

# Quality Manual Concerning Antibacterial Proficiency Testing Program

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### 1. Objective

This quality manual concerning antibacterial proficiency testing program (hereinafter referred to as “quality manual”) is stipulated as the primary document for effectively operating the proficiency testing program in the antibacterial field provided by Society of International sustaining growth for Antimicrobial Articles (hereinafter referred to as “this society”).

### 2. Scope of Application

This manual is applicable to the proficiency testing program in the antibacterial field (other than fiber products) provided by this society.

### 3. Words and Terms

The words and terms defined in “JIS Q 17043” and “Policy Concerning IAJapan Proficiency Testing” are applied to major words and terms used in this manual.

### 4. Quality Policy

This society establishes a quality policy concerning the antibacterial proficiency testing program. The quality manager of this society shall disseminate the quality policy described below to the people involved in the antibacterial proficiency testing, including the members of the antibacterial proficiency testing implementing committee described in Term 6.2-(1). The chief of the secretariat of this society shall serve as the quality manager

- (1) To provide a high-quality service which satisfies the test laboratories participating in the proficiency testing
- (2) To observe related provisions, guidelines and this manual and provide a fair, harmonious, and transparent proficiency testing program for the purpose of ensuring the reliability of the testing evaluation results and expanding the use of the proficiency testing in the antibacterial field
- (3) To maintain and enhance the proficiency testing management and operation capacities appropriately, thereby improving its quality

### 5. Normative References

The standards, etc. cited in this manual are as follows:

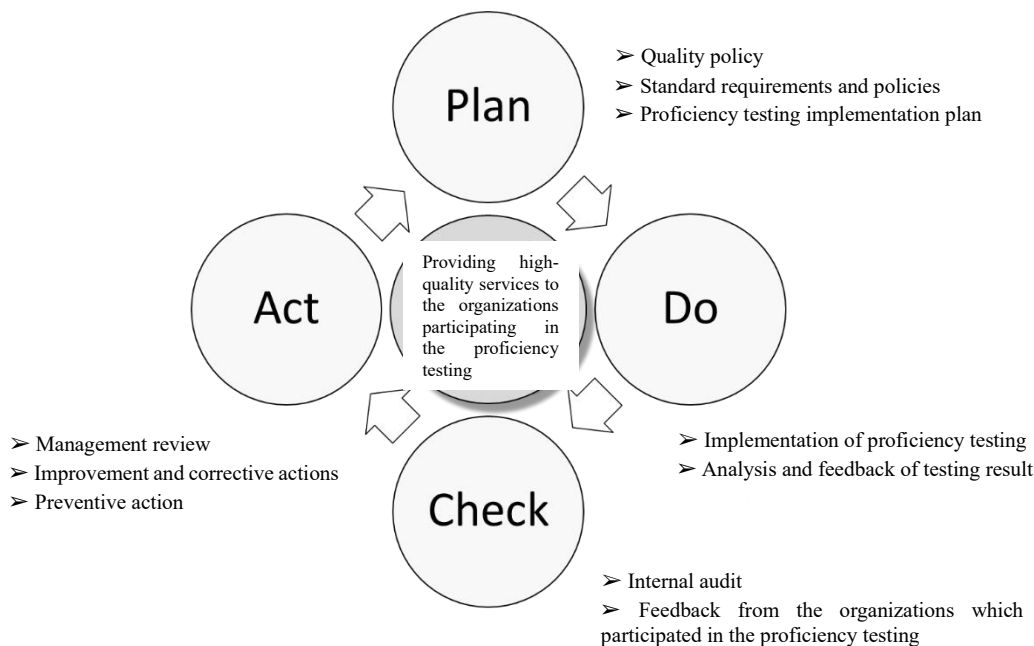
ISO/IEC 17043 (JIS Q 17043)

ISO/IEC 17025 (JIS Q 17025)

ISO 13528 (JIS Z 8405)

