HGPI Health and Global Policy Institute

AMR Alliance Japan

Policy Recommendations:

Towards Strengthening Microbiological Diagnostics as a Foundation for AMR Control

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Health and Global Policy Institute
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Policy Recommendations:Towards Strengthening Microbiological Diagnostics as a Foundation for AMR Control

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Background

It is estimated that antimicrobial resistance (AMR) is the direct cause of approximately 1.27 million global deaths each year, and this figure rises to 4.95 million deaths when including those associated with AMR.[1] According to projections, failure to address this situation may result in the annual number of AMR deaths to increase to about 10 million people globally by 2050,[2] so measures to combat AMR are an increasingly high-priority global policy issue. In response to these circumstances, a political declaration adopted at the United Nations General Assembly High-Level Meeting in September 2024 set a target of a 10% reduction of AMR-related global deaths by 2030, compared with the 2019 estimate of 4.95 million global deaths as the baseline.[3] This intent was later reflected in the May 2026 update of the Global Action Plan on AMR (GAP-AMR). One key objective of the GAP-AMR is strengthening surveillance systems and laboratory networks for the further advancement of evidence-based AMR measures.

In accordance with Japan's National Action Plan on AMR (NAP), 2023–2027, formulated in April 2023, integrated initiatives are being advanced across six areas: (1) Public Awareness and Education, (2) Surveillance and Monitoring, (3) Infection Prevention and Control (IPC), (4) Antimicrobial Stewardship, (5) Research and Development, and (6) International Cooperation.[4] Routine microbiological testing conducted at healthcare institutions and other facilities is the foundation for initiatives in two priority areas, namely surveillance and monitoring and antimicrobial stewardship. In the area of surveillance and monitoring, Japan has established a surveillance system to monitor trends in the emergence of AMR bacteria by continuously gathering the results of microbiological tests conducted by healthcare institutions and other facilities. As for stewardship, identifying causative microorganisms and confirming drug susceptibility through microbiological testing accelerates the transition from empirical therapy to targeted therapy, thus ensuring that the types and duration of antimicrobial therapy is limited to the minimum necessary. Efforts aiming to improve healthcare quality through effective, rapid, and appropriate testing is referred to as diagnostic stewardship (DS). DS is a foundational element of antimicrobial stewardship and is crucial in furthering AMR control.

Additionally, the importance of strengthening microbiological testing systems during non-emergency periods has been acknowledged in Japan and around the world. During the response to the COVID-19 pandemic, it was reported that regions where testing systems were inadequate faced insufficient capacity and delayed implementation,[5] while regions that had developed testing systems in advance were able to expand testing early on.[6] The number of tests that a laboratory can perform during an emergency depends on the levels of staffing, equipment, and quality control that they maintain during non-emergency periods. Whether viral or bacterial, all pathogens require equipment for safe specimen handling, frameworks to ensure high-quality testing, and personnel capable of making clinical decisions based on test results. In other words, the microbiological testing systems that support AMR control during non-emergency periods contribute to infectious disease crisis preparedness. After the adoption of a resolution titled "Strengthening diagnostics capacity" by the Seventy-sixth World Health Assembly in May 2023, the international community has reached a shared recognition of the importance of widening access to testing and diagnosis during non-emergency periods in the contexts of infectious disease management and AMR control.[7] This importance has also been recognized in Japan, where the National Action Plan for Novel Influenza, etc.[8] and prefectural Infectious Disease Prevention Plans[9] explicitly state the need to secure testing capability during non-emergency periods and to be prepared for the rapid expansion of testing systems during emergencies.

In the midst of growing political interest, the 2026 revision of the medical service fee schedule introduced a new item called the "additional fee for microbiological testing systems." Previous reimbursements mostly focused on the evaluation of individual test items, and there were few instances of microbiological testing capability or testing systems themselves being evaluated on an individual basis. Given this context, the evaluation of microbiological testing capability within hospitals as a separate item is a groundbreaking development that represents major progress in the effort to strengthen domestic microbiological testing systems.[10] However, one characteristic of microbiological testing is that it targets living microorganisms. Achieving more effective domestic microbiological testing systems will require further refinements of how systems are designed to better align with clinical realities.

With the Government of Japan set to present an updated version of the NAP for 2028 and beyond, the nation has arrived at a critical juncture where ideal systems for microbiological testing must be outlined in concrete terms that reflect domestic conditions, and a desirable future direction must be set. To contribute to these efforts, HGPI conducted interviews with experts and developed four pillars and eight recommendations on strengthening microbiological testing systems to serve as the foundation for AMR control.

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2) O'Neill J. Tackling drug-resistant infections globally: final report and recommendations. London: Review on Antimicrobial Resistance; 2016 (Accessed May 21, 2026). https://amr-review.org/

3) United Nations General Assembly. Political declaration of the high-level meeting on antimicrobial resistance (A/79/L.5). New York: United Nations; 2024.

4) Ministerial Council on the Response to Infectious Diseases that Pose a Threat to Global Society. National Action Plan on Antimicrobial Resistance (AMR) 2023–2027. Cabinet Agency for Infectious Disease Crisis Management, Tokyo: Cabinet Agency for Infectious Disease Crisis Management; 2023.

5) Banatvala J. COVID-19 testing delays and pathology services in the UK. Lancet. 2020;395(10240):1831.

6) Kim IH, Kang BH, Seo SH, Park YE, Kim GJ, Lee SW, Jang JH, Jo SK, Jeon JH, Kim JM, Chung YS, et al. Early laboratory preparedness of the Korea Disease Control and Prevention Agency and response to unknown pneumonia outbreak from Wuhan, China, in January 2020. Ann Lab Med. 2021;41(6):532-9.

7) World Health Assembly. Strengthening diagnostics capacity: resolution WHA76.7. Geneva: World Health Organization; 2023.

8) Cabinet Secretariat. National Action Plan for Novel Influenza, etc. (Revised July 2024). Tokyo: Cabinet Secretariat; 2024.

9) Ministry of Health, Labour and Welfare (MHLW). The Act to Partially Amend the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases and Related Laws (Act No. 96 of 2022). Tokyo: MHLW; 2022.

10) Medical Economics Division, Health Insurance Bureau, MHLW. Overview of the FY2026 Medical Service Fee Revisions: Areas Requiring Priority Attention (Cancer, Intractable Diseases, and Infectious Disease Control). Tokyo: MHLW; 2026 (Accessed May 21, 2026). https://www.mhlw.go.jp/content/12400000/001681130.pdf

Pillar 01 Establishing a clear definition for "microbiological testing system" and designing a framework for evaluating current practices

Recommendation 1-1 Assign a clear definition to "microbiological testing system"

Based on lessons learned during the COVID-19 pandemic, revisions of the medical service fee schedule have been expanding measures for infectious diseases since 2022. Among those revisions, the 2026 revision focused on microbiological testing systems with the introduction of the "additional fee for microbiological testing systems," which allocates 30 points to healthcare institutions that maintain in-house microbiological laboratories and are eligible for the Level 1 Enhanced Infection Control Measures Fee. This marked the first time the importance of in-house microbiological testing was recognized through a dedicated item in the medical service fee schedule. This additional fee is limited to 30 points billable on the first day of hospitalization, so it does not fully cover the costs of maintaining in-house testing systems. Nevertheless, the fact that microbiological testing itself has been included in the schedule is a major milestone. Studies suggest that healthcare institutions with on-site microbiology laboratories have lower proportions of AMR bacteria,[11] so expanding on-site testing systems can be viewed as a significant step for AMR control.

However, institutional requirements for what constitutes a "microbiological testing system" are not clearly defined in the medical service fee schedule or other frameworks. An examination of the facility criteria for the additional fee for microbiological testing systems shows that eligible facilities must have in-house microbiology laboratories that are utilized for various tasks related to antimicrobial stewardship teams (ASTs), such as monitoring on-site antimicrobial stewardship practices or participating in nosocomial infection surveillance.[12] However, there are no specifications regarding staffing levels, required equipment, or the range of tests these laboratories must be capable of performing. Therefore, even if eligibility criteria require facilities to have a microbiological testing system, it remains unclear what standards healthcare institutions must meet to be considered compliant. The same applies to staffing requirements. The additional fee for microbiological testing systems is provided under the Level 1 Enhanced Infection Control Measures Fee. The facility criteria for the latter require infection control teams to include a full-time medical technologist with three or more years of hospital experience, and that the AST include a full-time medical technologist with three or more years of hospital experience and who is involved in microbiological testing.[13] In both cases, the extent to which the laboratory must be engaged in microbiological testing and the scope of tests for which it is responsible remain unspecified. While the law does not restrict who can perform microbiological testing to individuals with specific qualifications, many situations require the judgment of a skilled medical technologist, like when detecting and interpreting AMR bacteria. In terms of hospital IPC, it is also necessary for medical technologists who are well-versed in microbiological testing to be proactively involved in infection control teams and ASTs.

