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โครงการประเมินคุณภาพห้องปฏิบัติการทางแบคทีเรียวิทยาโดยองค์กรภายนอก

Participant Manual 2025

External Quality Assessment Schemes in Bacteriology (EQAB)

ภาควิชาจุลชีววิทยาคลินิกและเทคโนโลยีประยุกต์

คณะเทคนิคการแพทย์ มหาวิทยาลัยมหิดล

The Department of Clinical Microbiology and Applied Technology, Faculty of Medical Technology, Mahidol University.

Table of Contents

1. Introduction

External Quality Assessment (EQA) is a crucial tool for quality assurance in medical laboratories. The Faculty of Medical Technology, Mahidol University, provides this service to ensure that laboratories meet high standards of accuracy and reliability. Among the many assessments offered, the External Quality Assessment Schemes in Bacteriology—covering Gram stain (EQAB 8010), AFB stain (EQAB 8020), and Bacteria identification and susceptibility testing (EQAB 8150)—are part of the 12 programs available. Participating laboratories can use the assessment results to improve their quality in alignment with several standards, including ISO 15189, Laboratory Accreditation, and the MOPH Standard set by the Ministry of Public Health. Furthermore, the EQAB program serves as a central hub for comparing testing accuracy across member laboratories and offers a platform for technical advice and academic support in bacteriology. For further reading, you may find useful resources in ISO 15189 guidelines and studies on EQA's impact on laboratory performance, which can offer deeper insights into the program's benefits and implementation.

2. Objectives

2.1 To evaluate the quality of laboratory testing in Gram staining, Acid-fast bacilli (AFB) staining, and bacterial identification and susceptibility testing.

2.2 To serve as a central hub for comparing the accuracy of test results among member laboratories.

2.3 To act as a medium for providing knowledge and technical consultation regarding bacteriology practices.

3. Program Administrators

Department of Clinical Microbiology and Applied Technology, Faculty of Medical Technology, Mahidol University, is operated by

Asst. Prof. Dr. Rungrot Cherdtrakulkiat	Scheme Coordinator
Assoc. Prof. Dr. Theeraphon Piacham	Technical Manager: Gram stain
Asst. Prof. Dr. Rungrot Cherdtrakulkiat	Technical Manager: AFB stain
Asst. Prof. Dr. Kanokwan Kittiniyom	Technical Manager: Identification
Assoc. Prof. Dr. Sakda Yainoy	Technical Manager: Susceptibility
Assoc. Prof. Dr. Warawan Eiamphungporn	Technical Manager: Susceptibility
Ms. Thitaree Sakdachansawat	Operator
Ms. Peerada Phuechpisut	Operator and project coordinator
TEL: 061 174 7884	E-mail : eqab.mtmu@gmail.com

4. Assignment of Participant ID

The Participant ID is an 8-digit numeric code assigned to each participant upon registration in the program. System access for members is granted based on this Participant ID and associated user account. All communications between the program and its members will reference this ID to ensure anonymity and maintain confidentiality.

5. Tests and Services Provided

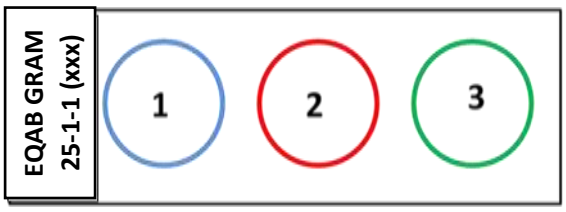
The External Quality Assessment Program in Bacteriology provides services through the following 3 programs:

1) Program EQAB 8010: Gram stain
2) Program EQAB 8020: Acid fast bacilli stain
3) Program EQAB 8150: Bacteria identification and susceptibility testing

6. Testing Samples

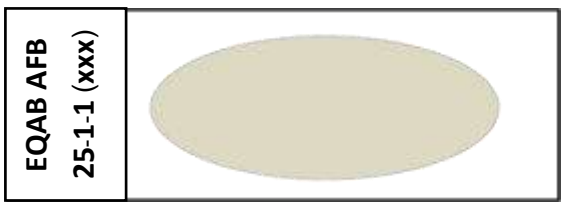
Test samples will be provided to members according to the program in which they are registered, accompanied by the Sample Testing Instructions (F/QP043-MIBT-01/12). Each distribution will consist of the following components:

6.1 Program EQAB 8010: Gram Stain provides two bacterial smear slides per testing round for Gram staining. Each slide contains bacterial smears within three designated circles as follows: Blue Circle: A control sample of Gram-positive bacteria, Red Circle: A control sample of Gram-negative bacteria, and Green Circle: An unknown sample, comprising no more than two mixed bacterial species, as illustrated.



