2026/03

From Striving to Thriving:
Global Health as the Next Frontier for In-Vitro Diagnostics

A CREATInG Initiative Insights Report

DukeNUS Medical School | Centre of Regulatory Excellence
昆山杜克大学 DUKE KUNSHAN UNIVERSITY
创领体外诊断出海 CREATInG Initiative

The CREATInG Initiative

Commissioned by the Gates Foundation
CoRE and Duke-Kunshan collaborative project to
Enable
Access
To
In-vitro diagnostics for
Global health needs

The CREATInG Initiative was commissioned by the Gates Foundation to bridge innovation, regulation and access, aiming to accelerate the time to market for in-vitro diagnostics (IVD) to meet critical global health needs. This project is co-led by the Duke-National University of Singapore (NUS) Medical School Centre of Regulatory Excellence (CoRE) and Duke Kunshan University (DKU) Global Health Program.

The project:

- Facilitates regulatory dialogue among IVD manufacturers and regulators to accelerate market access of essential IVD for Low and Middle-Income Countries (LMIC).
- Develops executive strategic leadership skills and deepens regulatory knowledge for diagnostics manufacturers to align and comply with global regulatory requirements and standards.
- Supports the Gates Foundation EDGE* Team's core strategic pillar to develop manufacturing capability of affordable diagnostics.

(* Enterics, Diagnostics, Genomics & Epidemiology)

Additional details:

Webpages for the Initiative (English)

Webpages for the Initiative (Chinese)

Contents

Strategic Overview

New global realities and a changing regulatory landscape are challenging the conventional models to enter international markets, prompting companies to seek alternate pathways for global business expansion. This Report aims to provide senior business leaders of in-vitro diagnostics (IVD) companies with insights to access international markets focused on addressing global health needs.

The Insights Report will discuss:
1.Horizon Scanning: Trends and Insights (2026-2030)
2.Opportunities in the Global IVD market
3.Challenges in Pursuing a Global Expansion Strategy
4.Blueprint for Access to Global Markets

Horizon Scanning: Trends and Insights

Affordable and innovative point of care diagnostics are changing the delivery of public health programmes and clinical care in emerging markets. These innovative IVD solutions are adaptable for decentralised testing, many of which accelerate time to results using molecular platforms that provide multiplexing and digital integration capabilities.

Opportunities

Demand from emerging markets could be the next major growth engine for IVD companies, as these markets seek cost-effective and innovative IVD solutions to support national public health programmes. For example, more countries are incorporating the National Essential Diagnostics List (EDL) as part of their national diagnostics and health transformation strategies. Furthermore, regulatory developments such as increased alignment with international standards and participation in regulatory cooperative mechanisms are creating new pathways for entry into key international markets.

Challenges in Pursuing a Global Expansion Strategy

Regulatory considerations are the predominant challenge for global market penetration by diagnostic manufacturers. Capacity building of regulatory knowledge and skills can help bridge regulatory gaps, particularly in areas such as market entry and quality production. Incorporating astute regulatory strategies into the overall business strategy allows efficient management of regulatory complexities and timelines and improve the chances of success in market access.

Sustaining Business Growth

A key growth strategy is to align with governments on health priorities to provide IVD solutions that support national public health programmes and add value to local health systems. Innovative, bespoke and locally integrated IVD solutions informed by a deep understanding of the needs of the target market will be crucial for continued business relevance.

Blueprint to Access Global Markets

Southeast Asia is a bright spot with growth opportunities despite global economic uncertainties. This presents an opportunity to use the region as a launchpad into other global markets. Facilitated regulatory pathways including those that leverage approvals by Stringent Regulatory Authorities (SRA) from Australia, Canada, European Union, Japan, Singapore and the United States of America could accelerate access into emerging markets.

Looking ahead, new business opportunities in emerging markets can hedge against global economic headwinds. A new frontier in global health is emerging, with the potential to fuel the next phase of growth for the IVD industry. Forging South-South collaborations, implementing astute regulatory strategies and capitalising on demand driven by national public health programmes in emerging markets are key success factors to bring innovative and valuable IVD solutions to the world.

Global Health as the Next Frontier

A New Normal

The global in-vitro diagnostics (IVD) industry has been undergoing a major upheaval. Among major economies in the Global South, China is a major producer of IVD. However, the boom seen during the COVID-19 pandemic was followed by waning demand and government-led volume-based procurement in China. The impact of narrowing profit margins has been felt across the industry, especially by smaller innovative start-up companies and low-value IVD producers. The intense competition in a saturated market known as involution or “内卷 (neijuan)” is pushing IVD companies to seek prospects in global markets.

Global Health as the Next Frontier for IVD

The global unmet need for affordable and quality diagnostics including in infectious diseases and in maternal and child health could be the new frontier to drive the next phase of business growth. 47% of the world's population and up to 81% of individuals in low resource settings have little to no access to even the most basic diagnostics[3]. Regions with the largest need for IVD solutions are Sub-Saharan Africa and South Asia, where communicable diseases, maternal, neonatal diseases and nutritional deficiency are most prevalent[4]. Globally, the market for donor-funded rapid diagnostic tests in 2024 was valued at US$224 million, with tuberculosis diagnostics supplied through the Global Drug Facility valued at close to US$100 million[5]. For malaria diagnostics, it is projected to be valued at US$1.1 billion by 2028, representing a compound annual growth rate (CAGR) of 6% per year[6]. Asia-Pacific is an untapped opportunity, with the IVD market valued at US$27.51 billion in 2023 and forecasted to be the fastest growing region to reach US$40.79 billion by 2030 at a CAGR of 5.4%[7].

This Report aims to provide business leaders of IVD companies with insights for developing global expansion strategies to sustain growth in global markets.

The information presented in this report is based on desk review, key opinion survey, and discussions with international experts (see Appendix for details).

81%

Up to 81% of individuals in low resource settings have little to no access to even the most basic diagnostics[3].

1. Yu M., Zhao Z., Dietzen D.J., Gruson D., Hu J., Killeen A.A., et al. Global IVD: Barriers, Trends, and Future. Clin Chem. 2026.72(2):225-31. DOI: 10.1093/clinchem/hvaf184.

2. Insights into Chinese Medical Device Companies Going Global -- Popular Target Markets Overview and Key Success Factors. Deloitte; February 2024. Available from: https://www.deloitte.com/content/dam/assets-zone1/cn/en/docs/industries/life-sciences-health-care/2025/deloitte-cn-lshc-chinese-medical-device-companies-going-global-en-240221.pdf.