Additionally, until now, there have been no specific standards for healthcare institutions to adhere to when performing in-house specimen or microbiological testing. This is because under the Medical Care Act, in-house specimen testing at a healthcare institution is considered to be part of medical care provided by that institution, with the assumption that testing is performed with physician supervision.[14] The enactment of the December 2018 Medical Care Act revision established criteria for ensuring accuracy and introduced new requirements for appointing a person in charge and developing standard operation manuals. However, the 2018 revision does not specify necessary staffing levels or equipment standards for microbiological testing. Even after revision, the Medical Care Act provides flexible operational requirements for testing to accommodate various sizes and roles of healthcare institutions and prevent placing excessive burdens on smaller institutions.

To enable the creation of more effective microbiological testing systems, best practices for their establishment should be provided in more concrete terms through the medical service fee schedule's facility standards. The intended purpose of the criteria in the Medical Care Act is to ensure that specimen testing at healthcare institutions meets minimum safety and accuracy standards. In contrast, facility standards in the medical service fee schedule outline specific recommendations that exceed baseline requirements, and healthcare institutions are encouraged to meet those recommendations to be eligible for fees. Furthermore, because the criteria

for fees apply only to healthcare institutions that bill them, it is likely that Medical Care Act criteria aiming to keep testing operational requirements flexible can comfortably coexist with specific requirements in the medical service fee schedule.

Personnel, equipment, and quality control are three areas where more specific requirements are necessary. The personnel requirement should involve assigning full-time technical specialists for microbiological testing based on factors such as the number of hospital beds. Rather than requiring facilities to obtain specific devices, the equipment requirement should mandate that facilities be equipped to perform the culture, identification, and antimicrobial susceptibility testing necessary for the functions of those facilities and the scope of care they provide, within clinically acceptable turnaround times (TATs). Since necessary equipment changes as technology advances, providing requirements that are based on functions rather than on particular devices will make testing systems more sustainable. Quality control requirements should include regular participation in external quality control programs.

Among these three areas, it may be possible to address personnel requirements with existing certification systems. As part of efforts to cultivate personnel capable of contributing to both microbiological testing and IPC, related academic societies and professional organizations have established Certified Medical Technologist in Clinical Microbiology (CMTCM) and Infection Control Microbiological Technologist (ICMT) certification programs. These two programs are administered by a council comprising seven organizations, including the Japanese Society for Clinical Microbiology, the Japanese Association for Infectious Diseases, and the Japanese Association of Medical Technologists. As of April 1, 2026, there were 1,080 CMTCMs and 887 ICMTs.[15] Since these credentials are issued by professional associations, careful consideration is required before incorporating them as reimbursement criteria in the medical fee schedule. The fact remains that the use of existing certification systems provides one option for setting microbiological testing personnel requirements and for the timely development of vital testing infrastructure.

It must be noted that the Act on Clinical Laboratory Technicians and its enforcement regulations provide clear legal standards regarding facilities, personnel, equipment, and management for clinical laboratories that conduct microbiological testing on behalf of healthcare institutions. This difference is due to the fact that as registered, independent, private organizations that specialize in testing, clinical laboratories must guarantee high-quality testing in environments without full-time physicians. Additionally, in recent years, mass spectrometry for species identification has become routine at regional core hospitals, while multiplex genetic testing is now used to target different diseases and symptoms across multiple panels. Standards for microbiological testing systems for both clinical laboratories and in-house laboratories at healthcare institutions should be updated as necessary to keep pace with these technological advancements.

Clarifying a definition for “microbiological testing system” in the manner described above will make it possible to elevate testing quality from the stage where simply having microbiology laboratories is considered sufficient, to the stage where microbiological testing systems can rapidly return accurate test results under a standardized framework and can be maintained and strengthened. At present, almost all core hospitals bill the Level 1 Enhanced Infection Control Measures Fee, and systems for preventing nosocomial infections have achieved a baseline standard nationwide. In addition to ensuring that core hospitals can maintain substantive testing systems, the overall quality of infectious disease response should be raised across a broader range of healthcare institutions.



11) General Assembly of the Central Social Insurance Medical Council (628th Session). Specific Issues (Item 8): Pediatric and Perinatal Care, Infectious Disease Control, Medical Safety, and Disaster Medicine (Doc #2). Tokyo: MHLW; 2025 (Accessed September 9, 2026), p. 92. https://www.mhlw.go.jp/content/10808000/001596968.pdf

12) Medical Economics Division, Health Insurance Bureau, MHLW. Overview of the FY2026 Medical Service Fee Revisions: Areas Requiring Priority Attention (Cancer, Intractable Diseases, and Infectious Disease Control). Tokyo: MHLW; 2026 (Accessed September 9, 2026), p. 14. https://www.mhlw.go.jp/content/12400000/001681130.pdf

13) Director, Medical Economics Division, Health Insurance Bureau, MHLW. Regarding the Handling of Procedures for Facility Standards for Basic Medical Care Fees and Related Filings (Health Insurance Bureau Notice No. 7, March 5, 2026). Tokyo: MHLW; 2026

14) Director, Health Policy Bureau, MHLW. Regarding Enforcement of Ministerial Ordinances Concerning the Revision of MHLW Ordinances Concerning the Partial Enforcement of the Act to Partially Amend the Medical Care Act, etc. (Health Policy Bureau Notice No. 1, August 10, 2018). Tokyo: MHLW; 2018

15) The Japanese Society for Clinical Microbiology. Recommendations on the Role of Clinical Microbiology Laboratories in ICT and AST Activities: The Importance of Certified Medical Technologist in Clinical Microbiology (CMTCMs) and Infection Control Microbiological Technologist (ICMTs). Tokyo: The Japanese Society for Clinical Microbiology; 2018 (Accessed September 9, 2026). https://www.jscm.org/uploads/files/guideline/227.pdf
CMTCM and ICMT figures are based on data published by the Council for the Certified Medical Technologists in Clinical Microbiology System and the Council for the Infection Control Microbiological Technologist System. (Accessed September 9, 2026). https://cmtcm-icmt.org/

Recommendation 1-2

Expand the Survey of Medical Institutions and develop a public statistical framework for examining current conditions for microbiological testing systems

Japan requires a public statistical framework that will provide the capacity to quantitatively assess current conditions for microbiological testing systems at healthcare institutions nationwide. Currently, one of the government's primary statistical surveys is the Survey of Medical Institutions, the purpose of which is to "Clarify the distribution and current conditions of medical institutions (hospitals and clinics), assess their clinical functions, and obtain basic data for healthcare administration." Despite the fact that numerous studies have already demonstrated that microbiological testing plays a crucial role in maintaining and strengthening infectious disease management capacity, the survey does not include items to determine whether facilities have on-site microbiology laboratories. In addition to incorporating questions to determine the presence of microbiology laboratories, the Survey of Medical Institutions should be redesigned to align with its original purpose by including questions that substantively assess the state of microbiology testing infrastructure. Questions should include those that examine testing equipment, items outsourced to external parties, and participation in external quality control and surveillance programs.

Regarding healthcare institutions that outsource microbiological testing, it is particularly important for the percentage and specific types of tests being outsourced to be continuously monitored. In addition to conducting surveys, mechanisms to collect and analyze detailed data on outsourced testing should be established in collaboration with clinical laboratories, which are the private reference facilities to which testing is outsourced. By gathering information that cannot be captured through in-house monitoring alone, these efforts will enable a more comprehensive understanding of current testing access. Data on outsourced testing has the potential to become essential data for assessing diagnostic capacity and vulnerabilities in each region as well as for verifying the effects of medical service fee schedule revisions on testing systems and outsourcing arrangements.

