Asia-Pacific Economic Cooperation

Capacity Building and Awareness of IVD for Public Health Issues

APEC Health Working Group

August 2025

Asia-Pacific
Economic Cooperation

Capacity Building and Awareness of IVD for Public Health Issues

APEC Health Working GROUP

August 2025

APEC Project: HWG 03 2022A

Produced by
Tiannan Guo, Ph.D.
Project Overseer
Principal Investigator, Westlake University

With the PO team at Westlake University

For
Asia-Pacific Economic Cooperation Secretariat
35 Heng Mui Keng Terrace
Singapore 119616
Tel: (65) 68919 600
Fax: (65) 68919 690
Email: info@apec.org
Website: www.apec.org

APEC#225-HT-01.3

Asia-Pacific Economic Cooperation

Table of Contents

This project is intended for capacity building centered on in-vitro diagnostics (IVDs) and laboratory-developed tests (LDTs), and possible applications for enhancing the public health management system. To facilitate a thorough discussion between the APEC economies, a survey was conducted, and a workshop and an online symposium were held in 2023, based on which we have compiled this Summary Report for publication in APEC.

Background

The global in vitro diagnostics (IVD) market is projected to grow to USD 87 billion by 2026 from USD 60 billion in 2018, reflecting its critical role in modern healthcare. Across the APEC region, economies are advancing tailored solutions to address local health challenges: Thailand's Medical Life Sciences Institute achieved 99.2% specificity in ISO 13485-certified rapid IgM/IgG tests, Mexico's InDRE reduced HPV test variability by 18.2% through a rigorous 4-phase validation framework, and Malaysia's decentralized PCR model at Sibu Hospital cut unnecessary antiviral use by 40% during encephalitis outbreaks. Despite these strides, disparities persist, particularly in developing economies with limited medical resources. Indonesia, a lower-middle-income economy of 270 million people spanning 17,000 islands, highlights these gaps—only 19% of its population has access to basic diagnostics, hampering infectious disease control and maternal health outcomes. The COVID-19 pandemic intensified the urgency of strengthening diagnostic infrastructure and regional collaboration, underscoring the need to overcome technical, logistical, and epidemiological barriers to deploy effective IVD solutions and laboratory-developed tests (LDTs) across APEC member economies.

Suitable IVD/LDT techniques, pivotal in disease testing and precision medicine, offer solutions to healthcare challenges like COVID-19, encephalitis, and cancers. However, scaling these requires addressing regulatory harmonization and accelerating translation from research to clinical/POCT use. To strengthen APEC-wide collaboration, governments, industry, and academia should align via unified regulations, joint R&D incentives, and knowledge-sharing platforms. Prioritizing accessible, affordable, and user-friendly IVD/LDT tools will enhance global health equity and disease management.

Effective nucleic acid tests and/or antigenic tests, and identification of high-risk cases at an early stage, will help increase the operating efficiency of the public healthcare system and control the negative impacts of diseases on public health and economy, especially in the face of public health emergencies. This will be especially important to the economic and social sustainability and resilience of developing economies. Through a workshop and a symposium, this project provides a platform for participants to share experiences and exchange views about recent advances in common and emerging LDT/IVD techniques, the translation of LDT tools into IVD products, optimizing healthcare resources management, and enhancing the capacity in response to public health emergencies. This project has involved a wide range of stakeholders including researchers, experts from the IVD industry, medical practitioners, policymakers, regulatory agencies, and students. We hope it will foster possible collaboration on future research and training programs in the field of LDT/IVD.

Survey responses on challenges faced in IVD capacity building and potential solutions across various domains.

The survey questionnaire for the APEC project HWG 03 2022A, specifically for the 2023 APEC Workshop on Capacity Building and Awareness of IVD for Public Health Issues aimed to gather insights into the challenges faced in IVD capacity building and potential solutions across various domains. The questionnaire was addressed to participants who have been invited and have experience in the IVD field.

The survey, targeting professionals with diverse backgrounds in the IVD sector, was divided into several aspects and sought to elucidate the multifaceted challenges in regulatory harmonization, cross-sector collaboration, quality systems, clinical utility, pre-market evaluation, post-market surveillance, supply chain management, and the integration of new technologies into IVD. The full questionnaire is provided in Annex 1.

Key Points from the survey responses:

Regulatory Harmonization

Diverse regulatory frameworks across regions were a significant challenge. Aligning regulatory requirements and approval processes was difficult. Participants suggested world-wide collaboration and the establishment of a global standard regulation.

Cross-sector Collaborations

Suggested strategies include partnerships, information sharing, regulatory convergence, and capacity building through training and educational programs.

Quality Systems

Common issues include variations in reagents, equipment, user practices, and lack of transparency in quality control processes. Challenges also involve equity and accessibility of IVD tests, change management, risk management, data privacy, and conflicts of interest.

Clinical Utility/Performance

Difficulties in designing effective studies, budget constraints, and the lack of standardized reference materials were highlighted.

Pre-market Evaluation

Technical file preparation, IVD risk-based classification, and the lack of reference standards were cited as challenges.

Post-market Surveillance

Data collection, timely reporting, signal detection, and legal implications were noted as challenges, along with ethical professional conduct in data and tissue sharing.

Supply Chain

Regulatory compliance, supply chain disruptions, logistics, and maintaining quality control throughout the supply chain were identified as challenges.

New Technologies in IVD

Challenges include regulatory approval, standardization, complexity, validation, data interpretation, safety, ethical issues, legal implications, and cost.

Omics and AI in IVD

Specific challenges when applying proteomics and AI to IVD were mentioned, such as validation difficulties, the need for expertise, and adjustments in development and manufacturing processes.

IVD Capacity Building in Developing Economies

Obstacles include regulatory challenges, insufficient infrastructure, lack of funding, limited awareness, and resistance to adopting new technologies. Suggestions to promote IVD capacity building include regulatory support, public-private partnerships, world-wide collaboration, technology transfer, and training.