3. Fleming K.A., Horton S., Wilson M.L., Atun R., DeStigter K., Flanigan J., et al. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet. 2021.398(10315):1997-2050. DOI: 10.1016/S0140-6736(21)00673-5.

4. GBD Results. Seattle, WA. Institute for Health Metrics and Evaluation (IHME); 2025. [Accessed on 27 November 2025]. Available from: https://vizhub.healthdata.org/gbd-results/.

5. Kates J. The America First Global Health Strategy and Pooled Procurement: What do we know about Existing Pooled Procurement Mechanisms? 12 January 2026.[Accessed on 26 January 2026]. Available from: https://www.kff.org/global-health-policy/the-america-first-global-health-strategy-and-pooled-procurement/.

6. Malaria Rapid Diagnostic Tests: Market and Supply Update. UNICEF Supply Division; February 2023. Available from: https://www.unicef.org/supply/media/16071/file/Malaria-Rapid-Diagnostic-Tests-Market-and-Supply-Update-Feb-2023.pdf.

7. Asia-Pacific In-Vitro Diagnostics Market 2026. [Accessed on 10 March 2026]. Available from: https://www.nextmsc.com/report/asia-pacific-in-vitro-diagnostics-market.

Horizon Scanning: Trends and Insights (2026-2030)

Key Market Trends:

- Key target markets over the next five years are Asia-Pacific, Europe and North America, followed by Latin America, Africa and the Middle East. There is a trend of companies prioritising mature markets or markets with low barriers to entry over emerging markets.
- Molecular-based platforms are the technology of choice, with a minority of companies also producing immune-based diagnostics still commonly used in low-resource settings.

Analysis Suggests:

1.Conventional entry paths into international markets may no longer guarantee success.

Typical market entry approaches prioritise first entry into mature and high-value markets of Europe and North America, or markets with low entry barriers, followed by entry into emerging markets via a donor-funding approach. However, new global realities and a changing regulatory landscape are challenging the conventional models to enter international markets. With the transition in the European Union (EU) from In Vitro Diagnostic Directive (IVDD) to In Vitro Diagnostic Regulation (IVDR), companies with prior experience in the EU IVDD framework are finding the stricter requirements of the IVDR framework challenging to comply with and possibly pose a barrier to product innovation[8]. In response, the EU has embarked on efforts to streamline processes that reduce regulatory administrative burden and better support breakthrough innovation[9]. More recently, the amendment by the United States Food and Drugs Administration from the previous Quality System Regulation to the Quality Management System Regulation (QMSR) is intended to align with the ISO 13485:2016 Medical devices – Quality management systems[10]. These dynamic regulatory developments reflect a trend by mature markets toward enhanced regulatory stringency while balancing the enabling role of regulation on health product innovation.

2. Point of care IVD solutions that are molecular based with multiplexing and digital integration capabilities are useful to support decentralised testing for global health needs.

The global market for point of care diagnostics is set to grow by a CAGR of 4.07% from 2026 to reach US$29.94 billion by 2033[11]. Next generation, point of care IVD solutions using molecular platforms that have multiplexing and digital integration capabilities can accelerate time to results and support decentralised testing across different diseases and diverse care testings. Specifically, digital integration capabilities provide useful and timely insights to support medical care and guide public health and policy decisions. Several IVD companies have begun incorporating artificial intelligence (AI) that support medical decisions, such as integrating DeepSeek for human papilloma virus (HPV) testing.[12]

US$29.94 billion

The global market for point of care diagnostics is set to grow by a CAGR of 4.07% from 2026 to reach US$29.94 billion by 2033[13].

8. Eglovitch J.S. EU-commissioned study finds MDR, IVDR have dampened medical device investment 19 January 2026. [Accessed on 11 February 2026]. Available from: https://www.raps.org/news-and-articles/news-articles/2026/1/eu-commissioned-study-finds-mdr-ivdr-have-dampene?utm_campaign=regulatory_focus.

9. Commissioner Várhelyi to open high-level event on medical devices. 2026. [Accessed on 17 March 2026]. Available from: https://ec.europa.eu/newsroom/sante/newsletter-archives/73104.

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12. AI 驱动 IVD 行业变革，从概念炒作到产业落地有多远？ | AI 医疗浪潮 2026.[Accessed on 17 March 2026]. Available from: https://www.21jingji.com/article/20250306/herald/247e8ae6698632db9e25efb0488f5034.html.

Opportunities

Opportunities from Emerging Markets for Innovative IVD Solutions

Demand from emerging markets could be the next major growth engine for businesses, driven by the need for affordable and quality IVD solutions in national public health and disease prevention programmes. For example, India expanded the Free Diagnostic Services Initiative between 2014-2015 and 2021-2022, with a three-fold increase in government spending per capita on health including diagnostics[13]. More countries have also incorporated the National Essential Diagnostics List (EDL) as part of their national diagnostics and health strategy, with six more countries publishing their EDL between 2021 to 2024[13].

Boxed Story 1: Indonesia's Health Transformation Plan: An Example of Demand for IVD in Emerging Markets

The Indonesian IVD market is expected to grow at a projected CAGR of 7.5% from US$1.19 billion in 2023 to US$2.04 billion in 2030[14], stimulated by demand generated from the Indonesian national health transformation efforts aimed at early detection of priority diseases. Besides existing screening programmes for maternal and child health, new initiatives include free birthday health screenings covering tuberculosis, hepatitis B and C, and sexually transmitted diseases such as human immunodeficiency virus (HIV) and syphilis.

Increasingly, affordable and innovative diagnostics originating from the Global South hold the potential to meet public health needs from emerging markets. In particular, point of care diagnostics that are simple to operate and accelerate time to results tend to be compatible for use in rural settings. For example, the POCT for HPV developed by Sansure Biotech is being used to support the national cervical cancer screening programme in Zimbabwe and is attracting strong interest from other African countries including Zambia, Mozambique and Botswana[15].

Boxed Story 2: Current Opportunities for Innovative IVD Solutions on Tuberculosis

Every year, approximately 3 million new cases of tuberculosis are undiagnosed due to limited access to diagnostics[16]. Technological advancements in swab-based platforms developed during the COVID-19 pandemic are being applied to address the unmet need for user friendly molecular diagnostics in tuberculosis. Companies such as Coyote, Hugobiotech, Molbio and Pluslife have developed rapid molecular tests compatible with the novel tongue swab sample type and are simple to operate in rural settings or when it is challenging to collect conventional sputum samples.[17-19]. In particular, Pluslife's breakthrough innovation is named as first-in-class by World Health Organization (WHO) for the point of care nucleic acid amplification

13. Horton S., Wilson M.L., Cheung A.N.Y., DeStigter K., Kohli M., Sayed S., et al. Moving the dial on diagnostics: an update from the Lancet Commission on diagnostics. Lancet. 2025.405(10496):2241-54. DOI: 10.1016/S0140-6736(25)00804-9.

