Asia-Pacific
Economic Cooperation

APEC Diagnostics Landscape Assessment



APEC Health Working Group
November 2026

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About APEC

The Asia-Pacific Economic Cooperation (APEC) is a regional economic forum consisting of 21-member economies who aim to create greater prosperity for the people of the region by strengthening health systems in support of sustainable economic growth. APEC operates as a cooperative, multilateral forum. Member economies participate on the basis of consensus and respect for the views of all participants. There are no binding commitments or treaty obligations within APEC. Commitments are undertaken on a voluntary basis and the principle of consensus and are implemented as appropriate based on the individual circumstances and conditions in each economy.

Capacity building programs play an important role in APEC as technical skills, resources, and capabilities vary considerably across the 21-member economies, which include Australia; Brunei Darussalam; Canada; Chile; People's Republic of China; Hong Kong, China; Indonesia; Japan; Republic of Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; The Republic of the Philippines; The Russian Federation; Singapore; Chinese Taipei; Thailand; United States; Viet Nam.

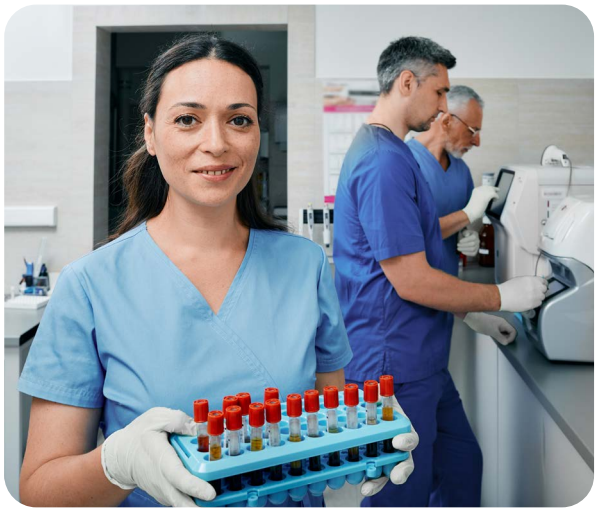
The APEC Diagnostics Landscape Assessment was developed in accordance with these fundamental principles and guidelines.



Executive Summary

Diagnostics adoption across Asia-Pacific Economic Cooperation (APEC) economies is entering a critical decade shaped by the dual role of the Coronavirus Disease 2019 (COVID-19) pandemic as both a stress test and an accelerator of reform. The pandemic revealed long-standing weaknesses in regulatory clarity, laboratory systems, supply chains, and domestic manufacturing capacity. At the same time, it prompted rapid modernization in regulation, reimbursement structures, procurement models, and data systems. Today, most APEC member economies have established the foundational elements of a diagnostic policy ecosystem – such as clearer regulatory mandates, emerging reimbursement frameworks, laboratory networks, and early-stage innovation environments – although the level of progress varies widely.

This report evaluates the readiness of APEC economies to support and sustain diagnostic innovation and access – globally, approximately 70% of healthcare decisions are made based on diagnostic test results, but only 3 to 5% of healthcare budgets go to diagnostic services.[1] Underinvestment in diagnostics functions as a cost-deferral mechanism, generating higher downstream fiscal and health burdens, particularly for non-communicable diseases. While the COVID-19 pandemic exposed these structural weaknesses in diagnostic systems, APEC economies are simultaneously experiencing sustained population aging and increasing prevalence of non-communicable diseases, both of which are driving greater demand for more sophisticated and advanced diagnostic capabilities.



To address this evidence gap and support APEC's commitment to strengthened diagnostics systems, this assessment evaluates the policy, institutional, regulatory, and infrastructural readiness of APEC member economies through a structured benchmarking framework. The framework applies seven interrelated policy indicators, covering economy-specific strategy, regulatory governance, financing, infrastructure, sector development, and market access, to provide a standardized baseline of diagnostic policy maturity and identify priority areas for coordinated regional action. These indicators were adapted from international benchmarking approaches and refined with expert input to reflect both health-system and industrial-policy perspectives relevant to APEC economies across all income levels.

Importantly, the maturity of diagnostics policy within APEC is not solely determined by income level. While many high-income economies have advanced, integrated systems, several middle-income members have demonstrated strong strategic coordination, institutional agility, and targeted reforms that allow them to outperform larger or wealthier economies where governance remains fragmented. Across APEC, differences in outcomes reflect variations in policy coherence, institutional capacity, and execution rather than resource availability per se. This highlights a pattern characterized by convergence in intent but divergence in implementation.

Institutional and regulatory coherence has improved but remains incomplete. While there is a growing recognition of diagnostics as a strategic priority, few economies have adopted a dedicated, economy-wide diagnostics strategy. Diagnostics instead tend to be embedded within broader health, innovation, or industrial plans, which elevates their visibility but also diffuses governance accountability. Regulatory convergence efforts – particularly through the APEC Regulatory Harmonization Steering Committee (RHSC) and the Association of Southeast Asian Nations (ASEAN) – have yielded progress in aligning standards and practices. However, implementation continues to lag due to uneven institutional readiness, limited assessor capacity, siloed authority across regulators, laboratories, and payers, and the persistent classification of in vitro diagnostics (IVDs) under general medical-device regulations. Gaps in digital infrastructure and interoperability further constrain regulatory effectiveness.

Financing and infrastructure developments reflect similar disparities. High-income economies typically reimburse diagnostics through domestic insurance and preventive-health schemes, supporting consistent access and innovation adoption. Middle-income economies often rely on pilot programs, partial reimbursement mechanisms, or disease-specific funding streams, while lower-income members remain dependent on donor financing. Although pandemic-era investments expanded laboratory facilities, Laboratory Information Management Systems (LIMS), and logistics networks, these gains have not been matched by long-term improvements in workforce capacity, data governance, or supply-chain resilience. Rural and remote areas continue to face shortages, stock-outs, and connectivity gaps, underscoring the need for both qualitative improvement and systems-level integration.

Taken together, these trends place APEC economies' diagnostic ecosystem at a defining transition point. The essential building blocks – diagnostic strategies within each economy, regulatory frameworks, financing pathways, infrastructure, innovation pipelines, and accreditation programs – are now largely in place. The region's central challenge is no longer awareness or intent, but deepening institutional coordination, securing sustainable fiscal integration, and operationalizing interoperability.

Achieving the transitions from fragmented capacity to integrated networks, from regulatory alignment to mutual recognition, and from infrastructure expansion to full interoperability would position APEC to strengthen regional health resilience and also serve as a global model for diagnostics-driven innovation and preparedness.

APEC Diagnostics Readiness by Indicator – Regional Progress (%)

Seven indicators were assessed across 21 APEC member economies on a 0–1 scale and converted to regional readiness percentages. Each indicator is scored on a three-point scale (0, 0.5, 1) based on documented evidence, and these scores are grouped into high, medium, and low readiness bands to support internal benchmarking and quality assurance. Composite scores and the detailed scoring matrix are used only for internal analysis and are not published at economy-level in this report.