Solutions Proposed

Solutions proposed by the participants include establishing regulatory alignment and a world-wide IVD association, offering training programs and sharing manufacturing and development facilities, collaborative research, early engagement with regulators, working with frontline professionals, public-private partnerships, technology transfer, and training. In Malaysia, with collaboration with private labs, they were able to boost economy-wide testing capacity (from 1,000 to 37,100 tests/day by 2020). And also they employed the Movement Control Order (March 2020) with centralized testing, contact tracing, and public education.

Other Comments and Suggestions

Interdisciplinary research can contribute to IVD development. The essentials and direction for IVD development should be identified, and regulation should support utilization.

Recommendations

The 2023 APEC Workshop on Capacity Building and Awareness of IVD for Public Health Issues was held from 9-10th September 2023, and the Online Symposium under the APEC Project HWG 03 2022A Capacity Building and Awareness of In Vitro Diagnostics (IVD) for Public Health Issues was held on 17 December 2023 during which experts from across the APEC economies in various domains such as government/regulatory agencies, research institutes, and the IVD industries had profound and thorough discussions with a focus on the key issues raised in the survey. The experts also shared insights into IVD/LDT development and medical laboratories' applications across many economies. The following recommendations are organized based on the Workshop and the online Symposium.

Figure 1. The 2023 APEC Workshop on Capacity Building and Awareness of IVD for Public Health Issues

Recommendations on how to build stronger public-private-academia collaboration for IVD across the APEC region.

Recommendation 1.1: Work more closely with world-wide industry trade associations on policy awareness and shaping related to IVDs and diagnostics in the Asia Pacific (APAC) region.

There is a huge demand for IVD products in APAC, driven by large populations and policy support. Economies like China and India have over 1 billion people each. New IVD technologies like digital diagnostic tools for lung diseases are entering APAC markets. In 2022, 40 such digital tools were mapped across China; Korea; Japan; and Singapore.

Thus, it is necessary to work more closely with world-wide industry trade associations, China's IVD industry, despite its growth, remains heavily dependent on imported raw materials for the upstream supply chain, while domestic companies dominate midstream manufacturing. This reliance highlights the need for global cooperation to ensure a stable supply of essential diagnostics, particularly during global health crises like the COVID-19 pandemic.

To enhance policy awareness and shape the IVD and diagnostic products industry in the Asia-Pacific region, closer collaboration with world-wide trade associations is recommended. The following steps can be considered:

a) Join world-wide trade associations: Understand and join relevant world-wide trade associations, such as the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), as a member. This will enable you to establish connections with other members of the association and participate in various activities and projects organized

by the association.

b) Attend conferences and seminars: Actively participate in conferences, seminars, and forums organized by world-wide trade associations. These events often provide opportunities to network and share experiences with professionals from different regions around the world, as well as to stay updated on industry trends and policy developments.

c) Provide expertise and experience: Share your professional knowledge and experience with other members of the world-wide trade association. This can be done through participation in lectures, presentations, working groups, or committees, to support and contribute to the activities and projects of the association.

d) Engage in policy development and advocacy: Actively participate in the policy development and advocacy efforts of world-wide trade associations. Collaborate with the association to influence government and regulatory bodies in policy formulation and regulatory reforms for IVD and diagnostic products in the Asia-Pacific region, to promote industry development and innovation.

e) Engage in world-wide cooperation projects: Collaborate with world-wide trade associations to undertake world-wide cooperation projects, such as research collaboration, development of technical standards, and training exchanges. Through these collaborative projects, partnerships between the Asia-Pacific region and other regions can be strengthened, collectively driving the development of the global IVD and diagnostic products field.

It is important to establish a proactive relationship with world-wide trade associations and demonstrate your professional knowledge and skills to foster cooperation and mutual development. At the same time, maintaining connections with relevant stakeholders in the Asia-Pacific region, including governments, academia, healthcare institutions, and industry organizations, is essential to ensure the representation and protection of the interests of IVD and diagnostic products in the Asia-Pacific region.

Recommendation 1.2: Create more public-private-academia partnerships and work streams to address policy barriers and support broader access to innovative IVD technologies in APAC markets.

Public-private partnerships can provide resource sharing, expertise, and experience, promoting technological innovation and development. The private sector typically possesses innovative capabilities and market orientation, while the public sector possesses policy-making and regulatory capabilities. As implemented by Thailand's partnership with Siam Bioscience to commercialize COVTECT-1 PCR tests during supply shortages, through collaboration, it is possible to accelerate the research and development, validation, and application of technology, promoting the innovation and advancement of IVD technology.

Policy barriers may hinder the promotion and application of innovative IVD technology. Public-private partnerships can help jointly address policy obstacles by, for example, driving policy reforms, providing scientific evidence support, and formulating relevant norms and standards. Through collaboration, a favorable policy environment can be created for innovative IVD

technology, promoting its widespread application, and thus better serving public health and clinical practice.

Public-private partnerships can help improve the accessibility and sustainability of innovative IVD technology. The private sector can provide professional capabilities in technology research and development, production, and supply chains, while the public sector can facilitate the popularization and sustainable development of technology through policy support, funding, and market access. Collaboration can ensure the widespread application of technology, benefiting more people from the progress of innovative IVD technology.

Public-private partnerships contribute to knowledge sharing and collaborative communication. The private sector typically possesses rich practical experience and market insights, while the public sector possesses professional knowledge in areas such as clinical and epidemiological data. Through collaboration, knowledge exchange and cooperation within and outside the industry can be promoted, jointly addressing technological and policy challenges, and driving the development and innovation in the field of IVD.

