Request for Quotation (RFQ) -

Market Research to support the go-to-market strategy for near Point-of-Care (POC)multi-pathogen, molecular diagnostic platforms in Southeast Asia and Latin America & the Caribbean Markets

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ABOUT FIND

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and save US$1 billion in healthcare costs to patients and health systems. We are co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit www.finddx.org

1. BACKGROUND

Since the beginning of the COVID-19 pandemic, molecular testing has played a critical role in the management of suspected cases as well as contact tracing worldwide. COVID-19 and other common respiratory infections (such as influenza) can cause similar symptoms early on. They include fever, chills, cough, difficulty breathing, fatigue, body aches, headache, sore throat, runny nose, nausea, vomiting, and diarrhoea.

Testing is the only way to correctly identify the pathogens causing these symptoms. Respiratory pathogens can cause illnesses that range from mild to severe, and in some cases, can lead to death. Although these infections can affect all ages, the very young, the elderly, and people with weakened immune systems, chronic kidney disease, lung disease, cancer or obesity are at particular risk of severe disease. Also at risk of infection are people in close contact with one another or in confined spaces, such as hospitals, nursing homes, schools, and military facilities.

The ability to test for multiple respiratory pathogens from a single sample means less discomfort for the patient compared to collecting a separate sample for each test. Testing a single sample for multiple pathogens also uses fewer resources as compared to running several individual tests on multiple samples to detect different pathogens. These technologies are able to address the need for a simplified and efficient differential diagnosis between SARS-CoV-2 and other respiratory pathogens.

Similarly, molecular testing plays an important role in fast identification of bacterial infections and antimicrobial resistance (AMR) in hospitalized patients with blood stream infections (BSI). Current workflow can take up to 5-7 days to get final pathogen identification and drug susceptibility testing, which increase patients mortality and increase the transmission of AMR.

Developments in the COVID-19 panel can be applied to improve the multiplexing capabilities of near-point of care technology. This in turn can be applied to additional viral/bacterial targets that could either be currently feasible at the platform level or potential candidates for menu expansion at a later stage (e.g., RSV, Flu A/B, Tuberculosis, M. Pneumoniae, S. Pneumoniae, Parainfluenza, Rhinovirus/Enterovirus, etc.).

Globally, while the pandemic and evolution of COVID-19 continues, Stringent Regulatory Authorities (SRAs) in High-income countries such as the FDA have authorized new molecular-based tests that use a single sample and can distinguish between SARS-CoV-2, and other respiratory pathogens. Testing capacity, however, remains highly centralized, and often insufficient to meet the current demand. While countries in all regions have experienced these challenges, the needs are more acute in low- and middle-income countries (LMICs), where fragile health systems and exclusive reliance on global supply chains have often left LMICs unable to access to key commodities at affordable prices to roll out equitable testing strategies.

Key Definitions

Terminology	Definition
Point of Care molecular testing (POC MDx)	• **Testing to detect nucleic acid sequences (molecular testing) that is performed outside of a traditional laboratory setting at a site near to patient. Easy to use, performed at by non-laboratory healthcare personnel**
Near POC MDx (in scope)	• Benchtop instruments that require minimal infrastructure
	• Minimal training required; maintenance required
	• Automated or semi-automated process that can include external sample preparation steps
True POC MDx	• No laboratory infrastructure requirements, no or minimal maintenance, minimal training
	• Portable, battery-operated instrument with disposable cartridge containing all necessary materials and fully automated testing process
"Instrument Free" True POC MDx	• Single use disposable device containing all necessary reagents, no instrument requirements, compatible with home use and self-testing
Multiplexing	• Number of analytes that can be detected in a single sample simultaneously

2. PROJECT SCOPE

As the co-convener of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar, FIND has invested in the development and/or access of Multiplexed platforms tailored to the epidemiological needs and resource availability in LMIC markets.

FIND has active collaborations with several POC MDx manufacturers. Three FIND partner manufacturers are finalizing the development and preparing the commercialization plans for their near-POC platforms. All three platforms are benchtop instruments using PCR technology and that can be deployed in facilities with minimal laboratory infrastructure such as district hospitals (level 2 healthcare facilities):