Data on microbiological testing systems obtained in this manner will also be useful for ensuring that administrative plans formulated by the national government and local governments are effective. Medical Care Plans, Infectious Disease Prevention Plans, and similar plans mention efforts to strengthen testing capabilities, in both emergency and non-emergency periods, together with healthcare institutions that have concluded such agreements. However, these plans do not include the specific criteria needed to fully assess actual testing systems. There is room to strengthen the foundation for evaluating progress and conducting regional comparisons on these plans. To ensure they can be effective, it will first be necessary to obtain a quantitative grasp of the distribution of regional diagnostic capacity as well as vulnerabilities. Establishing basic information, such as how many facilities are capable of culture testing and identification and where they are located in the region, will enable the rapid planning of initial government responses and effective coordination with private healthcare institutions and clinical laboratories during emerging infectious disease outbreaks.

It is important to note that some information on microbiological testing is gradually being accumulated through existing domestic surveillance systems. For example, the Clinical Laboratory Division of Japan Nosocomial Infections Surveillance (JANIS) gathers microbiological test results on an ongoing basis.[16] JANIS serves as the foundation for monitoring trends in domestic outbreaks of AMR bacteria, and participating facilities are required to possess quality control systems for bacterial testing data.[17] In addition, the Japan Surveillance for Infection Prevention and Healthcare Epidemiology (J-SIPHE) and its clinic counterpart, the Online Monitoring System for Antimicrobial Stewardship at Clinics (OASCIS), aggregate data on infectious disease clinical care, including antimicrobial usage, test counts, and bacterial species. These systems also include organizational details regarding infection control teams, ASTs, and microbiology laboratories.[18]

However, for all of these surveillance systems, participation is voluntary. Furthermore, JANIS only gathers test results data, so JANIS cannot be used to determine what personnel and equipment were used to obtain them. The primary objectives of J-SIPHE and OASCIS are to assess the implementation status of AMR measures and to improve those measures through feedback. These systems are not adequate to serve as the foundation of cross-cutting policy evaluations of testing systems themselves. To capture a complete picture of domestic testing across diverse healthcare institutions, it will be necessary to expand official statistics, centered on the Survey of Medical Institutions.

16) Japan Nosocomial Infections Surveillance (JANIS). List of Participating Hospitals (as of January 2026). Tokyo: MHLW. (Accessed September 9, 2026). https://janis.mhlw.go.jp/hospitallist/index.html

17) JANIS. Clinical Laboratory Division Outline. Tokyo: MHLW. (Accessed September 9, 2026). https://janis.mhlw.go.jp/section/outline/outline_kensa_ver3.0_20210413.pdf

18) AMR Clinical Reference Center. Manual for Participating Institutions in J-SIPHE, September 2026 edition (ver. 8.1.0.) Tokyo: Japan Institute for Health Security, National Center for Global Health and Medicine; 2026 (Accessed October 9, 2026), p. 11. https://j-siphe.jihs.go.jp/files/J-SIPHE参加施設マニュアル.pdf

Pillar 02 Ensuring diagnostic stewardship and reviewing reimbursements to accurately reflect the role of microbiological testing

Recommendation 2-1

After standardizing microbiological testing procedures under the leadership of academic societies and similar organizations, mechanisms for evaluating quality, turnaround times (TATs), and other aspects of testing should be incorporated into the medical service fee schedule

Microbiological testing is an essential component of AMR control and infectious disease management, but many healthcare institutions have traditionally viewed it as an unprofitable area. This perception is based on the fact that the current reimbursement model for laboratory testing does not adequately reflect the costs of personnel and equipment needed to maintain high-quality in-house microbiological testing systems.

In the medical service fee schedule, reimbursements for laboratory testing consist of laboratory test fees (which provide compensation for conducting tests) and laboratory test interpretation fees (which provide compensation for the interpretation of test results for clinical use). When laboratory testing fees are set, both findings from market price surveys (which track the actual prices charged by clinical laboratories) and requests from related organizations are taken into account. Clinical laboratories that aggregate specimens from many healthcare institutions can distribute fixed costs like personnel and equipment across high test volumes, keeping the unit cost per test relatively low. Conversely, microbiology laboratories at healthcare institutions must maintain a certain standard of operations entirely within their own facilities. In addition to covering personnel expenses for dedicated technicians and the costs of equipment maintenance and replacement, they must also remain on-call during nights and holidays to maintain facility preparedness for urgent infectious diseases and other emergencies. They must also maintain systems to ensure the rapid, accurate detection of AMR bacteria to inform clinical decisions regarding both treatment and on-site IPC. Meeting all these requirements means microbiology laboratories at healthcare institutions incur the same financial burden regardless of the number of tests performed.

Despite this financial burden, because laboratory testing fees are primarily determined using market rates at clinical laboratories, they remain inadequate as funding sources for the maintenance and reinforcement of in-house testing systems at healthcare institutions. This discrepancy has widened further due to recent price and labor cost increases.

In addition to differences in how operating costs are structured, there are also differences in utility in real-world clinical settings. In infectious disease management, the timely reporting of results from in-house testing can accelerate the transition from empirical to targeted therapy. Outsourced testing often requires several days for results, including the time for specimen transport, complicating efforts to make full use of results when setting a treatment plan in the acute phase of an infectious disease. Despite this clear difference in clinical utility, laboratory testing fees are reimbursed on a per-test basis, with the same amount of points assigned to both in-house and outsourced testing. In other words, the current reimbursement is awarded in a manner that provides little incentive for healthcare institutions to maintain and strengthen in-house testing systems.

To address this issue and create an environment that makes it easier for healthcare institutions to conduct in-house microbiological testing, a system should be introduced that not only evaluates whether a test was performed, but also evaluates the quality of the testing process quality and as well as how quickly results are reported. Specifically, in addition to the existing infection control prevention fee and the recently-introduced additional fee for microbiological testing systems, one option may be to introduce a new framework for fees that are subject to specific turnaround time (TAT) standards.

In the past, there have been calls for the inclusion of items assessing the timeliness of reporting in the medical service fee schedule, but this has yet to occur.[19)20)] This is partly because a clear academic consensus on appropriate TATs has yet to be established. While efforts led by academic societies and medical technologist associations aiming to standardize microbiological testing

procedures continue to progress, steps should be taken to build consensus on TATs by first standardizing testing processes. This should include defining standard times required for each step in testing and clearly identifying which steps must not be omitted. After doing so, efforts must be made to reach a consensus on standard TATs for each test type and on clinically acceptable TATs while systematically collecting and analyzing real-world data from clinical settings.

It must be noted that the definition of TAT changes depending on how start and end points are defined. Several items can be designated as start or end points, including specimen receipt, positive culture confirmation, species identification, interim reporting of drug susceptibility, and final reporting. Depending on which points are chosen, TAT values can vary significantly, even for the same test. This means that when using TATs to assess reporting speed for reimbursements , it will be important to clearly define TAT start and end points for each test type.

Care must also be taken to ensure that rapid reporting does not become a goal in and of itself. Rapid reporting is valuable only when it informs clinical decisions, such as when to transition from empirical to targeted therapy, to change to a more suitable antimicrobial, or to discontinue antimicrobial therapy when unnecessary. Mechanisms that make it possible to capture the extent to which shorter TATs actually contribute to antimicrobial stewardship should also be incorporated when designing this system.

Of course, simply introducing additional fees for in-house testing or TAT targets will not change the structure of market price surveys, which serve as the basis for laboratory testing fees. In the medium to long term, other extremely important actions for ensuring testing system sustainability will be distinguishing how costs are incurred for in-house testing facilities and clinical laboratories and reviewing how market price surveys for testing technologies are designed to reflect actual market prices according to the respective roles of those facilities.



19) Japanese Association of Medical Technologists (JAMT). Request Regarding Points Assigned to Clinical Laboratory Testing in the FY2026 Medical Service Fee Schedule Revision. Tokyo: JAMT; 2025 (Accessed May 21, 2026). https://www.jamt.or.jp/data/asset/docs/86aa02ce6ce3d9c49202839977048e2859a1e4ba.pdf

20) Expert Committee on Insured Medical Materials, Central Social Insurance Medical Council. Opinion Statement (JACRI/AMDD/EBC). Tokyo: MHLW; 2025 (Accessed May 21, 2026). https://www.mhlw.go.jp/content/10808000/001548661.pdf

Recommendation 2-2

Develop reimbursement mechanisms that accurately reflect the value of new testing technologies for infectious disease management

Technologies that support the diagnosis of infectious diseases have greatly diversified beyond conventional culture tests. In addition to Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS), which has already been introduced at many healthcare institutions, a number of new technologies are also beginning to take root, such as multiplex genetic testing, AI-enabled diagnostic support, and point-of-care testing (POCT). Among screening tests for preventing the spread of AMR bacteria within facilities, there has been progress in automation, improvements in efficiency, and more widespread use of rapid, highly sensitive tests. While conventional culture testing requires at least several days to obtain results for microbial isolation, identification, and antimicrobial susceptibility, utilizing the latest technologies makes it possible to rapidly and accurately detect pathogenic microorganisms and genes associated with resistance. In some cases, these technologies enable the same-day initiation of optimal therapies guided by test results.