To establish more public-private partnerships and workflows to overcome policy barriers and support wider access to innovative IVD technology, several steps can be considered:

a) Appoint policy advocates: Identify individuals or representatives who are dedicated to communicating with government and regulatory agencies on behalf of the IVD industry. These advocates can establish connections with government officials, decision-makers, and regulatory bodies to propose policy recommendations related to innovative IVD technology, thereby promoting policy reforms and development.
b) Establish partnerships: Collaborate with government agencies, academic institutions, healthcare organizations, and other relevant entities to jointly develop and implement projects, policies, and initiatives aimed at facilitating the development, adoption, and dissemination of innovative IVD technology.
c) Provide scientific evidence and data support: Collect and provide scientific evidence and data that demonstrate the effectiveness, safety, and clinical benefits of innovative IVD technology. This evidence can be utilized to support policy-making and decision-making processes, as well as help eliminate policy barriers.
d) Establish norms and standards: Engage in the formulation and promotion of relevant norms and standards to ensure the quality, reliability, and consistency of innovative IVD technology. This helps build trust and reliability, while also facilitating technology adoption and market access.
e) Education and training: Offer education and training programs to introduce government officials, healthcare professionals, and decision-makers to the potential and advantages of innovative IVD technology. This helps increase awareness and understanding of IVD technology and enhances its application in public health and clinical practice.
f) Engage in policy-making processes: Actively participate in policy-making processes, including engaging in public consultations, submitting opinions and suggestions, as well as participating in public comments on policy evaluations and regulations. This helps ensure that the voice of the IVD industry is adequately heard and considered in policy-making.

By following the aforementioned steps, it is possible to establish more public-private partnerships and workflows, address policy barriers, and promote the development and application of innovative IVD technology. This requires collaboration and efforts from both within and outside the industry in order to achieve the goal of wider access to innovative IVD technology.

Recommendation 1.3: Simplify regulations, strengthen cooperation between supervision and the industry, and achieve standardization.

APACMed is a voice for the MedTech industry in APAC focused on improving standards of care via stakeholder collaborations. Its IVD Committee explores issues faced by diagnostics companies regarding regulation, funding, education, etc. APACMed helps companies navigate complex regulations across different APAC economies. In terms of regulatory approaches, APACMed advocates for harmonization. It facilitated an "Abridged Pathway Reliance Program" between regulators in Singapore and Thailand to accelerate approvals. Approval times in Thailand fell from 12 months to 3 months. APACMed sees opportunities for regulatory reliance models across APAC.

The research workflow, from planning to completion, covers activities such as vendor selection, establishment of the trial guidance committee, protocol design, ethical declaration, registration, trial initiation, subject enrollment, testing, monitoring, analysis, and reporting. Clinical Trial Management Systems (CTMS), electronic Trial Master Files (eTMF), and quality management systems (cQMS) contribute to process supervision and Good Clinical Practice (GCP) compliance.

Standardization relies on implementing metrological traceability - where results can be traced back to standardized reference materials and measurement procedures. However, there are gaps. Many reference materials lack validation for commutability - the ability to behave similarly to actual clinical samples. And desirable reference materials don't exist for most laboratory tests. Efforts to improve standardization include regulations in the EU and China requiring traceability for in vitro diagnostics, as well as scientific bodies like the Joint Committee for Traceability in Laboratory Medicine (JCTLM) that provide databases of reference materials globally.

Before being granted registration certificates, IVD products must undergo compulsory testing including safety, EMC, software quality, environmental requirements, and critically, performance evaluation per professional standards like economy-wide and industry norms. He listed some commonly used standards for electrical safety, EMC, packaging, etc. Two key standards in China are YY/T 1918-2023 for digital PCR systems and YY/T 1908-2023 for nucleic acid extraction systems, both taking effect in September 2024. These provide specifications for partition uniformity, temperature control, fluorescence linearity, magnetic bead residue, and consistency of nucleic acid extraction that manufacturers will need to meet.

For digital PCR, accuracy, repeatability, and linearity of nucleic acid quantification across the relevant concentration range are evaluated using standard reference materials like CMV DNA. Comparative testing has revealed significant differences between platforms. Similarly,

extraction consistency is assessed by qPCR of reference RNA/DNA materials after extraction using different systems. Elements like robotic precision and avoidance of cross-contamination are also checked. Extensive metagenomic sequencing is done to characterize reference materials like BIMT's in-house CMV.

In conclusion, standardized testing per upcoming IVD norms will ensure quality, consistency and fairness for manufacturers. As tests advance, requirements should also evolve from empirical validation towards determinants of real-world testing quality including usability. Global cooperation can also accelerate knowledge sharing on antigen test evaluation and application.

Recommendation 1.4: Strengthening industry-academia-government collaboration.

Collaboration allows for the pooling of knowledge, expertise, and resources from academia, industry, and government, leading to more robust and innovative research and development efforts in IVD. This collaboration can accelerate the discovery and development of novel diagnostic technologies, biomarkers, and testing methodologies.

Government institutions often have access to funding, research infrastructure, and regulatory expertise, while industry brings in technological capabilities and commercialization know-how. Academic institutions contribute scientific expertise and a long-term perspective. Collaborating allows for the efficient utilization of these collective resources, leading to the development of more effective and accessible IVD technologies. Collaboration facilitates the harmonization of data, methods, and standards across academia, industry, and government. This ensures that IVD technologies and practices meet regulatory requirements, are based on sound scientific principles, and are reproducible. It also promotes the adoption of standardized protocols, quality control measures, and data sharing, enabling improved comparability and reliability of diagnostic results.

Industry-academia-government collaborations can expedite the translation of research findings into practical applications. Academic institutions generate cutting-edge research, while industry has the capacity to scale up and manufacture diagnostic products. Government agencies can provide regulatory support and facilitate the adoption of new technologies. By working together, these stakeholders can streamline the translation process, bringing innovative IVD solutions to the market more efficiently.

Collaboration in IVD, such as the Malaysian Duke-SEGi-Sibu Hospital's RT-PCR testing collaboration, can address critical societal needs, such as improving healthcare outcomes, enabling early disease detection, and enhancing patient care. By combining the expertise of academia, industry, and government, collaborative efforts can better align research and development with the healthcare priorities of the population, leading to the development of IVD technologies that are more relevant and impactful.