14. Indonesia In-Vitro Diagnostics Market. Next Move Strategy Consulting; 2026. Available from: https://www.nextmsc.com/report/indonesia-in-vitro-diagnostics-market.

15. 圣湘生物向津巴布韦交付首批 HPV 筛查产品 . Changsha Daily. 28 January 2026.

16. Steadman A., Kumar K.M., Asege L., Kato-Maeda M., Mukwatamundu J., Shah K., et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using near-point-of-care platforms: a multi-country evaluation. eBioMedicine. 2025.121. DOI: 10.1016/j.ebiom.2025.105991.

17. MTB (M. tuberculosis) FlashDetect ™ LyocartE MTB Assay Coyote Bioscience Co., Ltd.; [Accessed on 26 November 2025]. Available from: https://en.coyotebio.com/reagent_detail/id/135.html.

18. Wang Y., Cui J., Li Y., Wang M., Han W., Liu A., et al. Rapid quantitative PCR on tongue swabs for pulmonary tuberculosis in adults: a prospective multicentre study. Eur Respir J. 2025.65(1). DOI: 10.1183/13993003.01493-2024.

19. Steadman A., Kumar K.M., Asege L., Kato-Maeda M., Mukwatamundu J., Shah K., et al. Diagnostic accuracy of swab-based molecular tests for tuberculosis using near-point-of-care platforms: a multi-country evaluation. EBioMedicine. 2025.121:105991. DOI: 10.1016/j.ebiom.2025.105991.

test (NPOC-NAAT)[20]. The pilot parallel WHO prequalification and tuberculosis policy assessment could also further accelerate access of this promising point of care test (POCT) for tuberculosis[21].

Policy Support as a Key Enabler of Product Innovation

Policy support can be an important driver of product innovation. As an example, the Chinese government's funding support for biotechnological innovation alongside private venture capital grew from US$2.1 billion in 2017 to US$7.3 billion in 2024[22]. At a regional level, initiatives such as the Forum on China-Africa Cooperation[23] and Association of Southeast Asian Nations (ASEAN) Plus Three[24] facilitate deepening of diplomatic ties among key global markets through international trade and economic cooperation.

Facilitated Regulatory Pathways into Key International Markets

Facilitated regulatory pathways such as those established between major economies in Southeast Asia can accelerate market approval into key target markets by leveraging prior market approval of another jurisdiction. Selected regulatory reliance(1) mechanisms that facilitate entry into key international target markets are highlighted below.

- **Leveraging the WHO Stringent Regulatory Authorities (SRA) mechanism to access global emerging markets:** WHO has an abridged prequalification assessment route that references the approval by SRA including from Australia, Canada, EU, Japan, Singapore and the United States of America (USA), reducing review times from up to 350 days to 180 days[25]. Following WHO prequalification, companies can apply to accelerate registration into participating countries of the Collaborative Registration Procedure (CRP), including to about 30 countries in Africa[26].
- **Leveraging the bilateral reliance mechanisms between Malaysia, Singapore and Thailand to facilitate entry into major Southeast Asian economies:** Malaysia's Medical Device Authority (MDA) and Singapore's Health Sciences Authority (HSA) have formalised a bilateral reliance programme since 1 March 2026. This accelerates market entry into both markets, with at least 15 HSA-registered products approved by MDA since the launch of the earlier pilot phase[27]. The

(1). Regulatory reliance is defined by the World Health Organization as the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.

20. Near point-of-care nucleic acid amplification tests (NPOC- NAATs) as a new diagnostic class for diagnosis of TB using sputum and tongue swabs. World Health Organization; [Accessed on 18 March 2026]. Available from: https://www.who.int/teams/global-programme-on-tuberculosis-and-lung-health/diagnosis-treatment/npoc-tongue-swabs-and-sputum-pooling-for-tb/npoc-naats.

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22. Mukherjee A. How China rewrote the rules of drug innovation 31 January 2026.[Accessed on 1 February 2026]. Available from: https://www.businesstimes.com.sg/opinion-features/how-china-rewrote-rules-drug-innovation.

23. China expected to help Africa's health industry [press release]. Nairobi: Forum on China-Africa Cooperation Forum, 10 March 2026 2026. [Accessed on 18 March 2026] Available from: http://www.focac.org/eng/zfzs_1/202603/t20260316_11875612.htm.

24. ASEAN-Plus Three (APT). Association of Southeast Asian Nations; [Accessed on 18 March 2026]. Available from: https://asean.org/our-communities/economic-community/integration-with-global-economy/asean-plus-three-economic-relation/.

25. Prequalification of Medical Products: In Vitro Diagnostics Timelines. World Health Organization; [Accessed on 4 December 2025]. Available from: https://extranet.who.int/prequal/vitro-diagnostics/timelines.

26. Countries participating in the WHO Collaborative Registration Procedure (CRP) for In vitro diagnostics - March 2025. World Health Organization; [Accessed on 4 December 2025]. Available from: https://cdn.who.int/media/docs/default-source/medicines/regulatory-updates/fpi/pq-crp-ivds-participating-countries.pdf?sfvrsn=612bb788_1.

27. HSA Deepens International Partnerships and Regulatory Reliances to Grow Biomedical Sector [press release]. Singapore: Health Sciences Authority, 12 March 2026. [Accessed on 18 March 2026] Available from: https://www.hsa.gov.sg/announcements/press-release/hsa-deepens-international-partnerships-and-regulatory-reliances-to-grow-biomedical-sector.

bilateral pilot abridged pathway between Malaysia's MDA and Thailand's Food and Drug Administration (FDA) (1 February to 30 April 2026) also reduces regulatory approval time from 60 days to 30 days in Malaysia and from 150 days to 120 days in Thailand[28, 29]. Moreover, Thailand's FDA has an expedited approval route for medical devices approved by Singapore's HSA, reducing review time in Thailand from 150 to 60 days[30].