- **1. Two manufacturers with fully developed near-POC platforms aiming to commercialize in 2023** a multiplex tests detecting SARS-CoV-2/Flu/RSV from respiratory samples and with growing pipeline of other assays including TB, STI, HPV, AMR, HIV and others) – *the priority use case is for surveillance & differential diagnosis at L2 facilities in LMICs, with progressive applications for screening, diagnosis, and treatment as the target assays are expanded.*
- **2. One manufacturer with a near-POC platform that has developed an assay for positive blood culture based testing-** basis blood culture, this detects multiple reporting targets simultaneously (pathogens and antibiotic resistance genes) - t*he priority use cases are diagnosis & treatment in L2 clinics, hospitals, and wet labs, with progressive applications for surveillance.*

3. OBJECTIVES

To support the market entry, FIND is providing market-specific insights that will inform the development of Go-to-Market Strategies (GTM) for these technologies. Priority countries are situated in both South East Asia and Latin America, though other countries in each of these regions may also be proposed by applicants if this will enhance the GTM planning process. Applicants are invited to bid on all or part of the countries in this proposal.

The primary objective of this work is to create GTM plans for the near-POC multiplex platform described above. The GTM plans will tactically guide manufacturers through critical activities and will ensure a successful launch of the product into the following priority LMIC markets:

Up to two priority countries South-East Asia :

- The Philippines
- Indonesia
- Thailand

Up to 2 priority countries for Latin America and the Caribbean:

- Argentina
- Brazil
- Colombia
- Peru
- Mexico

Kindly note FIND will prioritise markets and applicants where there is demonstrated ability to use previous sales and installed base capacity data, and in-country trade networks to inform GTM planning.

4. RESEARCH AREA & QUESTIONS

FIND seeks an individual, organization, or group that will be able to undertake market research activities described in the table below. Kindly note that the deliverables will need to be segmented by product type.

Theme	Activity	Key Questions	Key Outputs
Market size & segmentation <u>by product type</u> *<u>Kindly note the difference in the priority use cases for the two target product classes in scope for this RFQ</u>*	Market Segmentation and Target Market	How is the market segmented? What target market (geography, product class, use case) is this product? Who are the customers/stakeholders in that target market and their drivers? What are opportunities or barriers to entry? What are the value propositions? What does the patient journey look like?	- Major market segments and target market/use cases (e.g., public, private, L2, etc.) - Opportunities/barriers in target market - Customer profiles (e.g., user, patient, buyer, payor) and market perceptions - Value proposition/drivers/barriers to new product selection, decision making process - Patient journey
	Market sizing and competitive landscape	What is the current market size for near-POC molecular testing with a focus on the highlighted product classes within this category? What is the realistic market demand for the products? Who are the competitors in the market? What are key specifications/differentiators/perceived value of competitors?	- Demand forecasts, broken down by use cases and patient populations. - Market data share, prices and volumes, broken down by products - Competitive products in Target Market - Critical product requirements, specifications
Health Financing	Payors	Who will pay for these products? What are purchasing drivers and value propositions?	- Payors of product in target market (e.g., private hospitals, public agencies, etc.) - Procurement mechanisms - Reimbursement policies if any - Insurance/healthcare coverage for disease state/product - Financing trends, considerations - Willingness to pay analysis

Policy by product type	Stakeholders	Who are the stakeholders involved in the governing, purchasing, advocacy of this Product or product class?	- Global, regional, local stakeholders (e.g., global institutions, technical experts, policy makers, professional organizations, etc.) and their value propositions
	Policies	What are the global, regional, local normative guidelines (including regulation) for these products and/or product classes?	- Global, regional, local policies and guidelines influencing product/product class, Does the introduction of this test require change in guidelines. - Understanding the local regulatory pathways including which requirements need to be filled to register an IVD in the country, and how they can be included into disease guidelines. If yes, Identify relevant stakeholders and evidence for guideline recommendations
Product Launch by product type	Distribution	What are the Key distribution channels?	- Key distributors in target market, distribution selection criteria - Distribution process/mechanism in each channel (ie., public vs private) - Impact of margins along the value chain on the end user cost of products
	Service, Maintenance	How can the Product be serviced?	- Vendors to provide service in LMICs
Product Launch by product type	Advertising and Promotion	What are the channels to promote the Product?	- Local conferences, workshops, meetings Other channels/strategy recommendations
	Initial Target Customers	Who will be the early adopters of the Product?	- Potential early adopters, or product champions

5. DELIVERABLES

Key deliverables would be governed by the thematic outputs mentioned above in the document. For all the mentioned documents, draft/intermediary versions to be shared with FIND before sharing final detailed and synthesized versions –