Several strategies can be implemented to strengthen industry-academia-government collaboration:

a) Establish Partnerships and Consortia: Foster partnerships between academia, industry, and government agencies by creating consortia or collaborative networks focused on IVD research and development. These partnerships can facilitate regular communication, sharing of expertise, and joint planning of projects.
b) Funding Mechanisms: Develop funding mechanisms that encourage collaborative projects between academia, industry, and government. This can include grants, research contracts, and public-private partnerships. By providing financial support specifically for collaborative initiatives, barriers to collaboration can be reduced.
c) Knowledge Exchange and Technology Transfer: Facilitate the exchange of knowledge and technology between academia and industry. This can be achieved through joint research projects, internships, secondments, and technology transfer programs. Academic institutions can share their research findings and expertise, while industry can provide insights into commercialization and practical application.
d) Regulatory Support: Government agencies can play a crucial role in facilitating collaboration by providing regulatory guidance and support. They can work closely with academia and industry to ensure that regulatory requirements are met, while also promoting innovation and expedited approval processes for new IVD technologies.
e) Shared Infrastructure and Resources: Create platforms or shared infrastructure that allow academia, industry, and government to access and utilize common resources. This can include shared research facilities, data repositories, and testing platforms. By pooling resources and infrastructure, collaboration can become more efficient and cost-effective.
f) Education and Training Programs: Develop educational and training programs that promote collaboration and interdisciplinary skills. This can involve organizing workshops, seminars, and conferences where stakeholders from academia, industry, and government can interact, exchange ideas, and learn from each other.
g) Standardization Efforts: Encourage collaboration in the development and implementation of standards for IVD technologies. This can involve creating industry-academia-government working groups or committees dedicated to establishing common standards, protocols, and quality control measures.
h) Intellectual Property Management: Establish clear guidelines and frameworks for managing intellectual property (IP) rights in collaborative projects. This can help address concerns related to IP ownership and commercialization, allowing for a fair distribution of benefits among stakeholders.
i) Policy and Advocacy: Encourage policymakers to recognize and support the importance of industry-academia-government collaboration in IVD. Advocate for policies that incentivize collaboration, promote knowledge exchange, and facilitate technology transfer.
j) Continuous Communication and Evaluation: Maintain open lines of communication between academia, industry, and government to assess the progress of collaborative initiatives, identify challenges, and develop strategies for improvement. Regular evaluation and feedback can help refine collaboration processes and ensure that goals are being met.

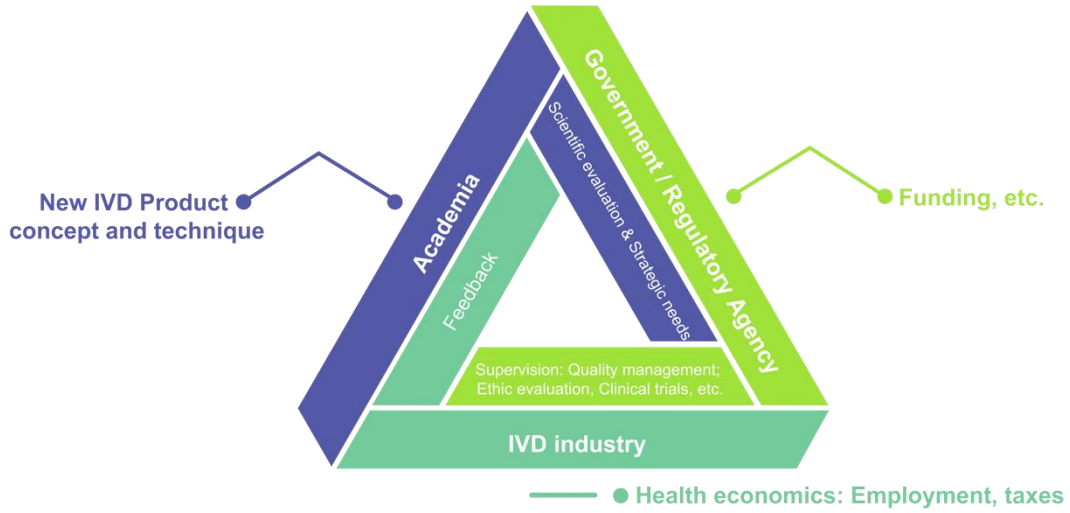

Figure 2. Relationships and recommendations in Government-Industry-Academia Collaborations for IVD development.

Recommendations to overcome the identified obstacles encountered by member economies.

Recommendation 2.1: Enhance the capability and coverage of virus detection for IVD products.

WHO data indicating 10% of economies still report increasing COVID-19 hospitalizations and mortality by now (2023). Hence diagnostic access remains important, though PCR supplies and infrastructure cannot meet testing needs. Antigen rapid tests are thus crucial, though less sensitive and requiring proper clinical validation.

The government swiftly introduced policies to incentivize R&D and accelerate regulatory approval of COVID diagnostics. Companies in China rapidly developed and scaled up production of nucleic acid, antigen and antibody testing reagents, reaching a daily capacity of 2.7 million tests by 2021. Many received world-wide recognition, with over 1100 companies in China obtaining EU CE marking for their COVID diagnostics. Similarly, rapid antibody tests for Zika/Dengue were critical during seasonal outbreaks, demonstrating the role of IVDs in decentralized surveillance.

The Department of Medical Sciences (DMSc) in Thailand developed and commercialized a real-time RT-PCR test kit, while also producing recombinant SARS-CoV-2 proteins to support serological assay development. It was soon deployed to screen traders during a COVID-19 outbreak and associated lockdown in Samut Sakhon province. Antibody prevalence studies in 2021 using this kit found rates of 0.4-5.8% across regions. The rapid test enabled large-scale community surveillance to guide containment measures.