1. *Blue Circle: Gram positive control*
2. *Red Circle: Gram negative control*
3. *Green Circle: unknown*

6.2 Program EQAB 8020: Acid fast bacilli stain provides two sputum smear slides per testing round for AFB staining. Each slide contains a single sputum sample smeared within one designated circle, as illustrated.



6.3 Program EQAB 8150: Bacteria identification and susceptibility testing provides two tubes per distribution round, each containing a pure bacterial culture preserved in semi-solid media. Each

tube contains one bacterial species, and the source specimen from which the bacteria were isolated is specified in the “Sample Testing Instructions”.

6.4 Sample Identification

Each test sample will be labeled with a code, which includes the following details:

EQAB	Name of the testing program	-	The last two digits of the year (AD)	-	Distribution No.	-	sample identification number.

For example, EQAB GRAM 25-1-1 (111): Gram stain, The year 2025 Round 1 Sample number 1 Sample identification number 111.

7. Homogeneity and Stability Testing of Test Samples

7.1 Homogeneity Testing

For each program, 10 samples from each test sample code will be randomly selected using systematic sampling and sent for homogeneity testing at the Microbiology Laboratory, Department of Microbiology, Faculty of Medicine, Siriraj Hospital.

7.2 Stability Testing of Test Samples

For each program, a minimum of 4 samples from each test sample code will be selected through systematic sampling and sent to 4 laboratories located in the most distant regions within each geographical area. Upon return, the samples will be subjected to stability testing at the Microbiology Laboratory, Department of Microbiology, Faculty of Medicine, Siriraj Hospital.

All samples prepared for each round undergo homogeneity testing and stability testing. Any samples that fail to meet the criteria for homogeneity or stability will not be included in the assessment process.

8. Sample Distribution Rounds

Samples are distributed 3 times per year, with each round consisting of 2 test samples per program. The samples for all 3 programs are distributed simultaneously according to the following sample distribution schedule:

Sample Distribution Schedule for All 3 Programs:

Distribution No.	Schedule
1	Feb 2025
2	Jun 2025
3	Oct 2025

For each sample distribution round, the project will inform members through the email address of the designated contact person provided to the program. This notification will be sent on the day the samples are dispatched via postal service.

9. Test Result Reports

9.1 Submission of Test Results via the Online System on the website https://eqamt.mahidol.ac.th/, according to the program in which the member is registered. Members must log in using their registered email and password, referencing the Participant ID for reporting results. The process is as follows: Log in with your registered email and password. ⟶ Click on "Submit Test Results." ⟶ Select the EQAB project for which you are reporting results (e.g., GRAM, AFB, or IDEN). ⟶ Click on "TRIAL." ⟶ Select the appropriate distribution round. ⟶ Click "Submit Results" and complete the online reporting form. Members are advised to review the accuracy and completeness of the information before confirming the submission. Members can consult the Online Test Result Reporting Guide on the website at https://eqamt.mahidol.ac.th/ ⟶ schemes: EQAB BACTERIOLOGY ⟶ Document download.

The program will send an email reminder 4 days before the reporting deadline to the contact person's email provided to the program.

9.2 Correction of Test Results

9.2.1 Correction of Test Results Before the Closing Date: Members can log in using their unique Username and Password to modify their submitted results online before the closing date. There is no need to notify the program of these changes.

9.2.2 Correction of Test Results After the Closing Date**:** Members can make corrections to their test results up to 3 days after the closing date by contacting the coordinator via telephone at 061 174 7884 or by email at eqab.mtmu@gmail.com. A formal request for result correction, signed by the head of the department, must also be submitted.

10. Test Performance Evaluation

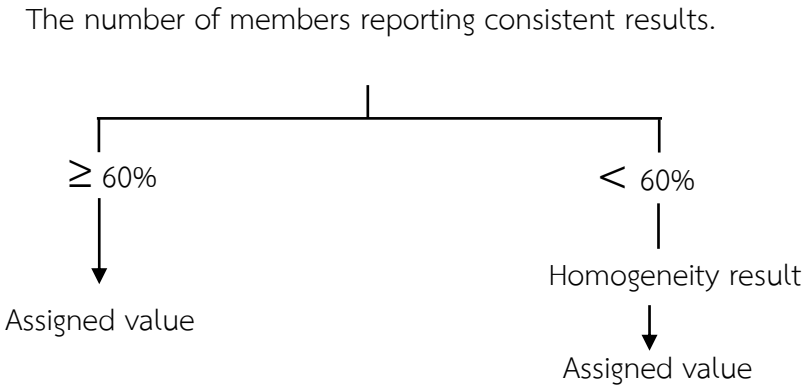
The evaluation of members' test results is conducted by comparing them with the assigned value**.**

10.1 Assigned value

The assignment of the Assigned Value for all programs follows the same criteria as outlined:

- The Consensus mode is used as the Assigned Value when 60% or more of the members report consistent results, and the results must match the homogeneity testing outcome.
- In cases where less than 60% of the members report consistent results, the outcome of the homogeneity test will be used as the Assigned Value.