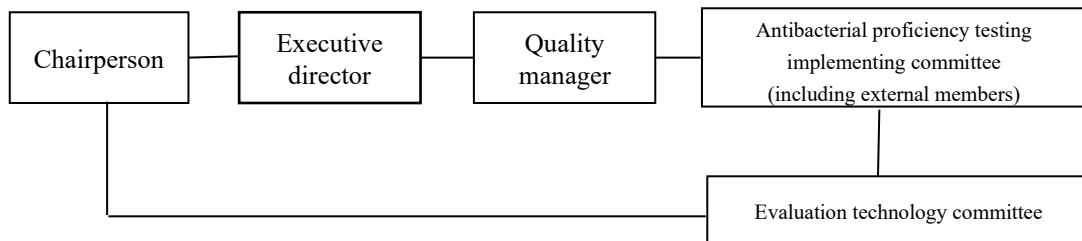
Policy Concerning IAJapan Proficiency Testing (IAJapan, National Institute of Technology and Evaluation)

### 6. Conceptual Diagram of Proficiency Testing Program



## 7. Organization for Operations Management

### 7.1 Organization Chart



### 7.2 Operation Undertaking System

- (1) As an organization for operating the antibacterial proficiency testing program, the antibacterial proficiency testing implementing committee including external members shall be established in this society. The person chiefly responsible for program development shall be the chairperson of this society, and the evaluation technology committee of this society shall provide technical support for developing the program.
- (2) The antibacterial proficiency testing implementation committee shall conduct preparations for the antibacterial proficiency testing such as planning, implementing the testing, analyzing and compiling the results, and preparing the testing report. This implementing committee shall avoid prioritizing a specific representative of the interest in order to preserve the fairness, considering the balance of interests. The details of the administrative affairs under the jurisdiction and operation of this committee are stipulated in Term 10.
- (3) The antibacterial proficiency testing implementing committee may consult with the evaluation technology committee about technical issues as needed. The evaluation technology committee shall study them and answer back with the results.

## 8. Fairness and Confidentiality

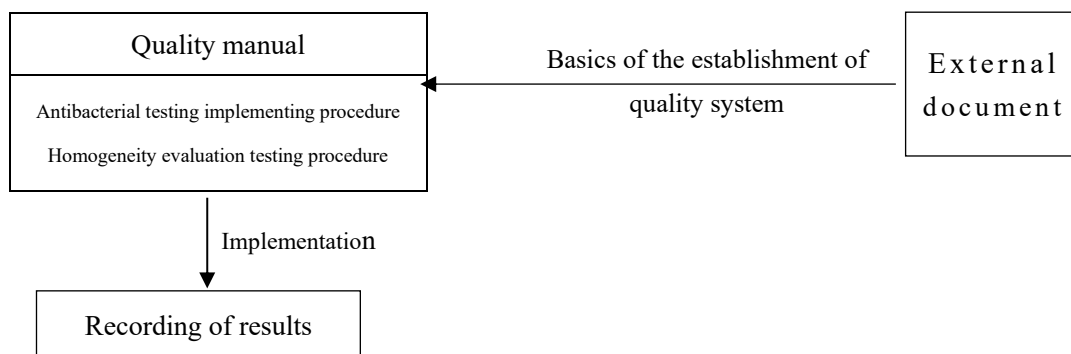
The following shall be observed to maintain the fairness and confidentiality in operating the antibacterial proficiency testing program:

- (1) When a corporation participates in the antibacterial proficiency testing program, unfair conditions which restrict use, such as restricting the size of the corporation and requiring them to be a member of a certain group shall not be made.
- (2) The antibacterial proficiency testing implementing committee shall be properly separated from other activity organizations in terms of both organizational management system and decision-making, in order to ensure that other committees and project activities in this society do not affect the confidentiality, objectiveness, and fairness of the proficiency testing. However, this does not preclude the employees of the member companies of this society from serving as both a member of the antibacterial proficiency testing implementing committee and a member of another committee.
- (3) No commercial, fiscal, and other pressures, which may affect the result of the antibacterial proficiency testing, shall be received. If coming under pressure occurs, it shall be rejected immediately and reported to the chairperson of this society, and the chairperson shall ensure to eliminate the pressure. The chairperson may entrust this operation to an appropriate board member of this society.
- (4) All confidential information on corporations, individual organizations and persons obtained in the operation of the antibacterial proficiency testing program shall be protected and not be disclosed outside of this society without written consent of the relevant party. However, a case where the disclosure of information is required by a law or the government is excluded.