Boxed Story 3: Singapore as a WHO SRA to Launch Innovative IVD into Markets across Asia Pacific and the World

Singapore, with the Health Sciences Authority (HSA) being a WHO SRA, can serve as a launchpad for innovative IVD solutions to access Asia and the Pacific and facilitate accelerated entry into global markets. HSA is also the first in the world to attain the highest maturity level 4 (ML4) under the WHO Global Benchmarking Tool Plus for Medical Devices[31-33]. To register an innovative IVD in Singapore, manufacturers can consider the Priority Review Scheme to reduce review time by 35%. This route is applicable for focus areas such as infectious diseases and for products designed to address unmet clinical needs or with meaningful clinical advantage[34]. The Pre-Market Consultation Scheme provides further support to accelerate regulatory review[35]. Following product registration in Singapore, initiatives by Singapore's HSA on regulatory cooperation with other regulatory authorities provide opportunities for products to reach beyond the country's shores. These include partnerships with Hong Kong Special Administration Region (SAR) of China and Uzbekistan on the sharing of technical information, expertise and best practices in regulating health products, as well as reliance programmes established with Australia, Malaysia, Philippines, Sri Lanka and Thailand[27, 36]. In addition, the Regulatory Innovation Corridor is a new fast track initiative inked between Singapore and the United Kingdom that further boosts access of advanced diagnostics to both markets[37].

28. Establishment Guide to Medical Device Registration Submission in MeDC@St Through Conformity Assessment By Way of Verification Process. Selangor, Malaysia. Medical Device Authority, Ministry of Health Malaysia; October 2025. Available from: https://www.mda.gov.my/index.php/documents/ukk/3766-final-medical-device-registration-submission-guide-for-conformity-assessment-by-way-of-verification-process-and-submission-of-application-in-medc-st-second-edition/file.

29. New MDA Guidance Expands Malaysia Verification Pathway and ASEAN Reliance. Asia Actual; 2025. [Updated 10 December 2025; Accessed on 26 February 2026]. Available from: https://asiaactual.com/blog/malaysia-verification-guidance-2025/.

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35. Medical Devices: Consultation Scheme. Health Sciences Authority; [Updated 28 July 2025; Accessed on 5 December 2025]. Available from: https://www.hsa.gov.sg/medical-devices/consultation-schemes.

36. HSA-SMF Partnership Pioneers Integrated Regulatory Support for MedTech Industry to Promote Access into Singapore and Other Markets [press release]. Singapore: Health Sciences Authority, 2 October 2025. [Accessed on 5 December 2025] Available from: https://www.hsa.gov.sg/announcements/press-release/hsa-smf-partnership.

37. UK and Singapore Team Up to Launch New Fast Track Pathway to Speed Up Access to Breakthrough Health Technologies [press release]. Health Sciences Authority, 12 December 2025. [Accessed on 17 December 2025] Available from: https://www.hsa.gov.sg/announcements/press-release/uk-and-singapore-team-up-to-launch-new-fast-track-pathway-to-speed-up-access-to-breakthrough-health-technologies.

Challenges in Pursuing a Global Expansion Strategy

57.7%

More than half (57.7%) of all key opinion leaders surveyed cited regulatory considerations as the predominant challenge for global expansion.

Regulatory Challenges

- Regulatory considerations were consistently identified as the predominant challenge for global expansion, cited by over half (57.7%) of the key opinion leaders surveyed. These include navigating regulatory complexities of individual regulatory frameworks, requirements and pathways to enter different target markets.
- Understanding the different data requirements for clinical evaluation to demonstrate safety and performance of the IVD.

Boxed Story 4: Embed Quality Production and Regulatory Compliance Early at Conceptualisation Stage

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd is one of the first Chinese IVD companies with products listed in the WHO prequalification programme, the most recent being its HIV urine self-test kit. Wantai embeds quality management systems early in the production life cycle beginning at product conceptualisation phase which could be one of the success factors. To date, Wantai has over 500 million HIV diagnostics supplied globally including to emerging markets.

Access Challenges and Strategies to Overcome Them

Business strategies to help overcome the common regulatory barriers and challenges along the product life cycle stages include:

1. During R&D and product development phase, develop a clear business strategy on market selection, assessing the **target market's disease patterns, market needs, government priorities and policies and map stakeholders in the local healthcare system.**
2. At clinical development, **utilise available open-source data and references to help overcome biobank access challenges for clinical evidence generation.**
3. At regulatory filing and market entry phase, **embed quality management systems early during product development, understand regulatory requirements and proactively engage regulatory authorities of target markets** to better manage regulatory complexities and timelines.
4. For market launch, **develop market intelligence and knowledge on the national mechanisms for health financing and procurement** of the target market to inform business decisions on pricing and sales channels.
5. In market development, **define business goals to determine the depth of local integration and extent of investment into the local market.** This guides how the registered product is managed locally and the level of engagement with local partners.
6. On organisational sustainability, businesses will need to take a longer-term horizon. Considerations include **value creation, access to capital for sustainable financing, understanding the local cultural context in managing international teams, clinical adoption, and maintaining quality management systems for quality manufacturing.**

Boxed Story 5: Market Development, Partnerships and Organisational Sustainability

Establishing a strong local presence can help build trust, which is critical to long-term organisational sustainability. Companies could think "glocally": to be globally integrated and locally empowered, setting a global vision and empowering local leaders who have in-depth local contextual knowledge[2]. An example is Guangzhou Wondfo Biotech, which localises operations in international markets as a key strategy for its medium to long term business growth.

(2). Cited by Mr Wong Fatt Heng, former General Manager of Roche Diagnostics (China) at the Gates-commissioned Executive Development Programme.

The company's local partnerships globally include with state-owned Kimia Farma in Indonesia and Microhaem Scientifics (MHS) in Uganda to localise production of affordable and locally relevant IVD [38, 39].

Building regulatory capacity is key to overcoming regulatory challenges as the main barrier for access to global markets. Capacity building of regulatory knowledge and skills is recommended in the four areas:

1.**Global regulatory requirements** based on IVD product risk classification and international standards.

2.**Facilitated regulatory pathways** such as the regulatory reliance mechanisms in Southeast Asia and the wider region that connect with and accelerate access to global markets.

3.**Data requirements for dossier submission**, including on analytical and clinical performance evaluations.

4.**Quality management systems** that comprise risk management, inspections, post-market requirements and corrective actions preventive actions (CAPA).

38. Microhaem Scientifics (MHS): Our Laboratory. 2025. [Accessed on 10 March 2026]. Available from: https://microhaem.co.ug/laboratory/.

39. Cooperation Agreement | Joint Efforts from Wondfo & KIMIA FARMA [press release]. Wondfo, 1 August 2023. [Accessed on 10 March 2026] Available from: https://en.wondfo.com/news/index175.html.