- When the homogeneity testing result is used as the Assigned Value for Bacterial Identification involving antibiotic-resistant strains, antimicrobial susceptibility test results will also be considered in conjunction with the bacterial identification to define the important antibiotic-resistant bacteria that must be reported.



10.2 The selection of antimicrobial agents for evaluation and scoring in Antimicrobial **Susceptibility Testing is based on the following criteria:**

1) The antimicrobial agent must be classified under Tier 1 according to the current CLSI guidelines.
2) The antimicrobial agent must be one that is specifically used for a particular type of specimen or applied to a specific group of microorganisms.
3) In cases involving resistant strains, the antimicrobial agent may be classified under Tier 2 and/or Tier 3.
4) Not an antimicrobial agent classified as intrinsic resistance.

The antimicrobial agent should not exhibit intrinsic resistance, and the antimicrobial agents selected for evaluation and scoring must be reported by no fewer than 60% of the members to establish the Assigned Value. In the case where antimicrobial agents are interchangeable as specified by the CLSI ("or") and belong to the same class, the number of members reporting these agents will be combined to meet the criteria for selection.

10.3 Scoring Criteria

The scoring for test results in the External Quality Assessment Program follows these guidelines:

10.3.1 Program EQAB 8010: Gram stain

Gram Stain Reporting is assigned a maximum score of 2 points per bacterial species. The scoring criteria are based on the accuracy of reporting Gram reaction, morphology, and/or arrangement, as well

as any significant features relevant to the identification of the microorganism, such as the presence of spores. The scoring is determined according to the following guidelines:

Assigned value	สมาชิกรายงาน			Score
	Staining	Morphology	Cell arrangement or distinctive characteristics*	
Gram staining, cell morphology, and/or arrangement, as well as any distinctive features (if applicable).	Correct	Correct	None / Correct	2
	Correct	Correct	Partially Correct	1.5
	Correct	Correct	Incorrect	1
	Correct	Incorrect	Correct / Incorrect	0
	Incorrect	Correct / Incorrect	Correct / Incorrect	0

* *Distinctive characteristics significant to the identification of the microorganism, such as the presence of spores.*

10.3.2 Program EQAB 8020: Acid fast bacilli stain

AFB Staining Reporting is assigned a maximum score of 2 points per test slide. The scoring criteria are based on the accuracy of reporting either AFB positive or No AFB Observed. The grading results provided by members will be displayed as a consensus value in the final report. The scoring is determined according to the following guidelines:

Assigned Value	Score from Reporting results				
	No AFB Observed	1-9 AFB per 100 fields	AFB 1+	AFB 2+	AFB 3+
No AFB Observed	2	0	0	0	0
AFB positive	0	2	2	2	2

10.3.3 Program EQAB 8150: Bacteria identification

Bacterial Identification Reporting is assigned a maximum score of 2 points per test sample. The scoring criteria are based on the accuracy and completeness of reporting both the Genus and Species of the bacteria, as well as any required reporting of Serogroup or Serotype, such as Vibrio cholerae serogroup O1 and/or serotype Ogawa. Additionally, the identification of antibiotic-resistant bacteria that must be reported, such as Carbapenem-resistant Enterobacterales (CRE), Vancomycin-resistant Enterococcus (VRE), and Methicillin-resistant Staphylococcus aureus (MRSA), will be taken into account. Scoring also considers the epidemiological significance of the bacteria, its relevance to infection control, treatment guidelines, and the importance of selecting appropriate antimicrobial susceptibility testing methods and interpreting the results. The points are awarded according to the following three scenarios, based on the provided guidelines:

Case No.	Assigned value	Report from Participant				Score
		Genus	Species	Antimicrobial resistant*	Serogroup/ Serotype **	
1	Genus Species	Correct	Correct	NA	NA	2
		Correct	Incorrect	NA	NA	1
		Incorrect	Incorrect	NA	NA	0
2	Genus Species and Antimicrobial resistant*	Correct	Correct	Correct	NA	2
		Correct	Correct	Incorrect	NA	1.5
		Correct	Incorrect	Correct	NA	1
		Correct	Incorrect	Incorrect	NA	0.5
		Incorrect	Incorrect	Incorrect	NA	0
3	Genus Species and Serogroup/ Serotype**	Correct	Correct	NA	Correct	2
		Correct	Correct	NA	Incorrect	1.5
		Correct	Incorrect	NA	Correct	1
		Correct	Incorrect	NA	Incorrect	0.5
		Incorrect	Incorrect	NA	Incorrect	0

** Significant antimicrobial resistance that must be reported, such as: Carbapenem-resistant Enterobacterales (CRE), Vancomycin-resistant Enterococcus (VRE) และ Methicillin-resistant Staphylococcus aureus (MRSA)*