These new testing technologies are gaining recognition for their utility, both academically and in terms of policy. The Japanese Association for Infectious Diseases revised its "Recommendations on Antimicrobial Stewardship for Respiratory Tract Infections" to specifically include the use of genetic testing.[21] In addition, culture-free testing technologies have been recognized as a priority R&D area for medical countermeasures (MCMs).[22]

However, fees for these new testing technologies outlined in the medical service fee schedule do not reflect actual costs for healthcare institutions. Reimbursements have not kept pace with the costs of reagents and testing devices, labor costs for medical technologists, or the costs of maintaining and upgrading equipment. As a result, healthcare institutions struggle to achieve profitability, even for clinically useful tests. In practice, the actual use of these tests remains limited to a small number of severe cases. Even tests that would ideally be widely utilized as new core technologies in infectious disease management face slow adoption. For hospitals under the Diagnosis Procedure Combination (DPC) system in particular, spending more on tests does not increase revenue because the costs of tests performed during hospitalization are included in the fixed daily reimbursement. In such cases, DPC hospitals must cover the difference. As a result, DPC hospitals tend to opt for less expensive tests, even if they yield slower results, and hesitate to conduct tests that are faster but more expensive.

In light of these circumstances, when evaluating new testing technologies, rather than simply applying the conventional framework in which fees are billed using test performance and interpretation fees, a framework with the capacity to evaluate the unique value of each technology must be developed. For example, these evaluation criteria could consider features not offered by conventional culture tests, such as multiplex pathogen detection or the ability to detect resistance genes without culture delays.

However, for multiplex genetic testing in particular, a system with integrated mechanisms ensuring DS must be established. Although multiplex genetic testing allows for the simultaneous screening of numerous pathogens and resistance genes, it carries the risk of overinterpreting detected pathogens as the causative pathogens. Therefore, it should only be used when clinically necessary. Academic societies have also compiled guidelines for conducting these tests for pediatric acute respiratory infections.[23] On the other hand, tests should not be withheld from patients who need them. Therefore, rather than assigning points based solely on the number of items a test can detect, a system that incentivizes the right tests for the right reasons should be considered. When doing so, incorporating criteria for facilities—such as those for AST capacity development, the involvement of clinical laboratory physicians and infectious disease specialists, and the formulation of in-house usage guidelines—is likely to help achieve both DS and the widespread adoption of multiplex genetic testing. When evaluating multiplex genetic testing, it will be necessary to establish evaluation criteria for assessing test suitability rather than testing volume alone.

21) The Japanese Association for Infectious Diseases. Recommendations on Antimicrobial Stewardship for Respiratory Tract Infections. Tokyo: Japanese Society for Infectious Diseases. (Accessed May 21, 2026). https://www.kansensho.or.jp/modules/guidelines/index.php?content_id=50

22) Study on Ensuring the Availability of Medical Countermeasures (MCM) (Report), MHLW. (Accessed May 21, 2026). https://www.cas.go.jp/jp/seisakukaigi/kenkouiryou/kansenshou/dai4/shiryou1-2.pdf

23) Joint Working Group on the Development of Multiplex Genetic Testing Guidelines (Japanese Society for Pediatric Infectious Diseases; Society of Ambulatory and General Pediatrics of Japan; Japan Pediatric Association). Guidelines for Multiplex Genetic Testing for Acute Respiratory Infections in Pediatric Outpatient Settings (First Edition). 2026. (Accessed September 9, 2026). https://www.jspid.jp/wp-content/uploads/2026/07/PCR_20260619.pdf

Recommendation 2-3

Consider mechanisms that ensure medical service fee schedule evaluations encourage testing system development

To maintain and strengthen microbiological testing, rather than simply introducing additional fees or expanding existing ones, reimbursements should guide revenue back to infectious disease management and microbiological testing. However, the purpose of additional fees is to evaluate compliance with facility standards, so the medical service fee schedule does not specify the allocation of the revenue they provide. Healthcare institutions incorporate this revenue into their overall budgets, and budget allocation is left up to the discretion of each institution. Even if additional fees that encourage in-house microbiological testing or mechanisms that evaluate innovative technologies are introduced to the medical service fee schedule, there is no guarantee they will directly lead to increased staffing or investments in laboratories. In other words, such fees are unlikely to create a virtuous cycle.

For DPC hospitals, it is especially difficult to grasp the relationship between testing systems and revenue. Under the DPC system (for inclusive payments), tests related to hospitalization are covered by a fixed-rate reimbursement according to diagnosis group. While test fees accumulate with each individual test performed, the resulting revenue is difficult to track as a standalone item. Even for fees that require facilities to have a microbiological testing system (such as the Enhanced Infection Control Measures Fee and the additional laboratory testing management fee), it is often unclear in DPC hospitals how much revenue is actually attributable to microbiological testing. This is because for DPC hospitals, fees for microbiological testing are incorporated into Functional Evaluation Coefficient I, which is added to the hospital-specific coefficient in accordance with facility reporting standards. In reality, at healthcare institutions, these fees are reflected in reimbursements for all inpatients. In other words, establishing in-house microbiological testing systems plays a crucial role in generating revenue both for the department itself and for the healthcare institution as a whole.

Given these circumstances, the national government must set its sights beyond simply assigning points when considering new items to include in the medical service fee schedule. Rather, it will be necessary to consider how reimbursement revenue will contribute to maintaining and strengthening testing systems. Simultaneously, healthcare institutions must consider how to allocate the revenue generated by said fees to place personnel in laboratories and invest in testing facilities, which will require determining the best internal distribution of resources and reinvestments in individual departments.

Column 01

Systems Driving Stewardship for New Antimicrobials

"Antimicrobial stewardship" refers to avoiding the unnecessary use of antimicrobials while ensuring that patients who need them receive appropriate drugs for only as long as necessary. Effective stewardship requires the selection of appropriate therapies after identifying causative microorganisms and confirming antimicrobial susceptibility through microbiological testing.

When using new antimicrobials, additional measures must be taken during microbiological testing. Antimicrobial susceptibility testing is typically performed in a single run using pre-configured plates containing multiple antimicrobials. Because standard testing plates widely used in Japan rarely include new antimicrobials, separate tests must be performed. In the past, healthcare institutions were responsible for covering the full cost of additional testing. This sometimes caused reluctance to run additional tests, even when clinically necessary.

Fortunately, this situation has been improving in recent years. After the 2026 revision of the medical service fee schedule, reimbursement is now available for antimicrobial susceptibility testing when medications with strict stewardship requirements are administered.[24)]

Pillar 2 of these recommendations examined how the medical service fee schedule does not adequately reflect the role and clinical value of microbiological testing and outlined the resulting challenges that healthcare institutions face when performing necessary tests or maintaining testing systems. Antimicrobials also face challenges that medical necessity alone cannot address. To ensure that appropriate antimicrobial therapies reach the patients who need them, the focus on microbiological testing systems must be expanded to encompass mechanisms supporting antimicrobial evaluation, R&D, and stable supply.

Among these are challenges that healthcare institutions encounter under the medical service fee schedule system. For example, under the DPC system, pharmaceutical costs incurred during hospitalization are bundled into a fixed daily reimbursement, and healthcare institutions must cover any shortfall when costs exceed the fixed rate. One mechanism for addressing this financial burden is an exception granted to DPC hospitals called the High-Cost Drug Classification. When pharmaceuticals that are newly-listed or have expanded indications exceed a specific drug cost threshold, their administration is excluded from bundled reimbursement for the corresponding DPC code until sufficient usage data is gathered. Treatment provided during hospitalization in such cases is billed on a fee-for-service basis. Under fee-for-service billing, reimbursements are calculated for each medical procedure performed, covering drug costs as well as hospitalization and examination fees.[25)]

Some new antimicrobials are eligible for High-Cost Drug Classification. During the eligible period, inpatient care for patients treated with these antimicrobials is reimbursed on a fee-for-service basis. This helps prevent healthcare institutions from incurring any financial burden that may occur when drug costs of expensive new antimicrobials exceed the fixed reimbursement.