The widest gap appears in Sector Development Incentives (41%), while Regulatory Convergence shows the strongest progress (81%). The range, from 41% to 81%, indicates that no indicator has achieved comprehensive regional maturity, underscoring that all economies have both the opportunity and the need to advance their diagnostic policy infrastructure.

Table: APEC Diagnostics Readiness by Indicator (% Regional Progress)

01

Diagnostics Strategy

Existence and implementation of a dedicated or integrated economy-level strategy for diagnostics development and access.

48%

Most economies lack dedicated strategy; diagnostics embedded in broader plans.

02

Dedicated Oversight Entity

Institutional presence of a specialized agency or taskforce coordinating diagnostics policy and governance.

45%

Governance fragmented across agencies; mandate overlaps common.

03

Regulatory Convergence

Degree of harmonization with regional norms and operationalization of risk-based, reliance-based approval systems.

81%

Regional harmonization advancing through IMDRF, GHWP, APEC RHSC and AMDC; operationalization still emerging.

04

Public Financing Models

Availability of public reimbursement, insurance coverage, or other fiscal mechanisms supporting diagnostic access.

45%

Financing remains fragmented and disease-specific; comprehensive reimbursement incomplete.

05

Sector Development Incentives

Policies and incentives that lower market-entry barriers, catalyze private investment, and build a sustainable, competitive diagnostics ecosystem.

41%

Incentives exist but are generic and weakly coordinated with health system demand.

06

Infrastructure and Laboratory Systems

Availability and quality of laboratory and point-of-care networks, including accreditation, digital integration, and workforce capacity.

71%

Infrastructure expanded rapidly, but digital integration and workforce gaps persist.

07

Market Access

Predictability of import, procurement, and reimbursement processes, including digital registration systems and equity measures.

62%

Market access improving; procurement and pricing transparency still needed.

Introduction

This report was developed to answer a simple but critical question: *how ready are Asia–Pacific Economic Cooperation (APEC) economies to support and sustain diagnostic innovation and access?* While approximately 70% of healthcare decisions are made based on diagnostic test results, only 3 to 5% of healthcare budgets go to diagnostic services. This reflects systematic undervaluation that manifests in a fragmented policy landscape, inconsistent infrastructure, and delayed innovation adoption.[2] In most economies, the cost of non-diagnosis is not avoided but deferred, and ultimately borne downstream through higher public expenditure. When conditions go undetected, health systems incur avoidable costs through increased emergency admissions, longer hospital stays, more complex and expensive interventions, and sustained productivity losses.

This dynamic is especially evident for non-communicable diseases (NCDs). Late detection shifts care pathways away from low-cost prevention and early outpatient management toward high-cost hospitalization, intensive treatment, and long-term disease management. Each delayed diagnosis increases per-patient lifetime costs, raises recurrent budget obligations, and reduces fiscal space for preventive care and system strengthening. From a public finance perspective, underinvestment in diagnostics functions as a cost deferral mechanism that ultimately magnifies future health liabilities rather than containing them. The COVID-19 pandemic exposed this vulnerability and APEC economies with pre-existing diagnostics strategies and coordinated laboratory networks demonstrated superior testing scale-up compared to those lacking strategic frameworks.[3]



The consequences extend beyond efficiency losses. Aging populations across APEC economies, where the share of those over 65 will nearly double to 22% by 2050, drive escalating demand for oncology, cardiovascular, and neurodegenerative diagnostics, while infectious disease burdens persist in emerging APEC economies.[4] Non-communicable diseases are expected to cause over 80% of all deaths in the region, yet many APEC jurisdictions lack systematic screening programs and timely diagnostic capacity for early detection.[5] Simultaneously, APEC Health Ministers have emphasized the transformative potential of AI-enabled diagnostics, precision medicine, and digital health platforms, yet their diffusion remains constrained by policy misalignment rather than technical limitations.

This benchmarking exercise addresses a critical evidence gap. Drawing from international benchmarking frameworks, this report uses seven indicators to evaluate the policy, infrastructural, and institutional foundations that determine whether diagnostic tools reach people quickly and safely. By comparing these indicators across economies, the report provides both an evidence base to help identify where systems are strong, where they are lagging, and where coordinated action is needed most.

Together, they offer a snapshot of how well each economy has translated the lessons of the pandemic into lasting policy resilience. This report is therefore not only an assessment tool but a **call to reimagine diagnostics policy as a core enabler of health security, innovation, and improved access across the region. Accordingly, the scorecard is designed as a practical document to support economies in their self-assessment, facilitate peer learning, and inform targeted technical cooperation.**

The analysis reveals that diagnostics policy maturity within APEC is not determined by wealth alone – middle-income member economies with strategic coordination often outperform larger economies lacking coherent governance. This suggests that policy design choices matter more than starting conditions, and that coordinated action among APEC economies through existing mechanisms like the Health Working Group and RHSC, or any other platforms could close current gaps. By establishing transparent baselines, identifying best practices among APEC members, and catalyzing regional dialogue, this scorecard supports a fundamental shift: treating diagnostics as a distinct, strategically important health system domain deserving dedicated governance frameworks and vehicles within APEC's regional cooperation architecture.



Research Scope

This research aims to assess the readiness and maturity of diagnostic policy structures across the 21 APEC member economies, using an indicator-based methodology. The scope encompasses policy, regulatory, institutional, financing, and infrastructure dimensions of diagnostics readiness, reflecting both health-system and industrial-policy perspectives. The study situates diagnostics not merely as clinical tools but as critical enablers of health security, innovation, and sustainable economic development.

1. Geographic and Institutional Scope

The research covers all 21 APEC economies, spanning high-income, upper-middle-income, and lower-middle-income contexts. This diversity provides a comparative lens to analyze how varying levels of economic development shape diagnostic system evolution. The study focuses on policy frameworks within each member economy's institutional arrangements, including ministries of health, industry, and finance, rather than individual hospitals or provincial/federal programs. Regional mechanisms (e.g. APEC RHSC) and ASEAN Medical Device Committee (AMDC) are included where relevant to capture regional policy convergence efforts.

2. Analytical Framework and Indicators

This scorecard applies seven interrelated policy indicators to assess diagnostics readiness across the 21 APEC member economies. Together, these indicators provide a standardized baseline of regulatory and policy preparedness for diagnostic technology development and access, covering strategy, governance, regulation, financing, infrastructure, sector development, and market access. The indicators were adapted from international benchmarking approaches and refined with expert input to reflect both health-system and industrial-policy perspectives relevant to APEC. In practice, they operate as a system: weaknesses in one dimension (for example, public financing) constrain progress in others (such as sector development and market access), while targeted reforms can generate reinforcing effects across the diagnostics value chain:



Indicator 1: **Diagnostics Strategy**

This indicator assesses the highest level of government commitment: the existence of a formal, high-level, actionable plan dedicated to developing a diagnostics ecosystem within each economy that guides subsequent implementation and financing decisions. A diagnostics strategy reduces uncertainty for investment, accelerates access to innovative tools, and signals sustained government priority, making it a core marker of readiness and ecosystem maturity.