1. **User-friendly market sizing model** for near-POC devices user guide, inputs (data and parameters / assumptions) and outputs (incl. visualizations) clearly shown in MS Excel format, and market sizing methodology in MS PowerPoint format. All inputs and data sources to be shared in raw data form.
2. **Financing landscape and recommendations report** in Microsoft word or PowerPoint format, detailing all the findings. A template/skeleton will be agreed with FIND at the beginning of the project.
3. **Stakeholder mapping and policy/regulatory landscape** along with recommendations in Microsoft Word or PowerPoint format, detailing all the findings. A template/Skeleton will be agreed with FIND at the beginning of the project for near-POC devices.
4. **Synthesized version of service and maintenance landscape** and recommendations in Microsoft Word or PowerPoint for near-POC devices.
5. **GTM launch plan** (just for near-POC devices) along with recommendations in Microsoft Word or PowerPoint format, detailing all the findings. A template/Skeleton will be agreed with FIND at the beginning of the project. This will focus on a subset of key stakeholders to operationalize basis the mapping and policy landscape findings under Output 3.

- A record of all interview guides, interviewee lists and transcripts from interviews.
- A reference list connecting key insights from the report to relevant source of literature

Details on expected deliverables available here

6. TIMELINE & REQUIREMENTS FOR PROPOSAL PREPARATION

The Project is expected to take a total of 4 Months. The project will commence on 5th of May 2023 latest and conclude by Q3 2023 with regular check-ins with FIND.

Candidates interested in responding to this RFQ should submit a proposal, in Microsoft WORD or POWERPOINT format, including the following information:

- Organizational profile
- Areas of expertise
- Experience, including a list of relevant projects you've worked on
- Proposed scope of work and workplan
- Methodology
- Budget (including breakdown)
- Proposed team (including CVs of members)
- Network and partnerships in high-priority LMICs
- Case studies

- Client references & Contact details (in case there is a follow-up from FIND regarding the proposal)

Please direct your submissions and any questions to the following email:

procurements_miu@finddx.org

Details on the evaluation and award process can be found here.

Key dates in RFQ process

Publication of RFQ	09/03/23
Closing for submission of written queries	18th of March 2023
Closing of RFQ submissions	5th April 2023
Interviews for shortlisted candidates	10th - 12th April 2023
Communication on award	14th of April 2023

7. APPENDIX A: DETAILS ON EXPECTED DELIVERABLES

Area	Outputs	Detailed process
General Guidance		• Source data/information from literature review provided in a readable format (preferably MS Word or Excel), list and folder of key documents reviewed
		• Skeleton and mock-up of all deliverables will be validated with FIND
		• Standard interview guides/ survey methodology validated by FIND – and subject to change based on content of literature review
		• List and contact info for stakeholders to be interviewed in MS Excel format stating country, type of organization, history of engagement if any in context of FIND project, and contacts (phone and/or email)
		• Detailed notes (or transcripts) for all key stakeholder interviews in MS Word format
Market- by product type *Understand true market size and opportunities to prioritize basis insights from demand forecasts, patient journey (based on priority use cases), & competitive landscape*		**Project Output 1: User-friendly market sizing model with user guide, inputs (data and parameters / assumptions) and outputs (incl. visualizations) clearly shown in MS Excel format, and market sizing methodology in MS PowerPoint format**
	Demand forecasts	• Training and handover session for FIND staff on model
	Patient journey for priority use cases; care seeking behaviour and entry points	• Summary of the results of the market model, methodology and market landscape synthesized with the other project outputs in the final deck or report. • Recommendations on commercial marketing plans, including a list of key events, target customers, stakeholders for further engagement and ranking of pathogens which could be included in the multiplex system.
	Competitive insights	

Area	Outputs	Detailed process
Financing- by product type *Understanding the macrofinancing landscape at a high level, identifying key players, gaps and opportunities to influence the market.* *Understanding the microfinancing landscape, including willingness to pay in both providers and patients in the public and private sectors.*	Financing landscape & county readiness	**Project Output 2: Financing landscape and recommendations report in Microsoft word or PowerPoint format, detailing all the findings. A template/skeleton will be agreed with FIND at the beginning of the project.**
	Payers/ Funders global and national landscape	• Synthesized version of financing landscape and recommendations in Microsoft word or PowerPoint
	Willingness to pay analysis – public sector, disaggregate by provider & patient	• Estimation of the willingness to pay for the product classes outlined in the scope for the public sector (within each target country).
	Willingness to pay analysis – public sector, disaggregate by provider & patient	• Estimation of the willingness to pay for the product classes outlined in the scope for the private sector (within each target country). • Estimate the likelihood of adoption for the product classes outlined in the scope.
	Policy & regulatory mapping	**Project Output 3: Complete stakeholder mapping and policy landscape along with recommendations in Microsoft Word or PowerPoint format, detailing all the findings. A template/Skeleton will be agreed with FIND at the beginning of the project.**