Strategic Discussion

US$16.36 billion

The diagnostics market for Southeast Asia is projected to be valued at US$16.36 billion by 2027.

Southeast Asia as a Regional Bright Spot

Southeast Asia is a regional bright spot with growth opportunities despite global economic uncertainties. ASEAN member states have a total population of 677 million[40]. The diagnostics market for the region is projected to be valued at US $16.36 billion by 2027 with a growth rate of 12.59% for the period of 2023 to 2027[41]. Diagnostics innovation and manufacturing are a key priority for the regional bloc, with the ASEAN Diagnostics Initiative (ASEAN DxI) established in 2018 aimed at the co-development of diagnostics innovation and the ASEAN Diagnostic Security and Self-Reliance (ADxSSR) aimed at boosting manufacturing and diagnostics access in the region[42, 43]. To gain market entry into individual ASEAN member states, the ASEAN Common Submission Dossier Template can be used[44]. Market entry could also be accelerated by various facilitated regulatory pathways.

Boxed Story 6: From Singapore to Southeast Asia: Fast-Tracked Market Access of Fit-for-Purpose, Globally Relevant Diagnostic Innovations

CorDx, a global leader in POCT diagnostics, together with the Diagnostics Development Hub (DxD Hub) have established a POCT Centre in Singapore, a new joint laboratory to accelerate diagnostic innovations including for infectious diseases and women's health.The partnership leverages Singapore's R&D ecosystem and capabilities to fast-track, validate and commercialise solutions that are relevant for the Southeast Asian and global market[45].

Potential Global Target Markets

Considerations on target market selection could include disease burden, market value and market size. As illustration, Table 1 presents selected markets of interest, reflecting key target markets in Sub-Saharan Africa as the region with large disease burden[4] and Asia-Pacific as the region projected to have the fastest IVD market growth[7].

40. ASEAN. World Economic Forum; [Accessed on 10 March 2026].

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42. ERIA and Indonesia Lead First Regional Meeting on ASEAN Diagnostic Security and Self-Reliance [press release]. 17 June 2025. [Accessed on 24 February 2026] Available from: https://www.eria.org/news-and-views/eria-and-indonesia-lead-first-regional-meeting-on-asean-diagnostic-security-and-self-reliance.

43. Healthcare Diagnostics Solutions by ASEAN, For ASEAN. DxD Hub; [Accessed on 25 February 2026]. Available from: https://www.a-star.edu.sg/dxdhub/asean-dxi.

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45. CorDx and DxD Hub Establish POCT Centre to Drive Global Health Innovation in Infectious Diseases, Fertility Health and Chronic Diseases Diagnostics [press release]. DxD Hub, 23 October 2025. [Accessed on 24 February 2026] Available from: https://www.a-star.edu.sg/dxdhub/news-events/news-and-events/news-events/cordx-and-dxd-hub-establish-poct-centre-to-drive-global-health-innovation-in-infectious-diseases--fertility-health-and-chronic-diseases-diagnostics.

Target Market	Disease Burden (DALYs per 100,000 in 2023) [3]	Estimated Market Value Based on Import Value of PCR-Based Diagnostic Reagents (US$1000)[4]	Population Size (Millions)[5]
Nigeria	34,176.29	30,629.50	232.7
South Africa	19,339.57	321,872.69	64.0
Tanzania	18,743.75	82,537.84	68.6
Kenya	14,753.02	113,582.72	56.4
Uzbekistan	7582.44	47,401.67	21.9
Philippines	7443.35	186,324.54	115.8
Indonesia	7338.54	228,795.48	283.5
Thailand	4808.76	448,558.33	71.7
Malaysia	3878.38	196,259.17	35.6
Singapore	1768.95	600,772.96	6.0
United Kingdom	1614.52	1,657,943.17	69.2
Australia	1061.34	756,493.87	27.2
Hong Kong SAR, China	N.A.	635,530.83	7.5

Table 1. Selected target markets, disease burden, estimated market value based on import value of PCR-based diagnostic reagents, and population size.

(3). Disease burden by disability-adjusted life year (DALY) per 100,000 people for communicable, maternal, neonatal and nutritional diseases. Global Burden of Disease Results from Institute for Health Metrics and Evaluation (IHME). https://vizhub.healthdata.org/gbd-results/

(4). Estimated market value based on 2024 World Integrated Trade Solution (WITS) import data for polymerase-chain reaction (PCR)-based diagnostic reagents. https://wits.worldbank.org/trade/comtrade/en/country/ALL/year/2024/tradeflow/Exports/partner/WLD/nomen/h5/product/382200

(5). Estimated market size using World Bank population estimates. https://databank.worldbank.org/reports.aspx?source=2&country=LKA

Blueprint for Access to Global Markets

A blueprint for innovative IVD solutions to reach global target markets could include key markets in Southeast Asia serving as a launchpad. It leverages facilitated pathways and cooperative mechanisms between major economies, including approvals by SRA and other trusted agencies to accelerate access to emerging markets in the Global South. Although some initiatives in regulatory cooperation are still in development, advantages such as the epidemiological profile of Southeast Asia and regulatory coooperative mechanisms are important considerations in formulating a viable strategic approach to accelerate international expansion.

Major Southeast Asian Markets

Singapore

- IVD products registered in Singapore can be eligible for the abridged WHO prequalification assessment pathway that leverages Singapore's HSA as a WHO SRA and the WHO CRP mechanism to accelerate access into global emerging markets[26, 32].
- Access to major economies in Asia Pacific is facilitated by reliance initiatives established between Singapore and Australia, Hong Kong SAR China, Malaysia, Philippines, Sri Lanka, Thailand and Uzbekistan[27, 36].
- Manufacturers of advanced diagnostics can accelerate access into high value markets of Singapore and United Kingdom simultaneously by leveraging the Regulatory Innovation Corridor, a new fast-track pathway for breakthrough technology[37].
- The abridged evaluation route in Singapore cuts review timelines from up to 310 days to 220 working days for class B, C and D medical devices including IVD, referencing assessments by regulatory authorities in the USA, EU, Australia, Japan and Canada[48].

Indonesia

- Indonesia is the largest market in Southeast Asia, with a population of over 280 million[47]. The country is leading the ADxSSR initiative, an important step towards ASEAN's regional resilience in diagnostic manufacturing. By working to align regulatory standards and incentivising local production, Indonesia is paving the way for accelerated market entry into ASEAN markets[42].