Indicator 2: **Dedicated Oversight Entity**

This indicator looks at the presence of a specialized governmental body or taskforce overseeing diagnostics policy and regulation. A dedicated oversight entity enables coordinated governance, clearer accountability, and better alignment with health priorities, reducing fragmentation across agencies and strengthening the capacity to steward sustainable diagnostics expansion.

Indicator 3: **Regulatory Convergence and Agility**

This indicator examines whether economies have a comprehensive regulatory framework for diagnostics (including IVDs and related technologies) and the degree to which it is harmonized with international standards. A convergent, risk-based regulatory framework reduces duplication, accelerates approvals, and builds trust among manufacturers and providers, positioning diagnostics systems to adopt innovation safely and efficiently.

Indicator 4: **Public Financing Models**

This indicator assesses the availability of public funding mechanisms that support access to diagnostic technologies. Robust public financing reduces out-of-pocket expenditure, supports improved access, and underpins the scale-up of innovative diagnostics, making it a critical determinant of long-term affordability and system resilience.

Indicator 5: **Sector Development Initiatives**

This indicator examines policies specifically designed to encourage ddiagnostics industry development, including R&D and manufacturing. Targeted sector incentives lower market-entry barriers, catalyze private investment, and support the emergence of a sustainable, competitive diagnostics ecosystem that can respond to regional needs over time.

Indicator 6: **Infrastructure and Laboratory Systems**

This indicator measures the presence of adequate diagnostics infrastructure, including high-throughput (HTP) laboratories and decentralized point-of-care capacity, supported by quality systems and digital connectivity. Strong infrastructure underpins timely access to diagnostics, supports workforce effectiveness, and reflects an economy's ability to deliver complex and essential tests across both urban and rural settings.

Indicator 7: **Market Access**

This indicator evaluates whether diagnostics benefit from clear, predictable pathways for market entry, including importation, procurement, pricing, reimbursement, and supply chain readiness. A coherent market access framework supports affordability, transparency, and reliable availability of diagnostics, and its presence signals government commitment to integrating diagnostics into routine care.

3. Scope Limitations

The research focuses on policy and institutional readiness, not clinical performance or epidemiological outcomes. While it assesses alignment with regional standards, it does not rank economies by competitiveness or innovation output. Instead, it seeks to illuminate systemic strengths, reform trajectories, and policy bottlenecks relevant to advancing regional diagnostics capacity. The analysis is also based on publicly available policies, stakeholder inputs, and secondary sources, which may not fully capture informal implementation practices across economies members.

Summary of Findings

APEC economies are institutionalizing diagnostics strategy into their policy frameworks. Across the APEC membership, most economies now possess at least some elements of a coherent diagnostics policy environment: defined policy mandates, public funding instruments, laboratory infrastructure, and a growing innovation base. The COVID-19 pandemic served as a structural accelerator, driving digitalization, procurement reforms, and incentives for domestic manufacturing. However, the post-pandemic normalization period has revealed uneven capacity and institutional gaps.

High-income economies exhibit a convergence between regulation, industrial strategy, and health-system financing. Diagnostics in these economies are embedded within universal coverage frameworks and supported by R&D pipelines, ISO-accredited laboratory networks, and public–private partnerships for production.

Upper-middle-income members show dynamic progress but remain in transitional phases, with fragmented governance and partial reliance on global reference approvals. Lower-middle-income economies continue to rely on donor-driven initiatives, vertical disease programs, and ad-hoc import mechanisms.

Across APEC, there is strong convergence in vision where most economies now explicitly recognize diagnostics as central to health security, industrial development, and innovation. The trend is reflected in post-COVID pandemic preparedness strategies, the adoption or expansion of economy essential diagnostics lists, and the incorporation of diagnostics within life-sciences and biotech industrial roadmaps in economies such as People's Republic of China; Republic of Korea; Singapore. Yet divergence persists in execution.

Case study examples

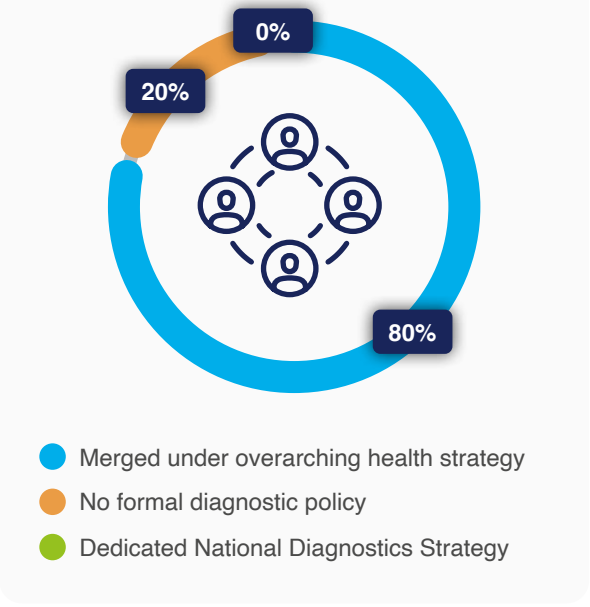
Economy	Republic of Korea	Malaysia	Singapore
Baseline	Laboratory networks were strong but data integration between labs and public health surveillance systems was fragmented, limiting real-time visibility during outbreaks.	IVD approvals relied primarily on full domestic review processes, leading to longer timelines and higher regulatory burden for manufacturers.	Diagnostics governance and approval processes were largely embedded in general medical device frameworks, with limited explicit emphasis on diagnostics as a distinct strategic priority.
Result	Expanded LIMS adoption and improved interoperability with monitoring platforms now enable faster reporting, better outbreak monitoring, and more coordinated public health response.	The Medical Device Authority (MDA) operationalized risk-based, reliance pathways that allow reference regulator approvals to inform domestic decisions, materially shortening review timelines while maintaining rigor.	Diagnostics are now explicitly integrated into health security, life sciences, and biotech roadmaps within each economy, aligning MOH, regulatory, and industrial policies to support innovation, rapid adoption, and pandemic preparedness.
Indicator	Indicator 6: **Infrastructure & Laboratory Systems**	Indicator 3: **Regulatory Convergence**	Indicator 1: **Diagnostics Strategy**

Indicator 1: Diagnostics Strategy within each APEC economy

No APEC economy maintains a dedicated economy-level diagnostics strategy, but almost all economies include diagnostics within broader health, innovation, or industrial plans. In advanced economies, diagnostics are governed through codified, risk-based, and globally harmonized regulation that acts as a de facto strategy and robust post-market vigilance, together functioning as integrated roadmaps that operationalize access, quality, and innovation without a standalone diagnostics plan. These economies coordinate their ministries to synchronize R&D, market access, and health insurance coverage. This creates an enabling environment for rapid translation of innovation into practice.