Area	Outputs	Detailed process

	Policy and regulatory Landscape	• Synthesized version of stakeholder mapping and policy landscape in Microsoft Word or PowerPoint
		• Include information about regulatory requirements which could impact the introduction of these products into the market for these countries.
		• Gather detail on the evidence requirements needed for Diagnostic Guideline Inclusion for each country. This information can help guide clinical trial design for manufacturers planning on entering the markets.
		• *Potential stakeholders to be interviewed or surveyed will include:*
		  · *Program managers from relevant areas at the national and sub-national levels*
		  · *Healthcare providers and laboratory staff at facilities with a high volume of respiratory disease burden (public and private)*
		  · *National Ministry of Health public health policymakers*
		  · *Ministry of Health surveillance and monitoring staff*
		  · *Regional and in-country implementation partners*
		  · *Health Technology Assessment advisors/Medical society/academic leads in charge of drafting clinical guideline recommendations*
		  · *Distributors/eCommerce other B2B*
		• A checklist of documents required and contact information for the registration/regulatory body.

Area	Outputs	Detailed process
		• Recommendations for how to fast track process with CE-IVD and/or existing SRA approvals and/or regional regulatory mechanisms • A description of in-country validation and verification requirements with or without EUL
Commercial Support- by product type	National Distribution Strategy	**Project Output 4: Synthesized version of service and maintenance landscape and recommendations in Microsoft Word or PowerPoint**
	National Service and maintenance strategy	• Complete distribution landscape and recommendations in Microsoft Word or PowerPoint format, detailing all the findings. A template/Skeleton will be agreed with FIND at the beginning of the project.
	Distribution landscape	• Synthesized version of distribution landscape and recommendations in Microsoft Word or PowerPoint • Size of promotional team/sales force

Area	Outputs	Detailed process
GTM Launch plan- by product type *Develop technology and product class specific GTM plan*	Advertising and Promotion	**Project Output 5: Complete launch plan for near-POC devices) along with recommendations in Microsoft Word or PowerPoint format, detailing all the findings.** A template/Skeleton will be agreed with FIND at the beginning of the project.
	Target use cases & Likelihood of adoption	• Synthesis of key use cases and target populations for each of the products listed in the scope, in each country. • Summary of key access considerations and recommendations to ensure successful GTM for each target user type. • Where feasible, consider relative cost effectiveness across use cases to inform prioritization.

8. APPENDIX B: EVALUATION AND AWARD PROCESS

The evaluation process is designed to be objective, independent, and transparent to ensure that the most suitable proposals are identified. Proposals from candidates will be evaluated by an internal review panel comprising Access and R&D team members within FIND. Proposals will be evaluated against the following criteria:

- The quality of the financial proposal as well as the transparency and breakdown of all financial elements included in the final quote. Candidates should provide as much information as possible to explain their proposed budget**.**
- The proposed scope of the work, indicating candidates' understanding of the scope of work and the extent to which proposed activities match the activities listed in this RFP.
- Market research expertise, i.e. candidates' experience and expertise in the various market research topics listed in this RFP and their experience in performing similar market assessments; executing specific market intelligence deliverables (e.g. disease management/policy landscape analysis, funding landscape analysis, procurement and distribution landscape analysis, market landscape and market sizing analysis); and conducting secondary and primary market research (through key opinion leader (KOL) interviews, surveys, focus groups, etc.)
- Experience in conducting market assessments in LMICs and in the diagnostics field.

- Proposed team: the “quality” (i.e. composition, experience) of the team that will work on the RFP Candidates must describe the team members, detailing their background and experience; complete CVs for all proposed team members must also be submitted.
- Networks or physical locations of candidates in the countries of scope, e.g. access to networks of relevant stakeholders in LMICs/specific project countries.

With regards to the evaluation, each criterion will have the same weight except for the criteria “quality of the financial proposal” and “the proposed Scope and methodology proposed” (weight of x2).

Where FIND judges more than one application to be complementary, FIND reserves the right to suggest partnership within the RFQ process.

If applicants choose to prepare the grant budget using a different currency, the budget should be converted using a 6-monthly average rate from a trusted source (e.g. Central Bank or Oanda).

CONFIDENTIALITY

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested Applicants/Bidders prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. Review of proposals will be carried out by an internal FIND team all of whom are under confidentiality and are recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team.