During the COVID-19 pandemic, early detection and diagnosis are crucial for controlling the outbreak. Strengthening the capacity and coverage of virus testing can achieve several important benefits:

a) Early identification of infected individuals: Rapid, accurate, and reliable virus testing methods can help identify COVID-19 infected individuals, including those who are asymptomatic or have mild symptoms. This aids in timely isolation of infected individuals, containment of virus transmission, and reduction in the spread of the epidemic.
b) Effective tracing and monitoring: Through widespread virus testing, it is possible to better track and monitor the spread of the virus within communities. This assists in taking necessary measures in a timely manner, including isolating contacts, conducting epidemiological investigations, and implementing targeted prevention and control measures.
c) Facilitating effective treatment: Virus testing not only serves as a diagnostic tool but also helps in determining treatment strategies. By determining whether patients are infected with COVID-19, appropriate treatment methods and medications can be chosen more effectively.
d) Protection of healthcare workers: Strengthening virus testing can help protect healthcare workers from the risk of infection. By conducting timely virus testing on patients, COVID-19 patients can be identified and isolated more effectively, thereby reducing the exposure risk for healthcare workers.

Therefore, strengthening the capacity and coverage of virus testing is one of the most important recommendations during the COVID-19 pandemic. This requires continuous improvement and development of fast, accurate, and reliable testing methods, as well as ensuring an adequate supply of testing resources. Additionally, collaboration with relevant organizations and government agencies is essential in developing and implementing comprehensive testing strategies to facilitate the control and management of the epidemic.

Recommendation 2.2: Promote the development of specialized laboratories in hospitals.

In many economies, including China, clinical labs and anatomical pathology are separate departments. Hospital labs typically consist of pathologists and technicians, providing in-house testing or external services, with quality ensured through ISO accreditation, quality control, and ongoing education. Key priorities include standardization, automation, localization, IT applications, biomarker discovery, and the translation of research into clinical practice. As healthcare models evolve, lab medicine is shifting toward precision testing and monitoring throughout life, enabling better screening, diagnosis, disease tracking, prognosis, prevention, and evaluation, particularly for chronic conditions. Future priorities for lab medicine include the development of better biomarkers, automation, advanced technologies like NGS and liquid biopsy, and clinician education on their applications. The development of specialized laboratories in hospitals can enhance the application level and quality of IVD, thereby positively impacting clinical diagnosis and treatment.

Firstly, the development of specialized laboratories in hospitals can provide more convenient and efficient IVD services. These laboratories are typically equipped with advanced instruments and skilled personnel, enabling more accurate and rapid testing and diagnosis.

This helps to reduce patient waiting time, improve diagnostic efficiency, and expedite early detection and treatment of diseases.

Secondly, the development of specialized laboratories in hospitals can promote innovation and progress in IVD technology. These laboratories serve as a good platform for research and development, facilitating the validation and improvement of IVD technologies. Through integration with clinical practice, specialized laboratories can continuously enhance and optimize the performance, accuracy, and reliability of IVD products, thereby improving the quality and effectiveness of clinical applications.

To promote the development of specialized medical laboratories in hospitals in order to facilitate the development of IVD, the following measures can be considered:

a) Providing advanced equipment and technical support: Supplying hospitals with advanced IVD equipment and technical support to ensure accurate and efficient diagnostic testing. This includes updating equipment, introducing new technologies, providing training, and technical support.
b) Establishing a sound quality management system: Establishing a scientific and standardized quality management system to ensure accurate and reliable test results in the laboratory. This includes standardizing operating procedures, implementing quality control, laboratory certification, and supervision.
c) Enhancing talent cultivation and recruitment: Cultivating and recruiting medical laboratory personnel with expertise and skills in IVD to improve the technical level and professional competence of the laboratory. Talent cultivation and growth can be promoted through internal training, external training, and academic exchanges.
d) Expanding the scope of diagnostics and applications: Exploring and expanding new diagnostic fields and applications, collaborating with other medical departments to provide comprehensive and diversified IVD services. Collaborative relationships can be established with clinical departments, research institutions, etc., to conduct joint research and clinical trials.
e) Enhancing publicity and promotion: Actively promoting the IVD capabilities and services of hospital specialized laboratories to increase awareness and recognition among both internal and external stakeholders. Promotion can be achieved through academic conferences, forums, science popularization activities, and other means to showcase research achievements and technical advantages of the laboratory.
f) Paying attention to policy and market dynamics: Keeping abreast of and paying attention to policy and market trends in the IVD field, and adjusting the development direction and strategy of the laboratory according to needs and trends. Participation in industry associations, academic groups, etc., can help obtain the latest policy information and market intelligence.

Recommendation 2.3: Accelerate clinical translation of emerging biomarker techniques.

To accelerate the clinical translation of emerging biomarker technologies, the following methods and strategies can be considered:

a) Emphasize reliability and accuracy: The clinical application of biomarker technologies requires providing reliable and accurate results. Therefore, researchers should conduct sufficient validation and verification to ensure the stability, specificity, and sensitivity of biomarkers. This can be supported by large-scale clinical trials and studies and validated with other related research.
b) Promote interdisciplinary collaboration: The clinical translation of biomarker technologies requires interdisciplinary collaboration. Experts from fields such as medicine, biology, computer science, and statistics can collaborate to conduct research, integrate various technologies and methods, and enhance the clinical application capabilities of biomarker technologies.
c) Enhance data management and analytical capabilities: Biomarker technologies produce a vast amount of data, requiring strong data management and analytical capabilities. Methods such as artificial intelligence, machine learning, and big data analysis can help interpret and explain the complex data generated by biomarker technologies, and extract useful information and patterns.
d) Establish clinical databases and biobanks: Establishing clinical databases and biobanks to collect and store clinical data and biological samples related to biomarker technologies can provide resources and support for clinical translation research. These databases and biobanks can facilitate multicenter studies and interdisciplinary collaboration, accelerating the clinical application of biomarker technologies.
e) Make full use of electronic health records (EHRs): Electronic health records contain a wealth of clinical data that can be used for the validation and application of biomarker technologies. By utilizing automation technology and artificial intelligence algorithms, key information can be extracted and analyzed from electronic health records to identify potential biomarkers and expedite their clinical translation process.
f) Strengthen scientific communication and collaboration: Participate in academic conferences, workshops, and research collaborations to engage in communication and collaboration with peers and experts. This facilitates the sharing of research findings, obtaining feedback and suggestions, and promoting further development and clinical translation of biomarker technologies.