Middle-income members are at an earlier stage, drafting stand-alone diagnostic policies, often under communicable-disease preparedness frameworks, or pursuing integration through digital-health or pharmaceutical strategies. The trend is positive, with the conceptual visibility of diagnostics improved, but many economies still lack whole-of-government steering units, long-term investment frameworks, and accountability metrics to sustain implementation.

In lower-income economies, the diagnostic strategy remains largely implicit rather than formalized. Policy is driven by donor-supported programs, vertical disease initiatives, and emergency preparedness needs, with limited integration into health financing, industrial policy, or innovation agendas within each economy. Diagnostic investments decisions are often reactive and fragmented, constrained by fiscal limitations, workforce shortages, and weak planning capacity. As a result, the diagnostics systems in these economies are vulnerable to supply disruptions and less able to support early detection or routine care beyond priority diseases.



The principal constraint across all economies is the absence of whole-of-government coordination mechanisms. Many lack formal steering units, long-term investment frameworks, and performance or accountability metrics to translate strategic intent into sustained implementation. This limits coherence across policy, regulation, financing, and innovation functions. In practice, diagnostics strategy (Indicator 1) only translates into system-level change when it is backed by a clear lead oversight entity (Indicator 2), adequate public funding (Indicator 4), and incentives for sector development (Indicator 5).

APEC economies have an opportunity to strengthen their diagnostic strategy by institutionalizing cross-ministerial coordination mechanisms that align health, industry, science, and finance portfolios. Developing integrated diagnostics roadmaps, whether as standalone instruments or embedded within existing strategies, could provide clearer investment signals, improve accountability, and support more systematic progression toward resilient and innovation-driven diagnostics systems.

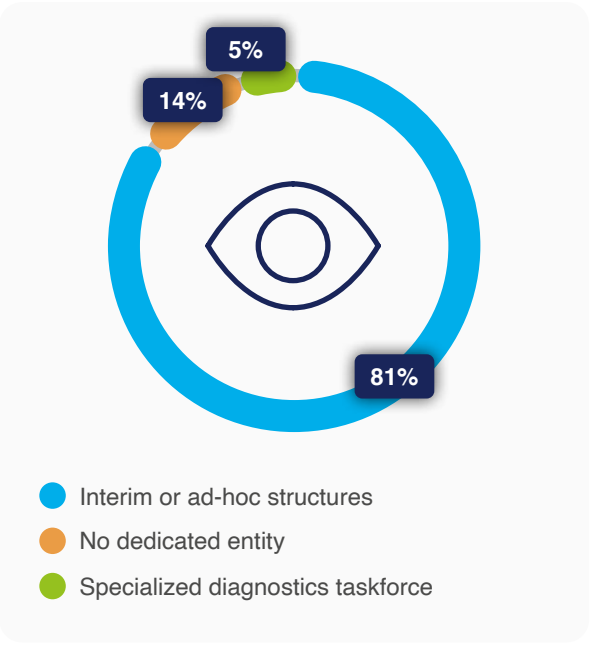
Indicator 2: Dedicated Oversight Entity

Diagnostic governance models across APEC are highly heterogeneous, so strengthening lead oversight entities, establishing formal inter-agency coordination, and having shared digital systems are key to improving system readiness. Advanced economies operate centralized regulatory authorities supported by specialized laboratory, accreditation, and biosurveillance bodies. These regulators hold clear mandates for IVD oversight, market authorization, vigilance, and quality assurance, therefore facilitating system-level accountability.

Middle-income economies typically distribute roles across multiple agencies: Ministries of health oversee policy, laboratory networks, and biosafety; specialized medtech regulators handle device/IVD licensing; accreditation bodies manage conformity assessment; and industry ministries supervise manufacturing and R&D.

This multi-agency model can be effective but often suffers from mandate overlaps, inconsistent technical capacity, and weak data exchange. Several economies lack a single body empowered to coordinate diagnostics across policy, regulation, quality assurance, and innovation – resulting in duplicated processes (e.g., separate approvals from ministries of health, standards agencies, and customs).

Lower-income members often rely on donor-supported structures, ad-hoc technical committees, or program-specific oversight bodies with limited legal authority. These arrangements struggle to integrate surveillance, laboratory, and regulatory functions, constraining system readiness.



Region-wide, governance is improving, but most economies still lack formal inter-ministerial governance platforms, centralized regulatory leadership, or public-private coordination mechanisms capable of steering the sector comprehensively. Without such coordinating entities (Indicator 2), diagnostics strategies (Indicator 1) remain difficult to implement, regulatory convergence (Indicator 3) is harder to operationalize, and financing and sector incentives (Indicators 4–5) are less likely to be aligned.

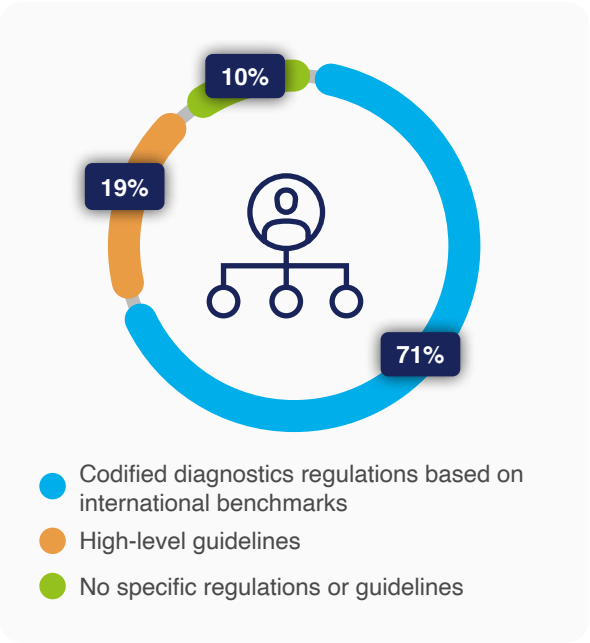
APEC economies could strengthen diagnostics governance by establishing or empowering lead oversight entities with clear coordinating mandates, supported by formal inter-agency mechanisms and shared digital infrastructure. Regional peer learning and technical cooperation, particularly on regulatory reliance, data exchange, and post-market surveillance, could further enhance governance effectiveness while respecting economy-specific institutional models.

Indicator 3: Regulatory Convergence

Gradual convergence is unfolding although hindered by uneven institutional readiness. Mature regulators use globally benchmarked, risk-based classification systems, electronic registration portals, and reliance/abridged review options. These systems reference approvals from major trusted authorities (e.g. U.S. Food and Drug Administration, EU In Vitro Diagnostic Regulation (IVDR)) and increasingly align with the International Medical Device Regulators Forum (IMDRF). Formalized post-market surveillance systems further strengthen their global competitiveness.