## 9. Management System

### 9.1 General

This society shall establish the quality document architecture as shown below as the management system for operating the implementation of antibacterial proficiency testing program, so that all relevant personnel can utilize it.



### 9.2 Management System Documents

#### (1) Types of management system documents

As described in Term 9.1, the types of the management system documents are as follows:

- (i) Quality manual: Primary document among management system documents
- (ii) Proficiency testing implementation procedure: A document which describes the content of proficiency testing specifically and is distributed mainly to organizations participating in the proficiency testing.
- (iii) Homogeneity evaluation testing procedure: A document stipulating the testing procedure for examining the homogeneity of a sample
- (iv) Operation instruction document: A document which is prepared for temporary use and may be issued when giving the followings:
  - a) Instructions with regard to the matters which are not stipulated in the management system documents
  - b) A supplementary explanation for understanding the management system documents

#### (2) Approval of the management system documents

The management system documents shall be approved by the following approvers concerning their appropriateness before issuance or amendment:

- (i) Quality manual: Chairperson
- (ii) Antibacterial testing implementing procedure, homogeneity evaluation testing procedure, and operation instruction document: Executive director

## 9.2 Internal Audit

- (1) An internal audit shall be planned and implemented after proficiency testing in order to verify that the antibacterial proficiency testing program management system is properly implemented and maintained, as well as to have the opportunity for improvement.
- (2) The quality manager shall be responsible for planning and implementing an internal audit.
- (3) An internal auditor shall be a person qualified as internal auditor for ISO 9001 or ISO 14001 in the organization to which the person belongs and shall be appointed by the quality manager.

## 9.3 Management Review

A review on activities related to the proficiency testing program shall be conducted after implementing the proficiency testing, in order to ensure that the management system related to the antibacterial proficiency testing is continuously operated properly and effectively, as well as for necessary change or improvement. The management review may be implemented in the executives' meeting or board meeting, etc. held by this society. The following shall be considered in the review:

- (1) Policy and procedure
- (2) Result of proficiency testing
- (3) Result of the immediate internal audit
- (4) Corrective and preventive measures
- (5) Feedback from the participants in the proficiency testing
- (6) Proposal for improvement
- (7) Other matters which are deemed necessary by the quality manager

## 9.4 Operation Check

The quality manager shall check whether the operations related to the proficiency program are conducted according to the management system, and shall take improvement measures in accordance with Term 11 if there is any problem.

## 9.5 Record Management

Necessary records shall be stored and managed based on the "document control procedure of this society", in order to demonstrate the appropriateness and effectiveness of the operation of the antibacterial proficiency testing program as well as conformance with the requirements for the participants in the proficiency testing.

## 9.6 Release of Documents Related to the Recruitment of Participants in the Proficiency Testing

The documents explaining the outline of the antibacterial proficiency testing program shall be released in a manner which enables wide dissemination, such as a website, for recruitment of and dissemination to the participants in this program. If there is any change in their contents, they shall be updated immediately, including transitional measures, etc.

## 10. Operation of Antibacterial Proficiency Testing Program and its Process

### 10.1 Frequency of Implementing the Antibacterial Proficiency Testing Program

The antibacterial proficiency testing shall be implemented every two years, as a rule.

### 10.2 Corporations Participating in the Antibacterial Proficiency Testing Program

The corporations participating in the antibacterial proficiency testing program shall fall under any of the following:

- (1) JNLA-registered test laboratories in the antibacterial field (excluding fiber products)
- (2) Corporations which are in the process of application for JNLA registration or planning registration in the antibacterial field (excluding fiber products)
- (3) Corporations which have ever used a testing method adopted in proficiency testing in the antibacterial field (excluding fiber products), and wish to participate in the antibacterial proficiency testing program

### 10.3 Testing method adopted for use in the Antibacterial Proficiency Testing Program and Performance Evaluation of Participants

The testing method adopted for use in this program shall be JIS Z 2801, and the performance of participants shall be evaluated based on interlaboratory comparison. As a rule, the results shall be

evaluated using the “z score” stipulated in Appendix B of JIS Q 17043, and satisfaction/dissatisfaction with the result shall be determined using the index stipulated in the same appendix.