By implementing the above methods and strategies, the clinical translation of emerging biomarker technologies can be accelerated, improving their application effectiveness in clinical diagnosis and treatment, and providing better medical services for patients.

Recommendation 2.4: Development of intelligent black-box IVD technologies incorporating AI

AI algorithms can analyze large amounts of data and identify patterns that are difficult for human experts to recognize. Applying AI to IVD technology can significantly improve the accuracy and reliability of diagnostic results. This will lead to more accurate disease detection, prognosis assessment, and treatment selection.

AI-driven black box IVD technology can also automate and simplify the diagnostic process, reducing the time and effort required for analysis. This will enhance the prompt feedback of

test results, facilitating timely decision-making and improving patient prognosis. Additionally, automation can alleviate the burden on healthcare professionals, allowing them to focus on more complex tasks.

Furthermore, AI enables the development of new diagnostic algorithms and models, able to identify complex relationships and biomarkers that traditional diagnostic methods may struggle with. This opens up new possibilities for early disease detection, personalized medicine, and targeted therapy. Intelligent black box IVD technology has the potential to reform the diagnostic field by expanding the range of diseases that can be accurately diagnosed. Integrating AI into IVD technology enables real-time monitoring of patient data, allowing continuous tracking of disease progression and treatment response. AI algorithms can analyze data streams and provide predictive analysis, alerting healthcare professionals to potential risks or changes in patient condition. This proactive approach can facilitate timely intervention and improve patient prognosis.

Intelligent black box IVD technology, through automation and optimized diagnostic processes, helps allocate medical resources more effectively. AI-driven systems can prioritize cases based on urgency, identify high-risk patients, and optimize the utilization of laboratory resources. This can save costs, reduce waiting times, and improve overall medical resource management. Once developed and successfully validated, AI-integrated intelligent black box IVD technology can be easily scaled for application in different healthcare settings. This benefits resource-limited areas and underserved populations by providing high-quality diagnostic capabilities that may otherwise be difficult to obtain.

The data generated by intelligent black box IVD technology can contribute to research and knowledge generation in the field of diagnostics. Aggregated and anonymized data can be used for population health studies, epidemiological research, and the development of novel diagnostic algorithms. This can drive medical advancements and contribute to evidence-based medicine.

The development of intelligent black-box IVD technologies incorporating AI requires careful planning and implementation. Here are some steps to consider:

a) Identify the IVD application: Determine the specific IVD application for which you want to develop an intelligent black-box technology. This could be in areas such as pathology, microbiology, molecular diagnostics, or oncology. Understand the challenges and requirements of the specific application.
b) Data collection and annotation: Gather high-quality and well-curated datasets that represent the target population and cover a wide range of cases. Annotate the data to provide ground truth labels or outcomes for training and validation purposes. This data should include a diverse set of samples, encompassing the full spectrum of possible diagnostic outcomes.
c) Develop AI models: Utilize machine learning and deep learning techniques to develop AI models that can analyze the collected data and make accurate predictions or classifications. Techniques such as convolutional neural networks (CNNs) for image analysis or recurrent neural networks (RNNs) for sequence data can be used based on

the nature of the IVD application.

d) Train and validate the models: Train the AI models using the annotated dataset. Optimize the model's performance through iterative training and validation processes. Employ appropriate validation metrics, such as accuracy, sensitivity, specificity, or area under the curve (AUC), to evaluate the model's performance.

e) Integrate the AI models into the black-box IVD technology: Incorporate the trained AI models into the black-box IVD technology. This may involve developing software algorithms or firmware that can run the AI models on the IVD device or system. Ensure that the integration is seamless and compatible with the existing IVD workflow.

f) Validate and verify the technology: Conduct comprehensive validation and verification studies to ensure the safety, effectiveness, and reliability of the intelligent black-box IVD technology. Assess the performance of the technology using clinical samples or simulated datasets to confirm its accuracy and robustness.

g) Obtain regulatory approvals: Comply with the regulatory requirements and guidelines for IVD devices in your target market. Conduct the necessary studies and submit the relevant documentation to regulatory authorities to obtain the required approvals or certifications for commercialization.

h) Continuously improve and update the technology: Monitor the performance of the intelligent black-box IVD technology in real-world settings and collect feedback from users. Continuously refine and update the AI models based on new data and emerging scientific knowledge to enhance their accuracy and adaptability.

i) Collaborate with domain experts: Collaborate with clinicians, pathologists, scientists, and other domain experts throughout the development process. Their insights and expertise can help refine the technology, address clinical needs, and ensure its successful translation into clinical practice.

j) Ethical considerations and transparency: Ensure ethical considerations are taken into account, such as data privacy, informed consent, and bias mitigation. Strive for transparency in the AI algorithms and decision-making processes to build trust among users and stakeholders.

By following these steps, you can develop intelligent black-box IVD technologies that incorporate AI, enabling accurate and efficient diagnostic capabilities for improved patient care.

Recommendation 2.5: More field-implementable technologies should be encouraged.

In some regions, such as the western part of Sarawak, Malaysia, stringent movement restrictions and large-scale testing measures were implemented in March 2020 upon the realization of the threat posed by the novel coronavirus. However, there were insufficient personal protective equipment and infrastructure. Through cooperation with businesses, Malaysia established a local RT-PCR testing system in March 2020. The strong contact tracing and containment measures limited the initial outbreak of the epidemic. However, limitations in testing, such as heat inactivation, gene targets, and extraction methods, posed challenges to case management. Clinical doctors require guidance to interpret complex

molecular data. In the face of a shortage of manpower and insufficient resources, providing high-quality specimens, understanding testing performance, conducting repeat testing, and collaborating across disciplines are crucial. Rapid antigen testing has proven to be useful for screening and isolation decisions. Therefore, we need to encourage the application of more field-implementable technologies.

