to distinguish between RhD negative, RhD positive, and weak D phenotypes. Accurate RhD typing is essential to ensure appropriate transfusion support and prevent Rh alloimmunization. In addition to distinguishing RhD negative, RhD positive, and weak D phenotypes, attention should also be given to the DEL phenotype, particularly Asian-type DEL, which is prevalent in Asian populations and is characterized by very low levels of D antigen expression. This makes it difficult to distinguish from RhD negative or weak D phenotypes using routine serologic methods.¹² Therefore, samples showing RhD negative or weakly reactive results should be considered for further testing by indirect antiglobulin test (IAT) to improve the detection of low-level D antigen expression and reduce the risk of misclassification of the RhD phenotype. When a DEL phenotype is suspected, additional serologic or molecular testing may be required for confirmation.¹³

The performance of participating laboratories for antibody screening was consistently satisfactory throughout fiscal years 2024-2025. Overall pass rates ranged from 96.4% to 97.1% across all distributions, indicating good consistency among participating laboratories. Regional hospital laboratories (PHRH) achieved a 100% pass rate in every distribution, reflecting a high level of technical competency and experience in antibody screening.

Similarly, the overall performance for unexpected antibody identification remained high, with pass rates exceeding 97% in most distributions. Slightly lower performance was observed in distributions 2/2024, 3/2024, and 1/2025, in which the test specimens contained multiple antibodies (anti-E and anti-Mi^a). Identification of multiple antibodies is generally more challenging than identification of a single antibody because overlapping reaction patterns may complicate interpretation. Notably, anti-E and anti-Mi^a are clinically relevant antibodies encountered among both Thai blood donors and patients,^{14,15} making their accurate identification

particularly important in routine transfusion practice. Despite the increased complexity of these specimens, the overall pass rates remained high, indicating that most participating laboratories were able to correctly identify these antibody combinations without substantial loss of performance. This finding is encouraging and suggests that the current EQA program is effective in assessing and reinforcing laboratory competency in the identification of clinically relevant multiple antibodies. Regional hospital laboratories (PHRH) maintained a 100% pass rate throughout the study period, further demonstrating a high level of expertise in antibody identification. These findings support the continued inclusion of complex antibody combinations in EQA materials and educational activities to maintain laboratory competency and minimize the risk of missed or incorrectly identified clinically significant antibodies.

Conclusion

The findings of this study demonstrate that most participating laboratories achieved satisfactory performance in the Blood Bank External Quality Assessment Program during fiscal years 2024-2025. However, performance declined when test materials contained uncommon blood group subgroups or complex combinations of antibodies that are infrequently encountered in routine practice. These findings indicate that, although overall laboratory performance was satisfactory, challenges remain in the recognition and interpretation of uncommon or complex serological findings. EQA therefore serves not only as a means of monitoring laboratory performance but also as an important tool for identifying errors and areas requiring improvement at the individual laboratory level. EQA findings can inform to guide continuous education, competency assessment, and targeted development of laboratory personnel's knowledge and technical skills, as well as to support ongoing quality improvement activities. Strengthening these activities based on EQA findings can enhance the accuracy and reliability of blood bank testing and ultimately contribute to safer transfusion practices and improved patient care.

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