Upper-middle and lower-middle-income economies commonly regulate IVDs through general medical-device frameworks, which can be appropriate when these rules are risk-based and adapted to diagnostic technologies. Some have also introduced reliance mechanisms to streamline approvals, with implementation shaped by regulatory capacity and digital infrastructure, which influences processing timelines alongside regulatory processes.

Lower-middle-income economies are also beginning to internalize convergence concepts. In Viet Nam, regulators have started accepting supporting evidence from approvals granted by trusted foreign authorities as part of the review process. While limited assessor capacity and digital infrastructure continue to constrain speed, early experience suggests that even partial reliance can reduce regulatory bottlenecks and improve market entry timelines for diagnostics. APEC RHSC and AMDC have accelerated dialogue, but true interoperability - where data from one economy can reliably inform approval in another - remains nascent. Progress is especially slow in economies without centralized medical devices regulatory bodies or sufficient assessor capacity. Institutionalizing policy reliance mechanisms with clear reference lists, building regional training pipelines for assessors and auditors, and digitizing submission and tracking systems to replace manual workflows could sustain progress.



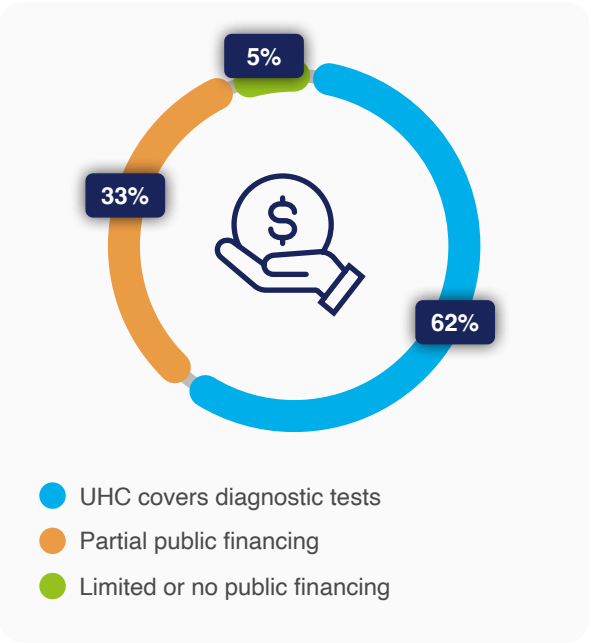
Fragmented regulatory autonomy is giving way to structured dialogue, but operational equivalence remains elusive. While convergence principles are increasingly aligned, gaps in assessor expertise, digital systems, and post-market data integration limit the ability of economies to operationalize reliance and achieve functional interoperability. Regulatory convergence (Indicator 3) is also a critical enabler of market access (Indicator 7): more predictable, reliance-based approvals reduce time-to-market and give payers and manufacturers clearer signals for pricing, procurement, and investment. APEC platforms such as the RHSC provide a foundation for deeper convergence. To complement these efforts, establishing a dedicated regional platform to convene stakeholders on institutionalizing regulatory reliance – including developing clear reference authority lists, strengthening regional training pipelines for assessors and auditors, and digitizing submission – could help move the region beyond harmonization discussions toward operational equivalence and mutual trust.

Indicator 4: Public Funding

Public investment in diagnostics has expanded across APEC but still leans toward disease-specific funding rather than comprehensive benefit integration. In high-income economies, diagnostics are routinely reimbursed through public insurance or prevention subsidies. For example, some economies cover recommended screening tests, while other economies' social health insurance integrates diagnostics within bundled clinical pathways.

Middle-income economies are experimenting with coverage pilots for select conditions (e.g., oncology, maternal health), yet these rarely scale due to limited fiscal space, weak tariff benchmarking, and gaps in cost-effectiveness evidence. In practice, some economies subsidize targeted screening within tax-funded systems but lack comprehensive reimbursement for advanced molecular tests; others provide broad essential diagnostics services, with advanced tests undergoing health technology assessment (HTA) prior to routine coverage. The effectiveness of this approach depends on the availability of robust HTA capacity for IVDs and medical devices. Meanwhile, lower-income members continue to rely heavily on donor financing, emergency budgets, or vertical disease programs, resulting in fragmented and unpredictable funding for diagnostics.

A regional challenge lies in transitioning from episodic donor or emergency funding toward predictable domestic budgets. This requires embedding diagnostics within Medium-Term Expenditure Frameworks (MTEF) and developing reimbursement models linked to outcomes. A few economies are exploring pay-for-performance schemes and pooled procurement for essential diagnostics.



Overall, APEC economies have an opportunity to ensure that funding reform moves from a focus on quantity toward quality and sustainability. While fiscal attention has grown, diagnostics remain peripheral to core health financing in many economies. Integrating them into essential health benefit packages and establishing transparent pricing and reimbursement evaluation systems will be critical next steps. Crucially, predictable reimbursement and budget integration under public funding (Indicator 4) are the primary engine for sector development incentives (Indicator 5): without a reliable funded market, manufacturers and innovators cannot justify long-term investment in production capacity or quality systems.

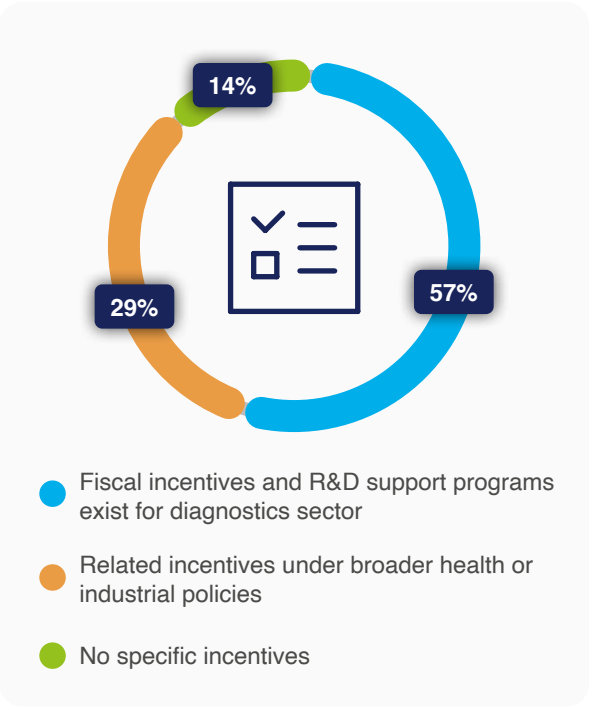
Indicator 5: Sector Development Incentives

Across APEC, sector development incentives for diagnostics exist, but their scope, design, and effectiveness vary substantially depending on income level. High-income members typically use coordinated, long-term industrial policy instruments, while middle-income and lower-income members rely on narrower, fragmented measures that do not yet create a predictable environment for private-sector investment.

