Request for Proposals

Seeking developers and manufacturers of mpox diagnostics to participate in a performance evaluation in low- and middle-income countries and accelerate product development

EXECUTIVE SUMMARY

Background	Mpox cases, caused by monkeypox virus (MPXV), are escalating in the Democratic Republic of the Congo (DRC) and crossing borders into neighboring countries, leading the Africa CDC to raise the alarm as a Public Health Emergency of Continental Security on 13 August and WHO to declare the regional outbreak as a Public Health Emergency of International (PHIEC) Concern the day after. The increasing number of cases demonstrates the lack of appropriate testing capacity urgently required to understand the impact of the outbreak and to guide the response to ensure communities who need it most get the urgent care they need. We need to better understand the different clades to tailor our health responses and have quick and accurate diagnoses at the primary care level to support the communities most affected. FIND is working with global partners to accelerate and expand the range of diagnostics available as part of the 100 Days Mission to reach communities equitably and fast. Gaps are evident as diagnostic capabilities are limited through lab-based tests that take days for results. Therefore, **FIND is collaborating with Africa CDC to support the mpox diagnostic response by ensuring the development, evaluation and availability of diagnostics suitable in decentralized settings and benchmarking activities to the 100 Days Mission for medical countermeasures.**
Purpose of partner engagement	FIND is opening a Request for Proposals (RFP) to find developers and manufacturers of antigen-detecting lateral flow tests (LFTs) and point-of-care molecular tests for the detection of monkeypox virus (MPXV) clade 1 (including clade 1b) and clade 2 to perform an independent performance evaluation in LMICs sites and accelerate product development.
Type of partners & Technologies	Eligible entities are original industry developers or manufacturers of antigen-detecting LFTs or point-of-care molecular tests capable of detecting clades 1 and 2, suitable for primary and community care levels. The mpox assay and device (when applicable) must be ready for an independent evaluation i.e., the technology readiness level (TRL) of the assay and device must be 7 or above. Applicants must be willing to commit to an affordable selling price for LMICs and other access conditions to be negotiated as part of the partner agreement. For further details, see section "Eligibility criteria".
Benefits for the applicants	Through this RFP, FIND will:

	• PHASE 1: Fund and independently evaluate test performance at FIND partner sites for mpox tests capable of detecting clades 1 and 2. • PHASE 2: Fund product optimization activities (depending on funding availability) **Throughout this project, commercialized point-of-care mpox tests will be assessed and recommended by Africa CDC depending on the quality of existing or newly generated data.**
Expected project timeline	• Start of the independent performance evaluation**: November 2024.**
Application deadline	The deadline for receipt of submissions is **20th September 2024 at 23h59 CEST.**
Contact	Please email questions to rfp.bi@finddx.org with the subject line: "RFP MPOX EVALUATION AUG2024"

SECTION 1: THE PROJECT

BACKGROUND

The global mpox outbreak, a viral disease caused by infection with the monkeypox virus (MPXV), which began in 2022, has resulted in over 100 000 confirmed cases reported to the WHO. The rapid spread of the new Clade 1b strain, particularly in eastern Democratic Republic of the Congo (DRC) and neighboring countries, and its recent detection in Sweden and Thailand, underscores the growing threat. Other clades, such as Clade 1a and Clade 2, are also spreading in various African countries, complicating the response. This escalating situation led to the declaration of a Public Health Emergency of International Concern on 14 August 2024 (source draft_sprp_mpox_2024.pdf (who.int)).

DRC is currently experiencing an extensive Clade 1 mpox outbreak characterized by a dramatic spike in cases and deaths, up to 23 (previously 11) out of the 26 provinces in the country are now affected, the emergence of new transmission routes, and children (<15yrs) now constituting a high-risk group. Over 21,000 suspected MPXV cases and 1,003 deaths have been reported in DRC from the beginning of 2022 to January 2024, and approximately 85% of deaths in this period were children under 15 years of age. More than 210 confirmed cases of clade 1b have been reported in Burundi, Kenya, Rwanda, and Uganda. Clade 1b mpox cases have also been reported in Sweden and Thailand, among people with a history of travel from Africa. The situation is further complicated by outbreaks of clade 1a in western DRC, Central African Republic, and Republic of Congo; and clade 2 in Cameroon, Côte d'Ivoire, Liberia, Nigeria, and South Africa.

Although timely diagnosis is critical in implementing stringent control measures such as case isolation, contact tracing, and treatment to mitigate the further spread of the disease, limited diagnostic capacity continues to impede mpox preparedness and response in the African Region.

Therefore, FIND is launching this Request for Proposals (RFP) to support field evaluation of antigen-detecting lateral flow tests (LFTs) or point-of-care molecular tests capable of detecting clades 1 and 2 (including clade 1b), suitable for primary and community care levels. FIND is also planning to support product optimization activities.