*** Serogroups/Serotypes that must be reported due to epidemiological significance, such as Vibrio cholerae serogroup O1 or O139 and/or the detected serotype. Other cases can be reported as V. cholerae non O1/non O139.*

10.3.4 Program EQAB 8150: Antimicrobial susceptibility testing

Antimicrobial Susceptibility Testing Reporting is assigned a maximum score of 2 points per antimicrobial agent, based on the Assigned Value. The scoring criteria are as follows:

Assigned Value	Report from Participant			
	Susceptible (S)	Intermediate (I)	Susceptible–dose dependent (SDD)	Resistant (R)
Susceptible (S)	2	0	0	0
Intermediate (I)	0	2	0	0
Susceptible–dose dependent (SDD)	0	0	2	0
Resistant (R)	0	0	0	2

10.4 Standard Score Calculation

The evaluation criteria and score calculation formula are as follows:

10.4.1 P-score value

For all programs, the P-score is used as the standard score to indicate the performance of the laboratory (Lab performance). The calculation formula is as follows:

$$\text{P-score} = \frac{\text{maximum score for each program} - \text{score awarded to the laboratory.}}{\text{Standard error}}$$

10.4.2 Standard error value: The calculation method is as follows

Example: When the test sample has a maximum score of 2 points.

1) Calculation of the value.

A = (2 - Average score of the test sample)^2 x No. of members who received a score 2

B = (1.5 - Average score of the test sample)^2 x No. of members who received a score 1.5

C = (1 - Average score of the test sample)^2 x No. of members who received a score 1

D = (0.5 - Average score of the test sample)^2 x No. of members who received a score 0.5

E = (0 - Average score of the test sample)^2 x No. of members who received a score 0

2) Average score of the test sample is the mean score for each test sample across all participating members.

3) Calculation of the value F = (A+B+C+D+E)/No. of all participant

4) Add the F values of each test sample (a total of 2 samples) to obtain the G value.

5) $$\text{Standard error} = \sqrt{G} + 0.5$$

(0.5 is used as a Continuity Correction for data that is discontinuous.)

10.5 Evaluation Criteria

The quality acceptance criteria for analysis is set at the standard score.

P-score	Meaning
≤ 1.96	Acceptable
>1.96	Unacceptable

11. Evaluation Reporting

The results that will be reported to members include the following:

11.1 Preliminary result

The program will issue a Preliminary Test Report using the Assigned Value, which is consistent with the results of the homogeneity testing. This report is provided to allow participants to review the data and make any necessary adjustments or corrections if their reported results differ from the preliminary findings. The preliminary report will be published within approximately 1 week after the closing date on the website https://eqamt.mahidol.ac.th/ ⟶ schemes: EQAB BACTERIOLOGY ⟶ Notification ⟶ "Preliminary result for EQAB"

11.2 Individual report

An Individual Quality Evaluation Report will be issued to each participant within 3 weeks after the closing date. Participants will be notified via email once the report is available. Participants can log in to the system via the website https://eqamt.mahidol.ac.th/ to view their evaluation results and print a copy of the Individual Report.

11.3 Final report

The final quality evaluation report (Final Report) will be issued to participants within 7 weeks after the closing date. Participants will be notified via email once the report is available. Participants can log in to the system to review the evaluation results. They can also save and/or print a copy of the Final Report for their records.

12. Request for New Test Samples

12.1 Participants can request replacement test samples in the following cases:

- The participant did not receive the test samples within one week after the scheduled dispatch date, as notified via email.
- The participant received incomplete test samples and/or the samples were damaged, necessitating a request for replacement samples.

12.2 Participants must request replacement samples at least one week before the closing date by taking the following steps:

- Call the project coordinator at 061 174 7884.
- Send an email to eqab.mtmu@gmail.com with the subject "Damaged Package," providing the Participant ID, laboratory name, hospital name, and the damaged test sample code, along with photos of the damaged sample.

13. Request for Document Copies

If participants require a copy of the quality evaluation report from 2022 onward, they can print it directly from the online system by logging in with their unique Username and Password. For copies of reports prior to 2021, participants should complete a request form for document copies by contacting the Center for Standardization and Product Assessment, Faculty of Medical Technology,

Mahidol University, or submit the request via the website https://eqamt.mahidol.ac.th/ under the "Submit Request" menu.

14. Prevention of Dishonesty by participant

The program assigns an 8-digit Participant ID to each participants upon registration. System access for participants is based on this ID and the associated user account.

If any dishonesty in result reporting is detected, the program will immediately revoke the participants 's eligibility to receive a certificate. This policy

15. Certificate Issuance

The program provides an Electronic Certificate (E-Certificate) to participants who submit their results within the specified timeframe for at least two rounds. The certificate will include the name of the organization and laboratory as provided by the participants.