High-income economies generally operate well-structured incentive ecosystems. These include:

- R&D tax credits for diagnostics and biomedical technologies
- Co-funding programs that share development costs between government and industry
- Innovation hubs and testbeds that provide access to research facilities, biotech clusters, and clinical validation
- Export promotion schemes that support regional market expansion for locally developed tests

What differentiates these systems is their alignment between industrial policy and health system priorities. High-income members typically match industrial incentives with clear domestic demand signals, such as reimbursement pathways, quality standards, and predictable procurement. This creates a reinforcing loop where innovation is accompanied by market certainty. In other words, sector development (Indicator 5) is most effective where public funding and reimbursement (Indicator 4) provide the stable demand base on which firms can plan and scale manufacturing.



Middle-income economies increasingly offer incentives, but these are often broad, medical-device-wide programs rather than diagnostics-specific strategies. Common tools include:

- Tax holidays or import-duty exemptions for manufacturing equipment
- General innovation grants without dedicated diagnostics criteria
- Industrial park incentives that improve access to land, utilities, or shared infrastructure

However, these incentives rarely connect to health system demand. Procurement remains price-driven, reimbursement is limited, and validation infrastructure is often incomplete. As a result, manufacturers face uncertainty about whether products will be adopted by public health systems. This limits the commercial viability of moving from small-scale assembly to high-value production. Lower-income economies display the least-developed incentive systems.

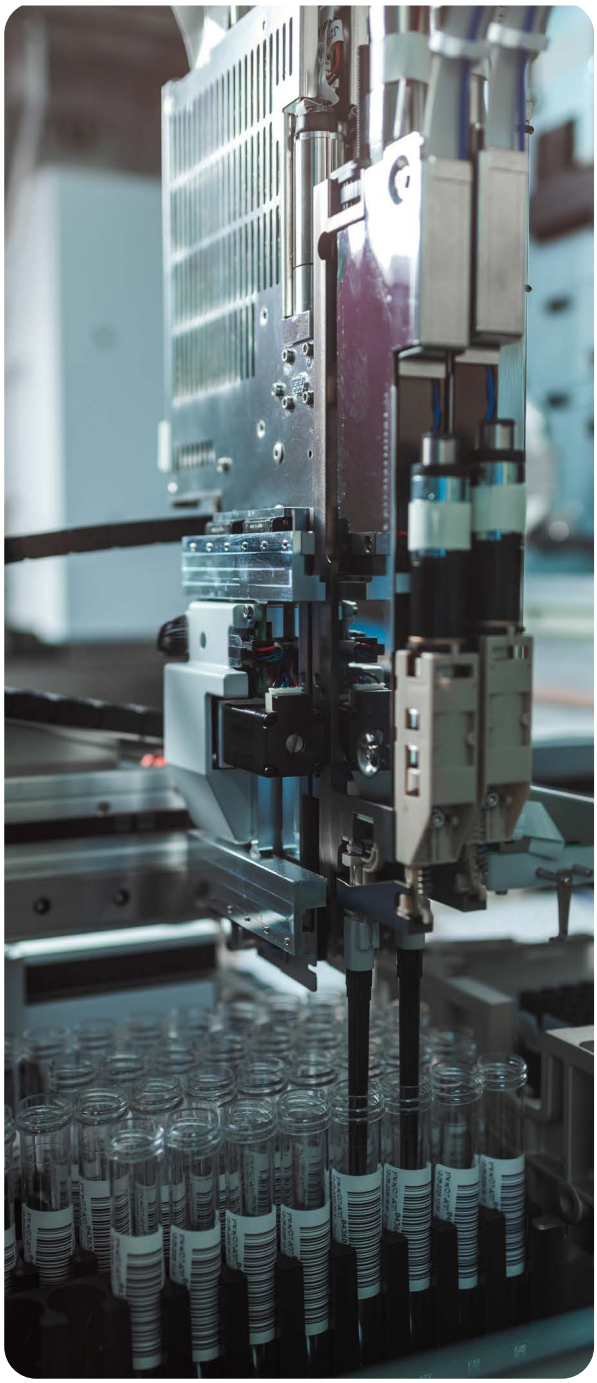
Their measures are typically limited to:

- Basic tariff exemptions
- Ad hoc tax reductions
- Occasional donor-supported technology transfer initiatives

These economies face structural gaps including limited domestic capital for diagnostics R&D, weak technical know-how, insufficient incentives to attract and retain specialized human capital, inconsistent procurement forecasting, limited good manufacturing practices (GMP)-compliant manufacturing capacity, and underdeveloped regulatory environments. Without predictable market pull-factors, private investors have limited motivation to enter or scale within the diagnostics sector.

Across all income groups, a persistent challenge is the absence of sustained demand mechanisms, such as reimbursement, essential diagnostics lists linked to financing, or innovation-friendly procurement criteria. Without these, industrial incentives function as temporary stimulants rather than long-term drivers of sector growth.

A major opportunity lies in regional collaboration. Shared clinical-validation platforms, pooled R&D funds, harmonized industrial standards, and cross-border manufacturing networks could significantly lower entry barriers, especially for middle- and lower-income members.



Indicator 6: Infrastructure & Laboratory Systems

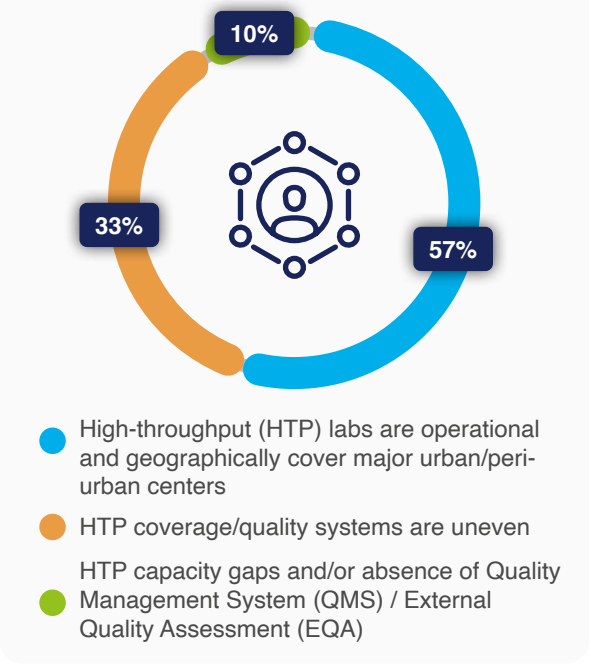
Infrastructure capacity is expanding rapidly; however, persistent gaps in digital integration and workforce capability continue to constrain system effectiveness.

Economies with broad geographical coverage operate tiered economy-level laboratory networks, especially high-throughput (HTP) labs with accredited quality systems, which signals an economy has advanced, scalable testing infrastructure to handle economy-wide screening or large-scale testing during outbreaks, and strong biosafety compliance.

These are commonly observed in advanced economies, where they typically maintain consolidated laboratory networks with standardized quality assurance, mature biosafety protocols, and widespread adoption of LIMS. These systems support real-time reporting to public health authorities and integration with surveillance platforms.