However, in principle, this exception is only granted as a temporary measure until the next medical service fee schedule revision. During the revision, a decision is made on whether to transition the treatment to bundled reimbursement or continue fee-for-service billing based on utilization data and other such information collected up to that point.[26)] Under the former scenario, there are two methods used to bundle the reimbursement: establishing new DPC codes for cases involving specific drugs and assigning reimbursement points; or incorporating drug costs into points for existing DPC codes. Although some new antimicrobials continue to be billed on a fee-for-service basis following the 2026 revision,[27)] they may transition to bundled reimbursement in the next revision.

To begin with, there is only a limited number of use cases for new antimicrobials and other pharmaceuticals that require robust stewardship. Consequently, when transitioning to bundled reimbursements, incorporating these drugs in points assigned to existing DPC codes means that points are also assigned to cases in which they are not used. This may prevent these codes from fully reflecting drug costs in cases where expensive new antimicrobials are actually used. Some have voiced concern that certain evaluation methods may discourage the use of necessary antimicrobials for financial reasons. To ensure the appropriate use of necessary antimicrobials,

it will be important to further clarify the criteria for transitioning to bundled reimbursements and to examine how to best structure DPC codes and reimbursements so healthcare institutions can continue the use of such drugs even after the transition without incurring financial burden.

It should be noted that challenges surrounding bundled reimbursements and fee-for-service billing faced by healthcare institutions are not limited to antimicrobials, but also affect other pharmaceuticals. In addition to evaluating microbiological testing in the medical service fee schedule, consideration must also be given to ensuring systems appropriately reflect medical necessity in terms of cost.

In addition to mechanisms within healthcare institutions, the structure of the pharmaceutical market also presents challenges in supporting R&D and ensuring the stable supply of antimicrobials. As a general rule, corporate profits increase in proportion to the volume of pharmaceuticals sold, meaning advancing stewardship efforts may decrease sales volumes and constrain corporate profitability. However, because the risk of AMR increases alongside usage volumes, reducing unnecessary use is vital. Specifically, the use of new antimicrobials targeting infections resistant to existing drugs are limited to cases where no other effective options are available. Nonetheless, to ensure these antimicrobials are available to the patients who need them, when they need them, a steady supply must be maintained regardless of usage volume. These factors make it difficult to secure the funding necessary for antimicrobial R&D and stable supplies when relying solely on market mechanisms that generate revenue through sales volume.

To address this issue, the government launched the Antimicrobial Securement Support Program in FY2023. Under this program, companies that comply with national AMR control measures and lose revenue as a result of limiting sales to appropriate volumes receive a fixed amount of revenue support from the government.[28] The program began covering cefiderocol[29] and ceftazidime/avibactam[30] in FY2024, and its scope is gradually expanding. Although there is room for further improvement, progress is being made toward establishing a system in which antimicrobial R&D and supply do not rely solely on market mechanisms, and in which corporate revenues are less dependent on sales volume.

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24) Medical Economics Division, Health Insurance Bureau, MHLW. Overview of the FY2026 Medical Service Fee Revisions: Areas Requiring Priority Attention (Cancer, Intractable Diseases, and Infectious Disease Control). Tokyo: MHLW; 2026:13. (Accessed September 9, 2026). https://www.mhlw.go.jp/content/12400000/001681130.pdf

25) Medical Economics Division, Health Insurance Bureau, MHLW. FY2026 Medical Service Fee Revisions: 5. Inpatient Care (DPC/PDPS). Tokyo: MHLW; 2026:15. (Accessed October 2, 2026). https://www.mhlw.go.jp/content/12400000/001696832.pdf

26) General Assembly of the Central Social Insurance Medical Council (628th Session). Measures Regarding New High-Cost Pharmaceuticals, etc., in the DPC System (Doc #4). Tokyo: MHLW; 2026. (Accessed October 2, 2026). https://www.mhlw.go.jp/content/10808000/001533230.pdf

27) Persons Designated by the Minister of Health, Labour and Welfare Pursuant to the Provisions of Paragraph 1, Item 5 of the Calculation Methods for Expenses for Medical Care in Hospital Wards Designated by the Minister of Health, Labour and Welfare (MHLW Notification No. 140 of 2012), Appendix 1 (as amended by MHLW Notification No. 219 of 2026). (Accessed October 2, 2026). https://www.mhlw.go.jp/web/t_doc?dataId=84ab2692&dataType=0&pageNo=1

28) Division of Disease Prevention and Control, Public Health Bureau, MHLW. FY2026 Antimicrobial Securement Support Program: Overview of Public Solicitation and Review Procedures (Reference materials, Second Meeting of the Study Group on Antimicrobial Market Incentives, FY2025). Tokyo: MHLW; 2026. (Accessed October 2, 2026). https://www.mhlw.go.jp/content/10906000/001684231.pdf

29) Department of Disease Prevention and Control, Division of Disease Prevention and Control, Public Health Bureau, MHLW. Request for the Appropriate Use of Cefiderocol Tosilate Sulfate Hydrate (Fetroja for IV Drip Infusion 1g) for the Treatment of Carbapenem-Resistant Enterobacterales (CRE) Infections (Administrative Notice, September 17, 2024). Tokyo: MHLW; 2024.

30) Department of Disease Prevention and Control, Division of Disease Prevention and Control, Public Health Bureau, MHLW. Request for the Appropriate Use of Avibactam Sodium/Ceftazidime Hydrate for Injection (Zabicefta Combination Drip Infusion) in the Treatment of Carbapenem-Resistant Enterobacteriaceae (CRE) Infections (Administrative Notice, December 26, 2024). Tokyo: MHLW; 2024.

Pillar 03 Strengthening quality control systems for microbiological testing

Recommendation 3-1 The national government should take the lead in establishing an external quality control framework for microbiological testing and develop mechanisms to encourage participation

The quality of infectious disease management and the reliability of surveillance data on AMR bacteria (such as the data aggregated through systems like JANIS) depend heavily on the accuracy of microbiological testing. External quality control is an evaluation of testing performed by a party other than the facility conducting the test, and it is an essential element in ensuring objective accuracy.[31] However, in Japan, external quality control for microbiological testing is only provided by relevant organizations on an individual and voluntary basis. Without a nationwide system to track participation rates and assessment results, the actual situation remains unclear.

Testing accuracy is becoming increasingly important as the applications of test results continue to expand. In the past, test results were primarily used to guide the treatment of individual patients. Today, in addition to being collected as basic data for AMR surveillance, test results are being used as training data for AI-enabled diagnostic support and in treatment plan recommendations. Regardless of the application, the starting point is test results obtained on a daily basis at each facility. If the accuracy of training data cannot be guaranteed, it is also impossible to guarantee the validity of analyses and decisions based on that data. Quality control is the foundation of accuracy, and the broader the secondary use of test results, the more essential quality control becomes.

Despite its importance, legal hurdles are hindering progress in external quality control. When the Act Partially Amending the Medical Care Act and Other Related Acts (Act No. 57 of 2017) came into effect in December 2018, it introduced new provisions for quality and accuracy control in clinical laboratory testing. When healthcare institutions conduct in-house laboratory testing, they are now required to appoint a person responsible for ensuring accuracy as well as to establish standard operating manuals, daily work logs, and records. However, institutions are under no formal obligation to implement internal quality control, participate in external quality control, or provide appropriate training, as these are non-mandatory provisions.

In particular, external quality control has been classified as a non-mandatory provision for the time being due to its "potential implications for community healthcare and similar factors."[32] This decision was made due to the wide variation in size and function among healthcare institutions. Some institutions lack the financial or human resources to implement internal quality control, so there was concern that a blanket requirement would force some institutions to discontinue in-house microbiological testing.