We should simplify the design and functionality of technology such as high-throughput sequencing (using PCR, LC-MS platforms, etc.), and extracellular vesicles (EVs)-based technologies to make it easier to understand and use on-site. Emphasis should be placed on user-friendly interfaces and intuitive workflows, requiring minimal training and specialized knowledge. Collaboration with organizations, institutions, or on-site practitioners that can assist in the implementation of the technology is also necessary. Active provision of comprehensive training programs and technical support should be provided to end-users in order to promote the adoption and effective use of technology on site. Ensuring that training materials and resources are easily accessible and tailored to different user groups is important. Continuous technical assistance and troubleshooting should be provided to address any challenges that may arise during implementation. Dealing with regulatory requirements and policy frameworks that may affect the adoption and use of technology on site is crucial. Close cooperation with regulatory agencies and policy-makers is necessary to ensure compliance and facilitate the integration of these technologies into existing frameworks. Advocating for policies that promote innovation, streamline approval processes, and incentivize adoption is also important. Financial barriers should be addressed by providing funding opportunities, grants, or incentives specifically for on-site implementable technologies. Supportive initiatives should be in place to provide affordable necessary infrastructure, equipment, or resources needed for implementation, overcoming resource constraints that may hinder adoption. Continuous monitoring and evaluation of the impact and effectiveness of on-site implementable technologies in real-world scenarios should be carried out. Feedback should be collected from end-users to measure outcomes and assess the benefits and challenges during the implementation process. This feedback loop allows for progressive improvements and demonstrates the value of these technologies.

Recommendation 2.6: Continued training, funding ecosystem support, and global cooperation are imperative.

The development of IVD technology and methods is rapidly changing, and continuous training ensures that healthcare professionals have the latest knowledge and skills. Training can cover new diagnostic methods, equipment operation, quality control and assurance, as well as data analysis and interpretation. Through continuous training, healthcare professionals can improve their professional level and ensure accurate and reliable diagnostic results.

The research and application of IVD technology require sufficient financial support. Funds can be used for research and development of new IVD technologies, purchase of advanced equipment and instruments, as well as support for clinical trials and implementation. In addition, funds can also be used for training healthcare professionals, establishing and

maintaining infrastructure for diagnostic laboratories, and supporting the promotion and application of technology.

Inter-economy cooperation such as the Singapore-Thailand abridged pathway or even global cooperation in the field of IVD is crucial for advancing technology development and application. Cooperation can promote the sharing of knowledge and experience, speeding up the pace of technological innovation. Global cooperation can also facilitate the development and promotion of standards, ensuring consistency and interoperability of IVD technology worldwide. Collaboration can improve resource utilization efficiency, avoiding redundant research and waste of resources.

Continuous training and global cooperation in the field of IVD can promote knowledge updates and technology transfer. New scientific discoveries and technological advancements can be disseminated to healthcare professionals through training and collaboration, thus driving improvements and innovations in diagnostic technology. Knowledge updates and technology transfer contribute to addressing new disease challenges, improving diagnostic accuracy and efficiency, and further advancing IVD technology.

Continuous training, financial ecosystem support, and global cooperation contribute to improving global health levels. By training healthcare professionals, they can provide better diagnostic services, timely detection, and treatment of diseases. Financial support and global cooperation can promote the widespread application of advanced IVD technologies in various economies and regions, improving the accuracy and accessibility of diagnosis. This helps improve people's health, reduce the spread and prevalence of diseases.

Acknowledgment

This report is the culmination of an APEC-funded project dedicated to the advancement of In Vitro Diagnostics (IVD) and their transformative role in public health across the APEC member economies. The project, titled " Capacity-Building and Awareness Project for In Vitro Diagnostics for COVID-19 Management," was initiated under the guidance of the APEC Health Working Group (HWG) and is supported by the collaborative efforts of APEC member economies including Indonesia; Malaysia; Mexico; the Philippines; Thailand; Viet Nam, and other health departments from APEC member economies.

The project's objective is to promote regional collaboration and enhance IVD technology development across APEC member economies. The insights and recommendations presented in this report are the results of extensive consultations with expert representatives from APEC member economies. These consultations took place during the Workshop and the online Symposium focused on critical areas such as IVD technology innovation, laboratory medicine, disease surveillance, and the integration of IVDs in healthcare systems. The sessions were attended by over 50 participants from 6 APEC economies, including representatives from government bodies, research institutes, healthcare providers, and non-governmental organizations.

The project organizers extend their heartfelt gratitude to all the speakers and participants who generously shared their expertise and insights during the thematic sessions. A list of key experts is included in Annex 3 of this report.

Annex 1 Survey Questionnaire

Project: HWG 03 2022A

Research Questionnaire for

In vitro diagnostics (IVD) Capacity Building:

Challenges and Solutions

Thank you for participating in this survey! The aim is to understand challenges faced in capacity building for in vitro diagnostics (IVD) across various domains and potential solutions. Your response will greatly assist in the organization of this workshop.
What challenges does the development and capacity building of IVD face? Are there solutions?
Please answer based on the domain you are familiar or specialized in. If it's outside of your expertise, we hope you will add comments related to your domain at the end:

Basic Information (Optional):
Name:
Position:
Organization/Institution:
Years of experience in IVD:

General Challenges:

For IVD Regulatory Harmonization:
Harmonization and Standardization: The Necessity and Challenges of Harmonization and Standardization in Clinical Testing
What do you think is the biggest challenge in Regulatory Harmonization?

How can cross sector collaborations be achieved?

Quality Systems:
What are the common issues and challenges in quality systems?