Malaysia

- Malaysia's Verification Pathway accelerates the market entry of IVD that have been registered in Australia, Canada, EU, Japan, Singapore, United Kingdom and USA. Since the launch of the earlier pilot phase, Malaysia's MDA has approved at least 15 Singapore-registered products under the Verification Pathway with Singapore which has been formalised on 1 March 2026[27, 49].
- The pilot Verification Program with Thailand (1 February to 30 April 2026) reduces registration time of medical devices including IVD from 60 days to 30 days[28].
- A pilot bilateral reliance programme

46. Medical test kits (382200) exports by country in 2024. World Integrated Trade Solution; [Accessed on 5 February 2026]. Available from: https://wits.worldbank.org/trade/comtrade/en/country/ALL/year/2024/tradeflow/Exports/partner/WLD/nomen/h5/product/382200.

47. Databank: World Development Indicators. World Bank Group; [Accessed on 5 February 2026]. Available from: https://databank.worldbank.org/reports.aspx?source=2&country=LKA.

48. Registration overview of medical devices. Health Sciences Authority; [Updated 14 August 2025; Accessed on 3 December 2025]. Available from: https://www.hsa.gov.sg/medical-devices/registration/overview.

49. Approval Issued by Health Science Authority (HSA) Permitted by MDA for Conformity Assessments by Way of Verification Process [press release]. Medical Device Authority (MDA), Ministry of Health Malaysia, 1 March 2026. [Accessed on 18 March 2026] Available from: https://www.mda.gov.my/index.php/announcement/1756-approval-issued-by-health-science-authority-hsa-permitted-by-mda-for-conformity-assessments-by-way-of-verification-process.

was established effective from 30 July to 30 September 2025 between China's National Medical Products Administration (NMPA) and Malaysia's MDA, which reduced regulatory approval time by MDA from 1 to 3 years to 30 working days[50].

Thailand

- The Concise Evaluation route by Thailand's FDA reduces review time from up to 8 months to 2 months. This covers class B, C and D medical devices including IVD approved by at least one of the regulatory authorities in Australia, Canada, EU, Japan and the USA, or has been WHO prequalified and marketed without any safety issues at least 1 year[51].
- The Expedited Review route for medical devices including IVD, which relies on regulatory approvals by Singapore's HSA, reduces average review times from 150 to 60 days[30].

Philippines

- The Philippines has an abridged pathway for Class B, C and D medical devices including IVD that have been approved by a regulatory authority of another ASEAN member state. This reduces turnaround time from up to 8 months to 30 working days[52].

Other Global Markets

African region

- Access into the African continent can be accelerated through the WHO abridged prequalification assessment route, which references the approval by a WHO SRA comprising Australia, Canada, EU, Japan, Singapore and the USA, cutting review times from up to 350 days to 180 days[25]. Following WHO prequalification, companies can apply to accelerate registration into countries participating in the CRP, including about 30 countries in Africa[26]. For example, Guangzhou Wondfo Biotech has gained market entry into Malawi, Nigeria and Zambia for its WHO prequalified HIV and malaria IVD products via the WHO CRP pathway[53].
- Kenya[54], Nigeria[55], South Africa[56, 57] and Tanzania[58] are some of the countries that have official guidelines or provisions on regulatory reliance, including listing reference regulatory agencies such as WHO SRA or WHO Listed Authorities (WLA), or participation in the WHO prequalification and CRP process.

Australia

- The abridged assessment by the Therapeutic Goods Administration (TGA) of

50. Malaysia Leads The World In Medical Device Regulatory Reliance [press release]. Kuala Lumpur: Medical Device Authority Malaysia, 16 July 2025. [Accessed on 3 December 2025] Available from: https://www.mda.gov.my/index.php/announcement/1611-press-release-malaysia-leads-the-world-in-medical-device-regulatory-reliance.

51. Announcement from Thai Food and Drug Administration: Criteria for Full Evaluation and Concise Evaluation. Nonthaburi, Thailand: Thai Food and Drug Administration; 30 September 2019. Available from: https://medical.fda.moph.go.th/media.php?id=479189436861652992&name=Full%20evaluation%20and%20Concise%20evaluation.pdf

52. FDA Circular No.2022-008 Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country. Food and Drug Administration Philippines; 2022.

53. In Vitro Diagnostic Products Registered Under WHO Collaborative Registration Procedure - March 2025 [Internet]. World Health Organization (WHO). 2025 [cited 26 February 2026]. Available from: https://extranet.who.int/prequal/key-resources/documents/ivd-crp-registrations.

54. Guidelines on Reliance Mechanisms for Marketing Authorization of Health Products and Technologies in Kenya. Republic of Kenya: Ministry of Health, Pharmacy and Poisons Board; 7 April 2025.

55. Regulatory Directive on Regulatory Reliance. National Agency for Food & Drug Administration and Control (NAFDAC); 29 August 2025.

56. Reliance Guideline. South African Health products Regulatory Authority (SAPHRA); 6 August 2025.

57. Medical Devices. South African Health Products Regulatory Authority (SAPHRA); 2026. [Accessed on 12 February 2026]. Available from: https://www.sahpra.org.za/medical-devices/.

58. Reliance Pathways. Tanzania Medicines & Medical Devices Authority; [Accessed on 12 February 2026]. Available from: https://www.tmda.go.tz/pages/reliance-pathways.

Australia references regulatory assessments of comparable overseas regulators and assessment bodies including from Canada, the EU, Japan, Singapore and USA, reducing document requirements and review time from up to 255 days to 120 days[59-62].

Hong Kong SAR, China

- The Department of Health for Hong Kong SAR, China takes into consideration the regulatory evaluation of medical devices including IVD that have been approved by Australia, Canada, China, EU, Japan, Singapore, South Korea and USA[63].

United Kingdom

- The Medicines & Healthcare products Regulatory Agency (MHRA) recognises regulatory authorities from Australia, Canada, EU, Switzerland, Singapore, Japan and the USA[64]. Under the International Recognition Procedure, this reduces review time from up to 210 days to 60 days[65].
- Manufacturers of advanced diagnostics can accelerate access into high value markets of Singapore and United Kingdom simultaneously by leveraging the Regulatory Innovation Corridor, a new fast-track pathway for breakthrough technology[37].

59. Comparable overseas regulators (CORs): Timeframes and milestones. Therapeutic Goods Administration, Australia; 2019. [Updated 24 October 2019; Accessed on 12 February 2026]. Available from: https://www.tga.gov.au/products/medicines/prescription-medicines/application-and-market-authorisation/supply-prescription-medicine/application-process-prescription-medicines/comparable-overseas-regulators/comparable-overseas-regulators-cors-timeframes-and-milestones.