Recently, there have been calls to revise the current non-mandatory classification of quality control. For example, at a February 2025 meeting of the Study Group on the Role of Advanced Treatment Hospitals and Regional Support Hospitals, there was a suggestion to make the implementation of internal quality control and external quality control surveys a mandatory responsibility of hospital administrators in advanced treatment hospitals, which must provide advanced medical care as a designation requirement.[33] However, this suggestion was not included in the report that the study group compiled in September 2025. It was also not reflected in subsequent amendments to the Medical Care Act Enforcement Ordinance. Nevertheless, the concept of adjusting the standards that a healthcare institution must meet according to the function of the institution itself can serve as a point of reference when examining the ideal arrangements for microbiological testing systems.

Another item of note is the fact that there are unique challenges facing external quality control for microbiological testing that are not present in other areas of testing. For example, most biochemical and blood tests are designed to measure levels of specific components. They rely on control samples that contain precisely-known quantities of target substances and meet international standards. Individual facilities can verify their own accuracy for these tests by purchasing control samples, measuring them, and comparing results with the control sample's assigned value.

In microbiological testing, however, samples contain unknown microorganisms. After causative organisms are cultured and identified, their susceptibility to various substances is evaluated through antimicrobial susceptibility testing. Because culture, identification, and antimicrobial susceptibility testing involve reporting qualitative results, semi-quantitative results, and

susceptibility categories, the accuracy of the overall process is difficult to evaluate solely by comparing measured values against the assigned values of control samples. Given this complexity, evaluating accuracy requires preparing quality control samples called reference specimens, which have predetermined target ranges. These ranges specify which organisms are present in the specimen and in what quantities. Healthcare institutions then compare their test results against reference specimens to evaluate testing accuracy.

Additionally, because reference specimens contain live microorganisms, their quality must be maintained during transport to each facility. This includes ensuring their bacterial species and antimicrobial susceptibility profiles remain fully accurate. External quality control relies on evaluation by external bodies. If participating facilities prepare their own reference specimens, it compromises the objective assessment of testing accuracy. Furthermore, producing suitable specimens while continuously maintaining specimen quality requires advanced technology and sustained financial investment—demands that individual healthcare institutions cannot meet on their own. When comparing results among facilities on a nationwide scale, reference specimens must be standardized to ensure meaningful comparisons. This includes maintaining uniform quality and homogeneity across all reference specimens. In other words, since each facility cannot prepare reference specimens on its own, reference specimens must be established as a shared resource.

However, external quality assurance programs in Japan are currently being conducted on an individual basis by various academic societies, medical associations, and associations of technologists. As a result, reference specimen quality and test result evaluation methods vary from one organization to another, and no common nationwide standards have been established. Also, microbiological testing is not covered in every survey. For example, one large-scale survey called the Japan Medical Association External Quality Assessment Survey covers clinical chemistry, immunology, hematology, and urinalysis, but it does not include items related to microbiological testing.[34] The absence of microbiological testing from these surveys makes it difficult to compare or assess testing accuracy across facilities on a nationwide scale. There are also lingering challenges related to the operational sustainability of these programs. From specimen preparation to collection and evaluation, the entire quality control process is entrusted to individual organizations and relies on the dedication of a few key experts. As a consequence, these programs are vulnerable to disruptions due to the retirement or transfer of key personnel involved in external quality control. This reliance also severely limits the potential for programs to expand, such as the inclusion of new testing methods.

To transition to sustainable mechanisms for external quality control, a quality control infrastructure should be established through efforts centered on the national government. When developing this infrastructure, the expertise and knowledge of the academic societies and other organizations that have voluntarily maintained quality control efforts in the past should be leveraged to the greatest extent possible. Specifically, one option may be for the government to designate academic societies or related organizations as third-party external quality control agencies and to commission them to implement quality control programs as official projects. Next, the national government and designated organizations should collaborate to establish common standards for reference specimen quality and test result evaluations. Based on these standards, the designated organizations would prepare and distribute reference specimens, collect results from each facility, and evaluate them. It will also be vital for the government to provide continued funding for maintaining and operating the external quality control infrastructure. Developing these programs into a national program will help guarantee sustainable and reliable external quality control.

When developing a quality control infrastructure, the fact that measurement characteristics vary depending on the equipment and reagents used in testing must be kept in mind. If uniform standards are applied to devices designed around different principles, the presence of diverse technologies may end up undermining quality control. Quality verifications can be conducted without hindering technological progress by establishing frameworks for comparison. For example, results could first be compared only within groups that share the same measurement principles, and differences between groups could then be evaluated separately.

It will also be necessary to present the findings of external quality control programs on a regular basis. Because each organization currently conducts its own quality control survey independently, results often go unpublished. However, if the national government uses public funds to develop a shared external quality control infrastructure for all healthcare institutions, the survey results generated using that infrastructure should be published for the benefit of society. Presenting nationwide external quality control participation rates alongside institution accuracy distributions will shed clarity on the relative standing of each healthcare institution. This transparency will help individual healthcare institutions recognize the need to improve testing accuracy and create opportunities for them to make improvements. It will also enable the national government and local governments to ascertain real-world circumstances around testing accuracy in each region and comprehensively assess testing systems. For facilities whose results fail to meet expectations, it will also be important to develop a mechanism that provides notifications, supports cause analysis, guides corrective actions, and verifies improvement progress.

In principle, the responsibility of ensuring testing accuracy lies with the healthcare institution conducting it. The costs incurred through external quality control participation should be classifiable as necessary expenses for conducting tests, just like laboratory personnel and equipment. The reasoning behind the decision in “Participation in external quality control was made a non-mandatory

provision after taking factors like the potential impact on regional healthcare into account"[35] is thus understandable. Given the clinical risks of continuing to use tests with insufficient or unverified accuracy, even if participation is not universally mandatory, methods of encouraging participation by clearly showing its benefits and the risks of non-participation must be devised.

Earlier, the primary focus has been specimen testing conducted by healthcare institutions themselves. For clinical laboratories, participation in external quality control surveys is mandatory under the Act on Clinical Laboratory Technicians and its enforcement regulations, and the Guidelines for Clinical Laboratories stipulate that their participation must be verified at least once per year.[36] Clinical laboratories are also subject to on-site inspections by prefectural governors. In terms of institutional framework development, more progress has been made for clinical laboratories than for healthcare institutions. At the same time, healthcare institutions and local communities that outsource testing to these laboratories have limited methods of verifying information such as the actual scope of the tests clinical laboratories perform or steps they have taken to ensure quality. This challenge is especially acute in regions where most microbiological testing is outsourced to clinical laboratories, which results in infectious disease management across the region becoming deeply dependent on results obtained from clinical laboratories. Given these circumstances, in addition to encouraging healthcare institutions to participate in external quality control, steps must also be taken to build mechanisms that ensure high-quality microbiological testing across regions through systems in which outsourcing healthcare institutions and local communities can verify which items are being tested at clinical laboratories, as well as the quality of outsourced testing.



31) These recommendations use the term "external quality control" to refer to systems in which facilities perform tests using specimens provided by external organizations with the results subsequently evaluated by a third party. While not strictly synonymous, such practices are referred to as external quality assessment (EQA) or proficiency testing (PT) in the international community. Since this document focuses on third-party evaluation, it refers to EQA and PT collectively as "external quality control." Additionally, in the context of microbiological testing, this document does not use the term "accuracy" to refer exclusively to the precision or reproducibility of measured values. "Accuracy" is applied broadly and covers the entire testing process, including specimen receipt, culturing, identification, antimicrobial susceptibility testing, and the reporting of results.

32) Director-General, Health Policy Bureau, MHLW. Regarding the Enforcement of the Ministerial Ordinance on the Revision of MHLW Ordinances in Conjunction with the Partial Enforcement of the Act Partially Amending the Medical Care Act and Other Related Acts. (Health Policy Bureau Notice No. 0810-1). Tokyo: MHLW; 2018.