Clinical Utility/Performance:
What are the main barriers you have encountered in evaluating the clinical utility and performance of IVD?

Pre-market Evaluation:
In your experience, what are the primary challenges in pre-market evaluation?

Annex 2 Cross-economy IVD Innovations

Economy	Key Contribution	Impact
China	Regulatory harmonization (YY/T standards), IVD export growth	Supplied 84.6B RMB diagnostics globally in 2021
Malaysia	Decentralized PCR for encephalitis (Sibu Hospital)	Reduced acyclovir use by 40%, cost savings of RM146.70/test
Mexico	Standardized IVD validation (CLSI/ISO)	Reduced HPV test variability; 18.2% tests clinically validated
Thailand	Rapid IgM/IgG tests (ISO 13485-compliant)	99.2% specificity in Samut Sakhon outbreak containment

Annex 3 List of Experts

Ms. Falah SAFIRA, Directorate of Pharmaceutical and Medical Devices Resilience, Ministry of Health Indonesia
Dr. Handika Yudha Kusuma, Directorate Production and Distribution of Medical Device, Directorate General of Pharmaceutical and Medical Devices, Ministry of Health, Indonesia
Dr. Jeffrey Lee, Research Medical Officer, Clinical Research Centre, Sibu Hospital, Ministry of Health Malaysia
Professor Dr. Toh Teck Hock, Clinical Research Centre, Sibu Hospital, Ministry of Health Malaysia
Dr. Noé Escobar Escamilla, Technology Development and Molecular Research Unit, InDRE; General Direction of Epidemiology, Ministry of Health of Mexico
Dr. Kyle Cedric Pilongo, Licensing Officer II, Center for Device Regulation, Radiation Health, and Research (CDRRHR), Food and Drug Administration, the Philippines
Ms. Lapasrada PATTARAPREEYAKUL, Department of Medical Sciences, Ministry of Public Health, Thailand
Dr. Panadda DHEPAKSON, Medical Life Sciences Institute, Department of Medical Sciences, Ministry of Public Health, Thailand
Mr. Nguyen PhuongNam, Vice Head of Pharmacy, General Hospital of Hanam Province, Viet Nam
Dr. Phan Anh Phong, Director General, General Hospital of Hanam Province, Viet Nam
Ms. Alicia Zhang, Asia Pacific Medical Technology Association (APACMed)
Dr. Beining Guo, Associate Professor, Huashan Hospital of the Shanghai FuDan University Medical College, PRC
Dr. Da Li, Beijing Institute of Medical Device Testing (BIMT), PRC
Dr. Guanhua Rao, CMO, GensKey Biotechnologies, PRC
Dr. Jeff Jianfei Yang, CSO, Phil Rivers Technology, PRC
Dr. Jian Yang, Associate Dean for Academic Aairs, School of Life Sciences, Westlake University, PRC; Deputy Director, Westlake Laboratory of Life Sciences and Biomedicine, PRC
Dr. Jiatao Lou, Centre for Laboratory Medicine, Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine, PRC
Dr. Jing Yao, Deputy Director, General Hospital of the Chinese People's Liberation Army, PRC
Dr. Jun Pan, Attending Physician, The First Affilliated Hospital Zhejiang University School of Medicine, PRC
Dr. Jun Zhang, Chairman of the Laboratory Medicine Committee, Zhejiang Medical Association; Director of the Clinical Laboratory Department, at Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, PRC

Mr. Kunhui Hu, Shenzhen YHLO Biotech CO., LTD. Representing PCEM (Professional Community of Experimental Medicine, National Association Health Industry Enterprise Management), PRC
Dr. Li Jiang, Director of Laboratory Medicine, Sichuan Academy of Medical Sciences, Sichuan Provincial People's Hospital, PRC
Dr. Lin Yang , School of Engineering, Westlake University, PRC
Dr. Luang Xu, R&D Director, Westlake Omics (Hangzhou) Biotechnology Co., Ltd., PRC
Dr. Qiaoqiao Huang, Deputy Director, Center for Medical Device Evaluation and Inspection, Zhejiang Medical Products Administration, PRC
Dr. Qimin You, Founder, Ustar Biotechnologies (Hangzhou) Ltd., PRC
Dr. Rui He, Section Chief, Center for Medical Device Evaluation and Inspection, Zhejiang Medical Products Administration, PRC
Dr. Shuijun Li, Director of Laboratory Medicine, Shanghai Xuhui Central Hospital, PRC
Dr. Tianjiao Zhang, National Center for Clinical Laboratories (NCCL), PRC
Dr. Tiannan Guo, Westlake University, PRC
Dr. Wei Guo, Director of Laboratory Medicine, Zhongshan Hospital Fudan University, PRC
Dr. Xiaobo Yu, National Center for Protein Sciences (Beijing), PRC
Dr. Xueqing Qian, Chairman, Shanghai RundaRongjia Biological Technology Co., Ltd. PRC
Dr. Yan Feng, Dean, School of Life Sciences and Biotechnology, Shanghai Jiao Tong University, PRC
Ms. Yan Zhang, Principal Project Consultant, Roche Diagnostics, PRC
Dr. Yanan Zhang, Research and development scientists, 3DMed DIAGNOSTICS, PRC
Dr. Yangmu Huang, Department of Global Health, Peking University School of Public Health, PRC
Dr. Yilin Wang, Deputy Director of Laboratory Medicine, Shanghai General Hospital, PRC
Dr. Yingshu Zou, Senior Engineer, Beijing Institute of Medical Device Testing, PRC
Dr. Yu Wang, Fudan University Cancer Hospital, PRC
Dr. Zhaohua He, Deputy Director General, Department of International Cooperation, National Health Comission of the PRC
Mr. Zhenxi Liu, Chief Investment Officer, FOSUN DIAGNOSTICS, PRC
Dr. Ziwei Wang, Director of Laboratory Medicine (Retired), Hangzhou First People's Hospital, PRC