60. Understanding processing timeframes for medical device applications. Therapeutic Goods Administration, Australia; 12 April 2022. [Updated 1 October 2024; Accessed on 12 February 2026]. Available from: https://www.tga.gov.au/resources/guidance/understanding-processing-timeframes-medical-device-applications.

61. Using assessments from comparable overseas regulators for medical devices. 21 June 2022. [Updated 24 August 2024; Accessed on 12 February 2026]. Available from: https://www.tga.gov.au/resources/guidance/using-assessments-comparable-overseas-regulators-medical-devices.

62. Understanding selection criteria for medical device application audits. Therapeutic Goods Administration, Australia; 25 September 2025. [Accessed on 12 February 2026]. Available from: https://www.tga.gov.au/resources/guidance/understanding-selection-criteria-medical-device-application-audits.

63. Guidance Notes for Listing Class II/III/IV General Medical Devices In: Division MD, editor.: Department of Health, The Government of the Hong Kong Special Administrative Region.

64. Guidance: International Recognition Procedure. Medicines & Healthcare products Regulatory Agency; [Updated 21 January 2026; Accessed on 12 February 2026]. Available from: https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure#:~:text=To%20be%20eligible%20for%20Recognition,may%20revert%20to%20Recognition%20B.

65. International Recognition Procedure - supplementary information. Medicines & Healthcare products Regulatory Agency; [Accessed on 12 February 2026]. Available from: https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure-supplementary-information.

Sustaining Growth After Market Entry

Value Creation

Adding value to the health system while addressing the specific needs of the market will be critical for continued business relevance in the longer term. This is as governments shift from a traditional reliance on donor funding towards government financing of public health goods. Business leaders will have to be innovative, creating bespoke solutions that provide governments with useful data and timely insights to guide public health and policy decisions.

Ecosystem-Based Solutions Through Multistakeholder Collaborations

It is critical that stakeholders recognise the public health and economic value of diagnostics and collaborate to catalyse ecosystem-based solutions that support:

- Sustained demand generation through market shaping, including demand forecasting, volume guarantees and pooled procurement.
- The development of local manufacturing capacities, through public-private partnerships, investments and technology transfer.
- Access to biobanks, with provisions rooted in equitable pathogens and benefits sharing.
- Global multi-regional clinical validation driven by South-South collaboration for development of IVD solutions that better integrate with the needs of emerging markets.
- Financing and investments in innovative IVD.
- Regulatory harmonisation and convergence towards internationally recognised standards and requirements.

Looking ahead, new opportunities in partnerships led by the Global South and current technological advancements can facilitate innovative and valuable IVD solutions to successfully reach international markets despite major global headwinds. One must seize these new opportunities in charting a new path forward, toward a future that is resilient, secure and where innovative global health solutions are accessible to all.

Appendix

Information Gathering

China is among the major Global South economies producing IVD for the global market. The key opinion survey comprised a set of questions specifically designed to explore market trends on international expansion plans of IVD companies based in China as well as market opportunities, challenges and support needed to scale internationally. Key opinion leaders were identified through stakeholder mapping, selective sampling and a snowball approach. The survey was conducted from 8 April 2025 to 6 June 2025. Companies were identified using the following criteria:

- China-based IVD companies producing innovative IVD that can address the unmet needs in global health on infectious diseases and maternal and child health.
- Potential to scale in international markets, including in emerging markets.

Semi-structured interviews were conducted over approximately 90 minutes. Key opinions were gathered from 13 entities, representing of 9 Chinese IVD companies, an IVD consulting firm, government, clinical research organisation and venture capitalist for wide perspectives on the IVD ecosystem.

Other supplementary information includes a pre-course survey of 26 participants of the CREATInG Executive Development Programme conducted between March to June 2025, document review of grey literature and scientific publications, and key discussions arising from the CREATInG International Roundtable and the Executive Development Programme held in July and September 2025 respectively.

Findings and Analysis

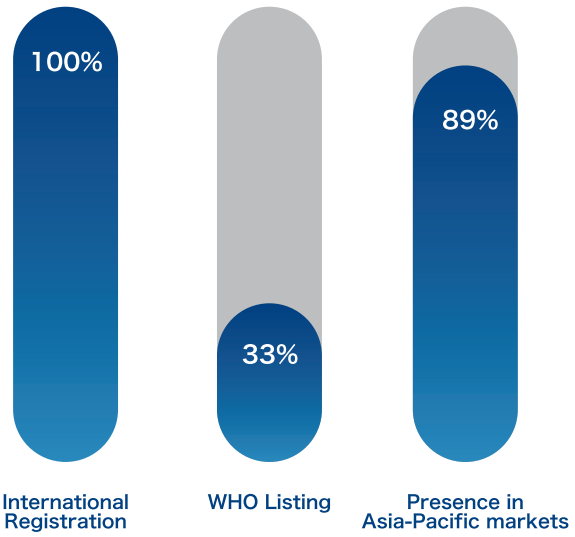
Overview of Current International Market Presence

All IVD companies surveyed have their products registered in at least one international market. 33% of companies have their products listed either in the WHO prequalification programme or have experience with the WHO Emergency Use Listing. 89% of companies have a current presence outside of China in the Asia-Pacific (Figure 1).