#### 10.4 Reporting of Results

The results of the antibacterial proficiency testing program shall be reported using “Proficiency Testing Report Related to the JNLA, Test Laboratory Registration System Based on the Industrial Standardization Act (Antibacterial Testing)”.

#### 10.5 Confidentiality of Results

The confidentiality of the participating corporations shall be preserved, excluding reporting to IAJapan, National Institute of Technology and Evaluation.

#### 10.6 Antibacterial Proficiency Testing Program Implementing Procedures and Organizations

As a rule, the processes of and the organizations implementing the antibacterial proficiency testing program stipulated by this society in order for effective and efficient implementation of this program shall be as follows:

Action items for proficiency testing program	Antibacterial proficiency testing implementing committee	Secretariat of antibacterial product engineering council	Remark
Planning of the proficiency testing program	○		
Preparation of the samples for the antibacterial proficiency testing		○	The secretariat places orders with manufacturers
Check of the homogeneity of the samples for the antibacterial proficiency testing		○	The secretariat places orders with test laboratories
Recruitment of test laboratories participating in the antibacterial proficiency testing		○	
Distribution of the samples for the antibacterial proficiency testing and antibacterial proficiency testing procedures, etc. to the test laboratories participating in the testing		○	
Collection of test results from the laboratories participated in the testing		○	
Compilation, statistical processing, and analysis of the testing results collected	○		
Preparation of antibacterial proficiency testing report		○	After the implementing committee checks the report, the secretariat arranges bookbinding.
Distribution of the antibacterial proficiency testing report to the laboratories participated in the testing and submission of the report to IAJapan of NITE		○	

The procedures for implementing the proficiency test and for evaluating the homogeneity of the samples for proficiency test (test item) are stipulated separately.

#### 11. Improvement

- (1) The effectiveness of the management system shall be improved continuously, through the analysis of the feedback information, etc. from the participants in the internal audit, management review, and antibacterial proficiency testing program.

- (2) Preventive measures for identifying non-compliant operations in the operation of the antibacterial proficiency testing program, correcting and preventing their recurrence, and eliminating the cause of potential non-compliant operations.
- (3) The quality manager shall determine the necessity of corrective and preventive measures, and implement them if they are deemed necessary.
- (4) The result of corrective and preventive measures shall be reflected in the management system documents.
- (5) The corrective and preventive measures shall be reported to the concerned parties, including the chairperson in the management review, and the appropriateness of the activities shall be ensured through the feedback.

## 12. Complaint Handling

- (1) Complaints from the National Institute of Technology and Evaluation as well as concerned parties shall be handled immediately and sincerely.
- (2) Handling of complaints shall be validated under the management of the quality manager, and corrective and recurrence prevention measures shall be taken if non-compliant operations are identified. Additionally, the result of handling the complaint shall be reported to the party who made the complaint.

	Revision history			
	Date of formulation and amendment	Reason for amendment	Prepared by	Approved by
01	November 30, 2006 SIAA antibacterial proficiency testing program document	Preparation associated with the initiation of the operation for cultivating the antibacterial proficiency testing program	Yoshiaki Fujimoto	Shuzo Tokumitsu
02	November 25, 2008 SIAA antibacterial proficiency testing program document	Amendment associated with the initiation of the operation for cultivating the antibacterial proficiency testing program for fiscal-2008	Yoshiaki Fujimoto	Tadashi Arishiro
03	September 22, 2011	Amendment associated with the initiation of the antibacterial proficiency testing program for fiscal-2011	Yoshiaki Fujimoto	Yoshifumi Moriya
04	December 3, 2013	Amendment associated with the initiation of the antibacterial proficiency testing for fiscal-2013	Yoshiaki Fujimoto	Yoshifumi Moriya
05	October 8, 2019	Review and amendment associated with the integration with the provision for the antibacterial proficiency testing program	Toshiyuki Nagata	Masataka Mizutani
06	December 4, 2019	Revision associated with the review of document approvers related to the antibacterial proficiency testing program	Toshiyuki Nagata	Masataka Mizutani