High-income economies typically maintain consolidated, tiered laboratory networks with standardized quality assurance, mature biosafety protocols, and widespread use of LIMS. These systems increasingly support real-time reporting to public health authorities and integration with surveillance platforms. Most of the high-income economies' cybersecurity has established baseline protections, including secure data hosting, access controls, and incident-response protocols.

Meanwhile, middle-income economies often rely on mixed public–private laboratory structures. While COVID-19 catalysed significant investment in polymerase chain reaction (PCR) capacity, cold-chain logistics, and data systems – gaps persist in rural coverage, supply reliability, and workforce distribution. Many are now seeking to optimize networks through consolidation, improved logistics, and incremental LIMS adoption, but integration



remains partial. Cybersecurity frameworks in these economies are uneven, while central laboratories may implement basic safeguards. Smaller private and provincial facilities often lack standardized data security protocols. Lower-income members tend to depend on donor-supported laboratories or program-specific infrastructure, with limited network planning and constrained digital integration. Cybersecurity in lower-income economies is generally minimal, with reliance on manual systems or standalone digital tools that lack secure connectivity. As digitalization expands, these economies face heightened risks of data loss, system disruption, and misuse of sensitive health information.

As economies continue to advance, interoperability between public and private systems remains limited, while gaps in cybersecurity, data standards, and connectivity infrastructure persist relative to hardware expansion. As a result, newly deployed platforms have yet to operate as a fully integrated regional diagnostic information environment.

These infrastructure and digital gaps are most acute in rural and remote areas, where laboratory access is limited, so many economies are turning to point-of-care (POC) diagnostics as a complementary approach. Across APEC, POC diagnostics – medical tests performed at or near the point of care that deliver rapid results – are increasingly used to extend access beyond centralized laboratories.

POC adoption and market growth are driven by demand for accessible testing in decentralized healthcare settings (clinics, primary care, home care), and have expanded in both high- and middle-income settings, although regulatory complexities and uneven integration into health information systems remain barriers in many middle- and lower-income economies. Investment and policy attention to POC tools such as rapid infectious disease assays and portable analyzers are seen as key to improving early diagnosis and patient management outside traditional labs, but scaling beyond pilot and ensuring connectivity to surveillance and reporting systems continues to lag infrastructure build-out.

Workforce shortages are also a recurring constraint across economies. Laboratory technologists and biomedical engineers are concentrated in major cities, while rural areas face weak retention and fragmented training. Few economies have standardized career pathways, continuous professional development, or sustained rural-service incentives beyond pilots. As a result, infrastructure expansion has outpaced service quality, reinforcing the need to prioritize network optimization, digital interoperability, and long-term human-capital investment.

APEC economies have an opportunity to shift from infrastructure expansion toward system optimization. Priorities include strengthening digital interoperability across LIMS, surveillance, and procurement platforms; establishing common data and cybersecurity standards; and investing in sustainable workforce pipelines through standardized career pathways, continuous professional development, and targeted rural-service incentives. Regional collaboration on reference laboratories, workforce training, and digital standards could further enhance resilience and help translate infrastructure investments into reliable, diagnostic service delivery. Such investments in infrastructure and digital connectivity (Indicator 6) directly support more sophisticated market-access and procurement models (Indicator 7), including reliance on real-time data for value-based purchasing and supply-chain management.

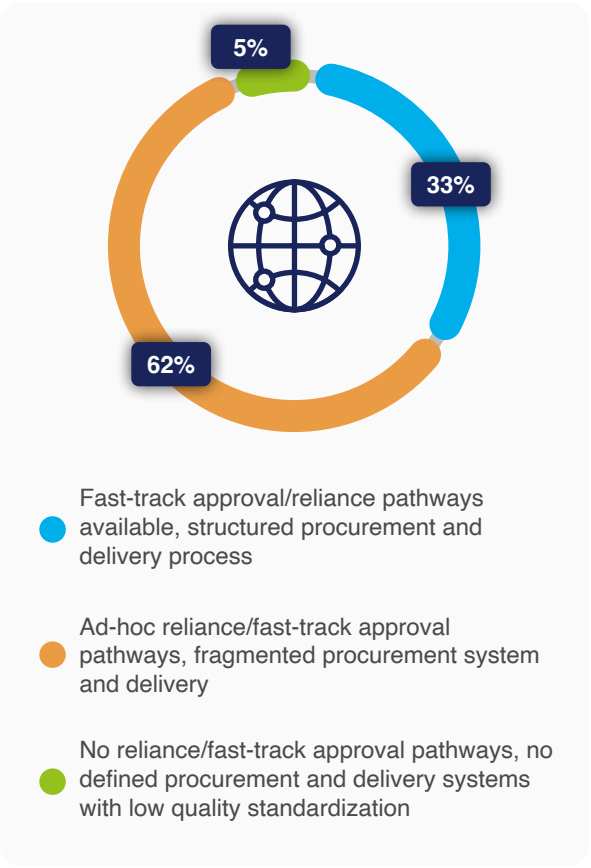


Indicator 7: Market Access

Digital access reforms are advancing across economies, yet persistent gaps in harmonization continue to limit system interoperability. Market access frameworks within APEC economies still vary. Advanced economies operate fully electronic registration portals, transparent procurement databases and predictable review timelines benefiting from Quality Management System (QMS) and External Quality Assessment (EQA), providing a stable environment for manufacturers.

Meanwhile, middle-income economies continue to face complex, multi-agency procedures that require separate submissions to health, customs, and standards authorities with uneven QMS and EQA utilization. Translation requirements, document legalization, and domestic performance verification add administrative burdens, while limited reliance or abridged pathways prolong approval times.