33) Twenty-third Meeting of the Study Group on the Role of Advanced Treatment Hospitals and Regional Support Hospitals. Regarding the Handling of Quality Control for Specimen Testing (Reference 3). Tokyo: MHLW; 2025. (Accessed September 9, 2026). https://www.mhlw.go.jp/content/10800000/001421839.pdf

34) Japan Medical Association. Current Status of the Japan Medical Association External Quality Assessment Survey (Reference Materials for the 2nd Meeting on Quality Control of Specimen Testing, etc.). Tokyo: MHLW; 2017. (Accessed July 28, 2026). https://www.mhlw.go.jp/file/05-Shingikai-10801000-Iseikyoku-Soumuka/0000185411.pdf

35) Director, Health Policy Bureau, MHLW. Regarding Enforcement of Ministerial Ordinances Concerning the Revision of MHLW Ordinances Concerning the Partial Enforcement of the Act to Partially Amend the Medical Care Act, etc. (Health Policy Bureau Notice No. 1, August 10, 2018). Tokyo: MHLW; 2018

36) Regulation for Enforcement of the Act on Clinical Laboratory Technicians, Article 12-2, Paragraph 2. For information regarding frequency, see: Director-General, Health Policy Bureau, MHLW. Revision of the Guidelines for Clinical laboratories, etc. (Health Policy Bureau Notice No. 1030-3), Appendix 1, "Guidelines for Clinical Laboratories," Chapter 2, Section 3. Tokyo: MHLW; 2018. (Accessed September 9, 2026). https://www.mhlw.go.jp/content/10800000/000911181.pdf

Column 02

Lessons From the Clinical Laboratory Improvement Amendments (CLIA) in the United States

In the latter half of the 1980s, inadequate quality control in clinical testing became a matter of major public concern in the United States. Specifically, severe problems emerged around pap smear tests used to screen for cervical cancer. A surge in false negatives (in which abnormal specimens were reported as normal) led to missed opportunities for early cancer detection across the country, and erosion of trust in test results themselves caused widespread public anxiety.

The United States Congress held hearings in response to these circumstances, which led to the enactment of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.[37] This statute required nearly all laboratories handling human specimens to obtain certification showing compliance with laboratory standards and to participate in external quality control. This quality control is referred to as “proficiency testing” and is conducted under nationally unified federal standards. Because laboratories lacking certification cannot submit insurance claims to Medicare or Medicaid, meeting CLIA obligations is directly linked to financial performance. This approach was innovative because, rather than relying on voluntary efforts by individual facilities, it established a legal quality control framework that protects patient safety and ties quality standards directly to payment systems.

While Japan has not experienced major quality control issues in microbiological testing, this does not mean the nation is free from clinical risks. For example, tests for Group B Streptococcus (GBS) sometimes indicate that erythromycin is ineffective and clindamycin is effective. Penicillin is the standard treatment for this condition due to its high effectiveness against GBS, while clindamycin offers an alternative for patients with a penicillin allergy. However, with this combination of test results, resistance to clindamycin may actually emerge during treatment—a phenomenon called “inducible resistance.” Identifying inducible resistance requires additional confirmation with a supplementary test known as the D-zone test. Despite this need, external quality control surveys have found that facilities sometimes omit the D-zone test or misinterpret its results. Overlooking inducible resistance can result in the selection of ineffective antimicrobials, leading to severe complications or death, especially in patients with bacteremia or neonatal infections.

With the enactment of CLIA, the United States introduced a systemic reform of quality control, strengthening it at a fundamental level to respond to a serious incident. Although introducing legally binding quality control measures requires careful consideration of differences in systems and treatment culture, it will be important for Japan to first take proactive steps to establish a nationwide quality control system that ensures patient safety.

37) Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Pub. L. No. 100-578, 42 U.S.C. §263a.

Pillar 04 Building a system for sharing the functions of microbiological testing within communities

Recommendation 4-1

Under the leadership of the national government, outbound and inbound specimen testing between healthcare institutions should be positioned as regional testing networks, and mechanisms for sharing costs and information should be developed

The majority of antimicrobials in Japan are prescribed in outpatient settings. According to the "Surveillance of Antibiotic Sales in Japan," oral antimicrobials account for approximately 90% of total sales,[38] the majority of which are thought to be used in outpatient care. However, most of the clinics and small- to medium-sized hospitals where outpatient care is provided do not have in-house microbiology laboratories. In addition to measures for strengthening in-house testing systems at individual healthcare institutions described in previous sections, systems that enable healthcare institutions within the same region to share testing functions and complement one another will also be necessary.

The purpose of establishing outbound and inbound arrangements for specimen testing among healthcare institutions is not to centralize testing functions at single locations. What is most important is ensuring that clinically necessary test results reach the healthcare institutions that need them within the required timeframes. This objective remains unchanged regardless of whether tests are performed in-house, outsourced to other local healthcare institutions, or outsourced to a clinical laboratory, and no single approach is recommended or should be favored for all scenarios. Given the nature of clinical laboratories as facilities that consolidate specimens across multiple healthcare institutions, they have distinct advantages in test standardization, quality control, and specimen transport, including collection. Although systems for outbound and inbound testing among healthcare institutions already exist, they are included in these recommendations because such arrangements are not being utilized effectively, with cost allocation left up to individual contracts.

Existing regulations already permit healthcare institutions to share testing duties within regions. Cost-handling procedures for outsourced laboratory testing to another hospital or clinic are stipulated by a Ministry of Health, Labour and Welfare (MHLW) notification titled, "Calculation Method for Test Fees, etc. for Outsourced Specimen Testing," which allows the outsourcing institution to bill in the same manner as if testing had been performed in-house.[39] The MHLW has also issued notifications with points of note for outbound and inbound laboratory testing arrangements between hospitals or clinics that provide specific requirements for the healthcare institutions that perform testing. These requirements include the appointment of a person in charge and a quality control officer, as well as securing the necessary equipment.[40] In other words, an institutional framework and requirements for outbound and inbound laboratory testing between healthcare institutions are already in place.

Nevertheless, inter-facility arrangements are not being fully utilized for testing, and mechanisms for facilities to share testing capabilities with other facilities in their regions have yet to be established. This is because outbound and inbound testing arrangements rely on individual agreements between healthcare institutions, and these agreements have not been positioned as mechanisms for determining the distribution of testing capability across regions. Even when testing capabilities are shared, because it is only the outsourcing healthcare institution that can bill for medical service fees, payment for the institution that performed testing depends on the contract between the two parties. The testing institution has no guarantee that it can recoup the costs required to maintain its testing systems, and it may face increased financial burden as the number of accepted tests increases. As a result, some healthcare institutions remain reluctant to perform testing for other facilities.

However, conducting external testing for nearby healthcare institutions supports diagnostic capacity for the entire region and is therefore significant for the public. Specifically, the number of tests that can be carried out in times of emergency depends on how well regional testing capacity is maintained during non-emergency periods. When healthcare institutions above a certain size maintain and strengthen in-house testing capability and build complementary relationships with other local facilities during periods of non-emergency, it contributes to preparedness for future infectious disease crises.

To support these efforts, the national government should lead the development of official statistics to quantitatively assess the actual state of testing systems at healthcare institutions. It should also clarify how services provided by reference facilities will be evaluated and supported through medical service fees and public finances. At present, laboratory testing fees are determined primarily based on market rates at clinical laboratories. This approach does not always accurately reflect the costs incurred by

healthcare institutions for testing system maintenance or outbreak response. The development of official statistics that capture real-world circumstances surrounding testing systems in healthcare institutions will provide a foundation for reflecting the cost of external testing and other costs borne by those institutions in the medical service fee schedule.

To share testing capabilities effectively throughout regions, steps must be taken to identify which tests should be centralized and which can be equally distributed, including for outbound and inbound testing among healthcare institutions. Microbiological testing covers a wide range of methods, from smear tests to culture and identification, antimicrobial susceptibility testing, and genetic testing, and the necessary techniques, equipment, and acceptable TATs differ depending on the test. Given this variety, decisions regarding centralized versus distributed testing should not be based on the test alone or how sophisticated its equipment is. Instead, such decisions must be based on factors such as clinical urgency, the impact that transporting specimens or isolates may have on the quality of results or TATs, how centralized the necessary technologies and equipment are, the ability to rapidly transition to follow-up testing, and the anticipated test demand and projected cost burden within the region. In light of these points, tests with rapid TATs of minutes to hours (such as antigen and smear tests for infectious diseases, or certain nucleic acid amplification tests) are unsuitable for centralization. Such testing functions should instead be distributed across healthcare institutions. Conversely, there may be potential to enhance both quality and efficiency by centralizing tests that require sophisticated equipment and skilled technicians, or that are performed infrequently.

However, whether a test can be centralized should not be based solely on the sophistication of the equipment. For example, while standardization and centralization are likely to improve quality for antimicrobial susceptibility testing, the results of these tests directly inform decisions on selecting and modifying antimicrobial therapy. Centralization must be considered to the extent that it allows for clinically-acceptable TATs, while accounting for transport times, strain quality, transitions to follow-up testing (such as identifying resistance mechanisms), and interim reporting. As for mass spectrometry for species identification, it is used in regional core hospitals to expedite routine tests. This makes it difficult to conclude definitively that it is suitable for centralization.