Target Markets

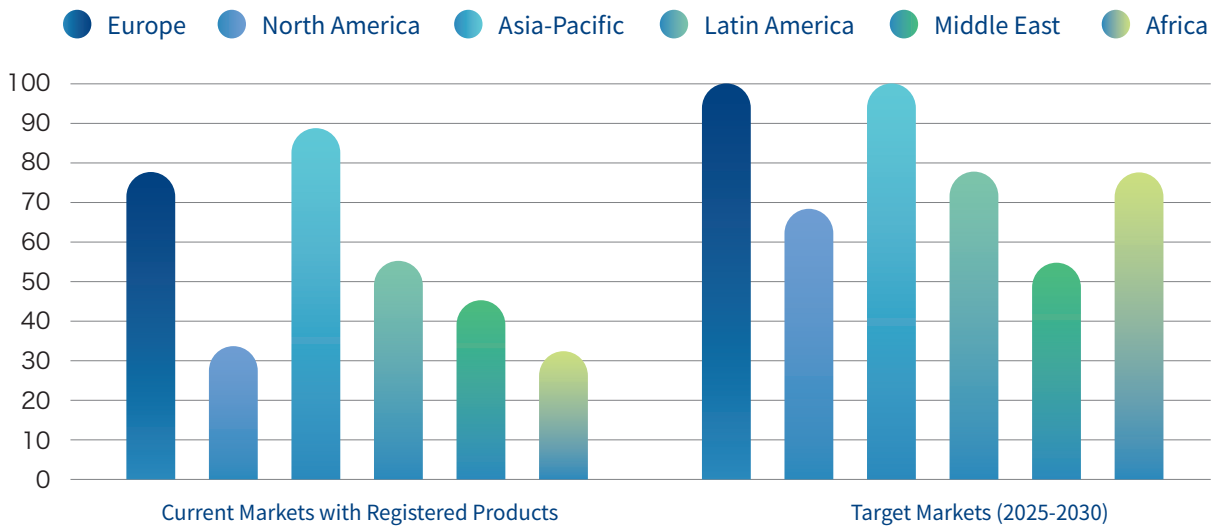
All companies expressed strong intention to expand globally. Mature markets of Europe and North America are key target markets of interest in the next 5 years (2026-2030), followed closely by Middle East and Asia-Pacific, then Latin America and Africa (Figures 2 and 3).

Figure 1: Market presence of companies surveyed



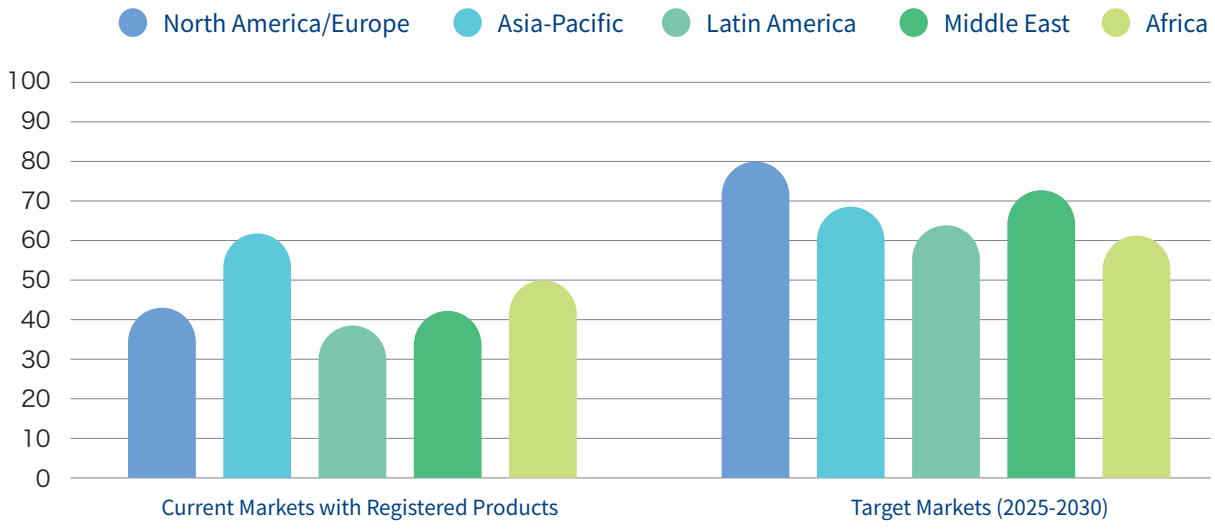
n = 9

Figure 2. Current and target markets of IVD companies. Data gathered from key opinion survey.



n = 9

Figure 3. Current and target markets of IVD companies. Data gathered from pre-course survey.



n = 26

Europe

Stakeholders interviewed generally regard Europe as a priority market. This is due to the market's maturity and clear regulatory framework, with the biggest advantage being the ability to access multiple international markets with a single regulatory approval, including across Europe and other global markets, as the approval is widely recognised by other jurisdictions outside Europe. However, the recent regulatory transition in the EU from IVDD to the more stringent IVDR framework is viewed as a major barrier to entry, prompting re-evaluation of the conventional entry path into international markets.

Asia Pacific

Within Asia Pacific, Southeast Asia was cited as another target market, for the low barriers to entry in terms of cost, proximity, familiarity with the market, perceived low competition and availability of local business connections. The main drawback is the fragmented regulatory landscape, which could be challenging when interpreting different country-specific regulatory requirements and potentially requiring substantial resources for product registration in each market.

Africa

Regulatory fragmentation and reliance on donor funding means entry into the African market can be challenging without first obtaining WHO prequalification. Target market selection is another major consideration, as Africa is the continent with the greatest number of countries and diverse markets in terms of political stability, market size and disease burden.

Middle East

Navigating the regulatory fragmentation is a key challenge especially for companies new to the Middle Eastern market. In contrast, for companies that are already serving the Middle Eastern market, the region is an attractive priority market due to the large business volume and established working relationships with the national regulatory agencies[6].

Latin America

While companies express strong interest in the Latin American market, hesitation is mainly due to limited understanding and experience in this region. Countries that companies have made in-roads into include Brazil, Columbia, Mexico and Peru. However, long regulatory timelines remain challenging.

Technology Platforms

All companies surveyed produce IVD of the molecular technology platform, known for its adaptability and ability to detect multiple pathogens in a single test. Examples include PCR, loop mediated isothermal amplification (LAMP) and sequencing. 60% of companies are producing POCT or near POCT. 30% of companies also produce immune-based diagnostics which are still commonly used in low-and-middle-income (LMIC) and rural settings, given cold chain requirements of some molecular diagnostics.

(6). Data was collected and analysed prior to the prevailing geopolitical uncertainties in the Middle East.

Acknowledgements

We thank the key opinion leaders for the insights that informed this report and support broader access to IVDs for addressing global health needs.

This report was prepared jointly by CoRE and Duke Kunshan colleagues in the CREATInG Initiative. The views presented in this report are those of individual contributors and do not represent formal consensus positions of the authors'organisations of Duke-Kunshan University Global Health Program or Duke-NUS Medical School's CoRE. The information presented in this report is accurate as of 13 March 2026.

The report was produced with funding support from the Gates Foundation.

Please cite the work as follows: "CoRE 2026. Gates-CoRE-DKU CREATInG Initiative. The CREATInG Initiative Insights Report: Enabling Access to In-Vitro Diagnostics for Global Health Needs. © CoRE."

CoRE CN: 2026_R001_CoRE_Gates-CoRE-DKU CREATInG Initiative: The CREATInG Initiative Insights Report: Enabling Access to In-Vitro Diagnostics for Global Health Needs.

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