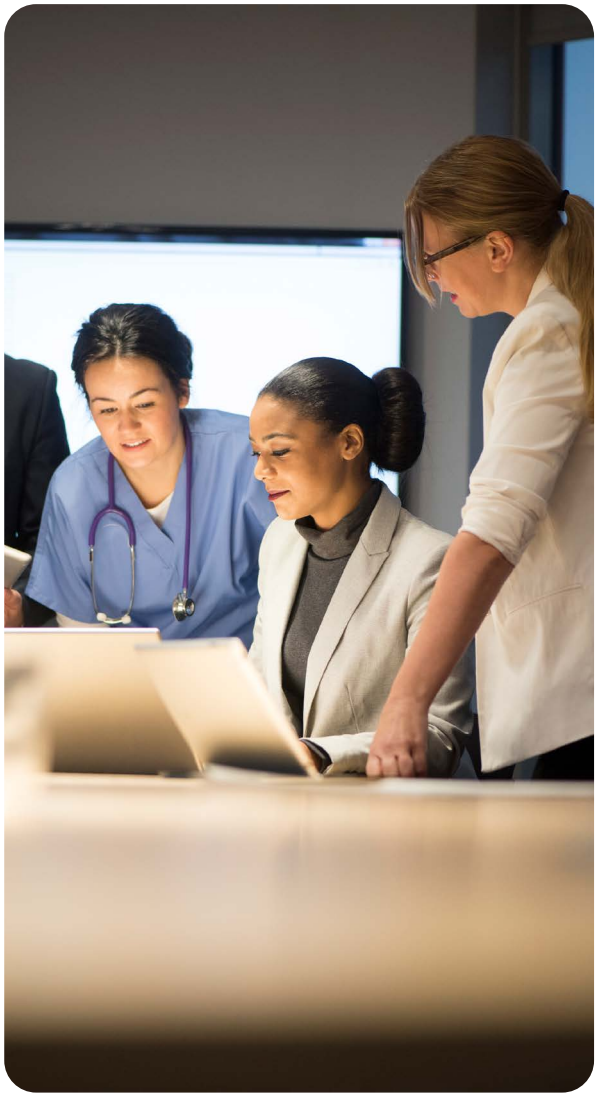
In lower-income economies, market access constraints are more structural and systemic. Registration and procurement processes are often paper-based, decentralized, or intermittently applied, with weak coordination across agencies. Limited regulatory staffing, underdeveloped digital infrastructure, and inconsistent application of quality standards constrain both speed and predictability. As a result, manufacturers face higher transaction costs and uncertain demand signals, while health systems experience supply gaps, limited product choice, and delayed access to essential diagnostics.



Value-based procurement is emerging as a pivotal lever for diagnostics innovation across APEC. Although high-income members apply value-for-money assessments, these economies still rely heavily on lowest-price bidding, which discourages innovation and weakens incentives for suppliers to invest in R&D and quality systems. Adding elements on diagnostics in e-catalogues within economies is expanding. However, transparency in evaluation criteria, consistency of quality thresholds, and systematic use of HTA–informed specifications remain uneven, limiting the ability of procurement systems to reward innovation and real-world performance rather than unit price alone.

Improving access is the next major hurdle. Even when products are registered, affordability barriers persist for rural or low-income populations. Out-of-pocket expenditure for diagnostics can exceed 40% of household health costs in some developing members. To address this, several economies are piloting subsidy schemes, mobile diagnostics units, and public–private partnerships targeting last-mile delivery.

Overall, APEC's market access environment is modernizing but fragmented. The direction of travel is positive, growing adoption of digital systems, reliance pathways, and HTAs. Effective market access (Indicator 7) therefore depends on upstream progress in regulatory convergence (Indicator 3), predictable public funding (Indicator 4), and robust infrastructure and data systems (Indicator 6), which together shape the commercial viability and diagnostics supply. However, harmonizing regulatory and procurement data standards across borders will be essential to transform economy-level improvements into a genuinely integrated regional market.



Next Steps

Taken together, the APEC diagnostic ecosystem is undergoing active reform, although uneven maturity and differentiation between frontrunners and late adopters are widening. While many economies have established foundational elements – strategic direction, policy frameworks, funding pathways, infrastructure investments, innovation pipelines, and accreditation programs – gaps persist in institutional depth, fiscal continuity, and system reach.

To translate these findings into coordinated regional action, further consultations with member economies would help validate the analysis and inform the design of targeted interventions that are needed. Below are three broad thematic areas that can help structure the engagement:

1. Moving from Fragmentation to Integration within each APEC economy

Understand how each economy organizes diagnostic governance and where coordination could be strengthened.

- Discuss interest in developing or strengthening economy-level diagnostic roadmaps that align financing, quality assurance, laboratory networks, and regulatory responsibilities within a single coordinated framework
- Assess the feasibility of establishing economy-level steering units, or strengthening existing ones, that coordinate multi-sector planning across laboratories, regulators, procurement agencies, and digital-health authorities
- Gather perspectives from each economy on what regional technical support or peer learning they would find most useful in enhancing coordination
- Leverage dedicated APEC platform to enable peer learning on institutional models and identify areas where regional technical assistance would add value

2. Transitioning from Infrastructure Expansion to Interoperability

Understand the needs of digital integration, workforce strengthening, and laboratory network optimization.

- Explore digital interoperability gaps, particularly linking LIMS, surveillance systems, procurement platforms, and health-insurance databases, and identify what technical or financial support would be most beneficial
- Assess economies' interest in capacity-building support for laboratory workforce pipelines, including accreditation, continuing education, and biomedical engineering training



- Discuss priorities for strengthening regional reference laboratories, high-throughput hubs, and biosafety systems, including pathways for shared investment or regional twinning arrangements
- Understand the policy and financing barriers economies face in transitioning from hardware expansion (e.g., PCR machines, LIMS pilots) to sustained system integration and operational quality, and explore market-shaping levers – such as innovation grants, co-financing schemes, industrial incentives, and predictable procurement commitments – to encourage long-term sector development
- Discuss ways to promote regional minimum standards and guidance for diagnostics-related cybersecurity, data protection, and cross-border data flows, building on existing APEC digital and health initiatives to reduce fragmentation, support cloud- and AI-enabled diagnostics, and address data sovereignty concerns
- Support APEC economies in scaling quality-assured POC diagnostics as a tool to bridge urban-rural gaps, focusing on sustainable supply chains, maintenance, connectivity, and integration with laboratory and surveillance systems

3. Advancing Regulatory Reliance and Mutual Recognition

Understand the need for regulatory harmonization and practical barriers to utilizing reliance pathways.

- Engage economies on the current use of reliance or abridged pathways, the constraints they face, and the types of support (training, digital systems, guidelines) that would enable broader uptake
- Understand how economies perceive the role of major regional platforms – APEC RHSC, ASEAN Medical Device Committee (AMDC), and other platforms in supporting shared standards, vigilance systems, and convergence
- Assess economies' priorities regarding fast-track approvals for essential diagnostics and how reliance models could reduce administrative burden without compromising safety
- Identify opportunities for economies to participate in, or benefit from, regional post-market surveillance networks
- Develop a follow-up APEC diagnostics development roadmap (with the awareness of the APEC RHSC) to document and guide strategic next steps for economies, with the aim of launching the roadmap in the second half of 2026, and presenting the framework at SOM3 of the APEC Health Working Group

Appendix

Member economy categorization*

Income category	APEC Economy
High income	Australia
High income	Brunei Darussalam
High income	Canada
High income	Chile
Upper-middle income	People's Republic of China
High income	Hong Kong, China
Upper-middle income	Indonesia
High income	Japan
High income	Republic of Korea
Upper-middle income	Malaysia
Upper-middle income	Mexico
High income	New Zealand
Lower-middle income	Papua New Guinea
Upper-middle income	Peru
Lower-middle income	The Republic of the Philippines
High income	The Russian Federation
High income	Singapore
High income	Chinese Taipei
Upper-middle income	Thailand
High income	United States
Lower-middle income	Viet Nam

*World Bank Income Classification, 2025

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