In addition to considering efficiency, decisions regarding centralized versus distributed laboratory testing should also take into account the expertise of academic societies and professional organizations as well as the current status of local healthcare delivery systems. It is also desirable that efforts to examine systems in which regional core hospitals perform advanced testing to support nearby healthcare institutions also allow for the selection of arrangements that are well-suited to the region in question.

It will also be essential to establish an information infrastructure for linking test results to clinical decision-making, especially when advancing centralization efforts. For example, if smear test results are not shared, it delays subsequent species identification and antimicrobial susceptibility tests, which then delays antimicrobial selection and administration. Failure to integrate centralization into the design of information sharing mechanisms may actually exacerbate delays in reporting.

When testing is outsourced, regardless of whether the reference facility is a clinical laboratory or a healthcare institution, final test results are almost always the only information reported to the outsourcing healthcare institution. Currently, outsourcing healthcare institutions often check testing progress by making individual inquiries to reference facilities. If outsourcing institutions and reference facilities have common platforms for sharing electronic medical records and other information, outsourcing facilities will be able to see progress on each step, such as when cultures are started, when species are identified, and the current status of antimicrobial susceptibility testing. This can help them stay updated even before final test results are obtained. In infectious disease management, decisions on strengthening infectious disease measures are made once a causative microorganism is suspected, and decisions on changing antimicrobials are made once drug susceptibility is confirmed. Rather than simply increasing the volume of information, healthcare institutions require the ability to access accurate information each time one of these decisions needs to be made. Sharing information in this manner requires both outsourcing and reference facilities to be connected to a shared information infrastructure, which must be designed to be compatible with information-sharing services for electronic medical records and other existing infrastructure. Discussions on standardizing clinical laboratory data are currently proceeding in parallel with efforts for digital transformation (DX) in healthcare. Further progress in the establishment of regional testing networks may be possible if microbiological testing is included in future discussions on standardization.

Linking test results to treatment will require systems that not only deliver results, but that also support the interpretation of results and the selection of antimicrobials. It is particularly difficult for small- and medium-sized healthcare institutions to secure personnel who can provide in-house support for infectious disease management and antimicrobial stewardship. When designing regional testing networks, in addition to distributing testing capabilities, an integrated support system in which local ASTs and infectious disease specialists can assist in making treatment decisions based on test results should also be established.

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38) AMR Clinical Reference Center. Surveillance of Antibiotic Sales in Japan. Tokyo: Japan Institute for Health Security. (Accessed May 21, 2026). https://amrcrc.jihs.go.jp/surveillance/020/20190902163931.html

39) Calculation Method for Test Fees, etc. for Outsourced Specimen Testing (MHLW Notice No. 22, February 18, 1985). Tokyo: MHLW; 1985.

40) Director of the General Affairs Division and Director of the Regional Medical Care Planning Division, Health Policy Bureau, MHLW. Points of Note When Outsourcing or Entrusting Specimen Testing Operations Between Hospitals or Clinics (Health Policy Bureau General Affairs Division Notification No. 1129-1 and Regional Medical Care Planning Division Notification No. 1129-1). Tokyo: MHLW; 2018.

Recommendation
4-2

Prefectural governments should take the lead in designing regional microbiological testing networks that are consistent with Infectious Disease Prevention Plans, Medical Care Plans, and other such plans

While the national government should develop a common nationwide framework with cost-sharing models, an infrastructure for sharing information, and other such provisions, prefectural governments should design testing networks tailored to local circumstances and clearly designate testing duties across the region. While agreements between healthcare institutions may be rational on an individual basis, relying solely on such arrangements can lead to gaps or redundancies in diagnostic capacity for the region as a whole. On that point, as the entities responsible for formulating Infectious Disease Prevention Plans and Medical Care Plans and concluding agreements on medical treatment and testing under the Infectious Diseases Control Act, prefectural governments should leverage existing arrangements when building regional testing networks. Because prefectural governments already have mechanisms to fully oversee regional healthcare delivery systems and consult with healthcare institutions, they are uniquely suited to leading the design of testing networks covering wide areas.

Other countries are also organizing testing capability across wide areas and are advancing efforts to centralize testing and share data. As part of reforms to consolidate services into two Public Pathology Networks, the Australian state of Victoria is establishing clear roles and capability standards across both networks.[41] Upgrades to technical capabilities are also being introduced to facilitate secure information-sharing and reduce redundant testing. In the United States, the Centers for Disease Control and Prevention (CDC) operates the Antimicrobial Resistance Laboratory Network (the AR Lab Network),[42] which connects state clinical laboratories with seven regional core laboratories and other institutions. This has created a well-established framework in which core laboratories provide free reference testing and publish findings when healthcare institutions detect atypical AMR strains.[43] Of course, since healthcare delivery systems and the roles of public testing institutions in Japan differ from those in the US and Australia, these systems cannot be adopted as-is. However, there is optimism that Japan will transition away from treating microbiological testing as the sole responsibility of individual healthcare institutions and establish regional systems that optimize testing capability and ensure cost is not a barrier to testing.



41) Department of Health, Victoria. Pathology reform. Melbourne: State Government of Victoria; 2026. (Accessed May 21, 2026). https://www.health.vic.gov.au/hospitals-and-health-services/pathology-reform

42) Centers for Disease Control and Prevention. Antimicrobial Resistance Laboratory Network. Atlanta: CDC. (Accessed July 29, 2026). https://www.cdc.gov/antimicrobial-resistance-laboratory-networks/php/about/domestic.html

43) Centers for Disease Control and Prevention. Antimicrobial Resistance Laboratory Network Testing. Atlanta: CDC. (Accessed July 29, 2026). https://www.cdc.gov/antimicrobial-resistance-laboratory-networks/php/about/testing-services.html

Conclusion

Microbiological testing extends beyond immediate patient care; it underpins infectious disease control at healthcare institutions, within local communities, and ultimately, across the nation. The Lancet Commission on Diagnostics positions testing as “central and fundamental to quality health care” and notes that improved access to testing and diagnosis will substantially enhance healthcare quality.[44] It is precisely for this reason that Japan should design microbiological testing systems as a shared infrastructure for society rather than relying solely on commitment from each facility. This infrastructure will provide the foundation that enables patients to receive appropriate, same-day diagnoses while allowing for the accurate detection of AMR strains and the selection of suitable treatments. Many medical procedures, including surgery and chemotherapy, carry an inherent risk of infection and are predicated on the ability to reliably diagnose and treat infectious diseases. In order to be safely treated in hospitals, patients also rely on microbiological testing and screening systems to prevent the spread of AMR bacteria. Strengthening microbiological testing systems will enable citizens to receive healthcare with peace of mind and continue leading healthy lives. The next NAP is expected to come into effect in 2028. Stakeholders from industry, government, academia, and civil society are encouraged to engage in continued discussions from their respective positions so that microbiological testing systems can become a foundation for society.

44) Fleming KA, Horton S, Wilson ML, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet. 2021;398(10315):1997-2050.

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AMR Alliance Japan is an independent platform for the promotion of multisector discussion on AMR countermeasures. Since its establishment in November 2018, AMR Alliance Japan has worked with Alliance members and partner organizations to deepen policy debate around AMR. Current Members (in alphabetical order, as of October, 2026) are bioMérieux Japan Ltd., GlaxoSmithKline K.K., Himeji City, Japanese Association of Medical Technologists, Japan Medical Association, Japan Pharmaceutical Association, Japan Pharmaceutical Manufacturers Association, Japanese Society for Pediatric Infectious Diseases, Japanese Society of Antimicrobials for Animals, Japanese Society of Chemotherapy, Japanese Society of Hospital Pharmacists, “Kodomo to Iryo” Project, Meiji Seika Pharma Co., Ltd., Merck & Co., Inc., Shionogi & Co., Ltd., The Japanese Association for Infectious Diseases, The Japanese Society for Clinical Microbiology, The Japanese Society for Infection Prevention and Control, The Japanese Society for Medical Mycology, The Japanese Society of Pharmaceutical Health Care and Sciences, The Japanese Society of Therapeutic Drug Monitoring, The Pharmaceutical Society of Japan, Health and Global Policy Institute (HGPI) serves as Secretariat of the Alliance.

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