PRODUCT SPECIFICATIONS

FIND is willing to evaluate tests for mpox that meet or target the following key product requirements[1]:

Category	Minimum requirements (LFT)	Minimum requirements (molecular POC)
Intended use	Tests to aid mpox (monkeypox) diagnosis in individuals of all ages and genders with clinical symptoms of mpox by detecting MPXV clades 1 and 2, suitable for primary and community care levels.	Same as for LFTs, but molecular POC tests should preferably be capable of distinguishing between Clades I and II.
Target technology	Antigen-detecting lateral flow tests (immunoassay) *Note: antibody-detecting lateral flow tests are out of scope.*	Point-of-care molecular tests *Note: Point of care refers to decentralized testing that is performed by a non-lab trained health care professional and/or lay health worker near a patient, and outside of a laboratory setting, where test results are generally made available during a single clinical encounter*
Target user	Non-lab trained health workers and/or lay community workers	Health workers with limited training on laboratory practices.
Target use settings	Within the community (Level 0) and above	Primary healthcare settings (Level 1) and above (outside laboratory setting)
Target analyte(s)	Demonstrates detection (coverage) of all circulating MPXV clades 1 & 2 (including clade 1b). *Note: Differentiation between the clades is not compulsory but strongly preferred.*	
Sample type/ Collection method	Lesion swabs; allow for the use of stored samples In the absence of lesion material: mucosal swabs (i.e., oro/nasopharyngeal and/or anorectal) or saliva	
Results interpretation	Qualitative	
Clinical sensitivity	≥ 80% (lesion swabs)	
Clinical specificity	≥ 97% (lesion swabs)	
Time to results	≤ 30 min	≤ 60 min
Sample preparation	Minimal pre-test processing required such as need for sample inactivation step and/or sample preparation / transfer step (e.g., placement of swab in proprietary buffer and then addition to the test). Minimal reagent reconstitution acceptable without any requirement for precise measurement.	

[1] For more details, please review the WHO TPP2 "Tests used as an aid to diagnosis by detecting orthopoxvirus (OPXV) antigens, which are amenable to decentralized use, including in the community (TPP2)", from Target product profiles for tests used for mpox (monkeypox) diagnosis (who.int)):

Test Kit components	All materials for sample collection, preparation and test operation included. IFU includes information on the viral region(s) being targeted. No additional laboratory equipment required.	
Operating temperature and shelf life	Shelf-life: ≥12 months, 4ºC - 30ºC, 80% RH (tolerates brief periods > 40°C) Operating range: 15ºC - 35ºC, 80% RH (able to withstand dusty conditions) No cold-chain shipping required.	
Result display & interpretation	Visual read-out is preferred (clear result for naked eye), but the use of a portable, affordable and battery-operated reader can be accepted if it justifies the improvement of performance.	Results are easily interpreted (e.g. visual or digital readout).
Size & Weight (in case of the use of a device/reader)	Handheld, portable or small footprint device Battery-operated or compatible with an external portable power bank to ensure operations for 4-8 hours operation between charges.	
Maintenance	None, swap out or replace ancillary devices when needed.	
Target price per test (ex-works)	≤ 5 USD	≤ 10 USD

OBJECTIVE AND SCOPE

FIND's priority is to work with global partners to accelerate and expand the range of diagnostics available as part of the 100 Days Mission to reach communities equitably and fast. Gaps are evident as diagnostic capabilities are limited through lab-based tests that take days for results. Therefore, **FIND is collaborating with Africa CDC to support the mpox diagnostic response by ensuring the development, evaluation, and availability of diagnostics suitable in decentralized settings and benchmarking activities to the 100 Days Mission for medical countermeasures.**

Specifically, FIND's immediate objective is to assess the performance of mpox diagnostic tests in decentralized settings. In that context, FIND is seeking eligible industry developers and manufacturers interested in having their mpox antigen-detecting LFT or point-of-care molecular test evaluated and willing to optimize their test. FIND aims to:

- PHASE 1: Fund and conduct an independent field evaluation of test performance at FIND partner sites for tests capable of detecting clades 1 (including clades 1b) and 2. The evaluation will consist of an analytical laboratory study as well as a clinical evaluation in clinical settings in DRC and possibly in other African countries, such as Nigeria. Formative study (e.g. on usability) might be conducted as well.
- PHASE 2: Fund product optimization activities.

The results of these performance evaluations will be published on FIND website and shared with the global health community so that affected countries have objective and independent evidence about the performance of available mpox tests suitable for decentralized settings. Test developers will have a chance to review the results and provide comments before their results are published. However, FIND and our evaluation partners will have final jurisdiction over publications. Neither FIND nor our study partners will endorse any assay or test developer over any other because of this performance evaluation study. Through the support of our donors, FIND will procure the company's tests and platforms for assessment and evaluation at the study sites.

OPPORTUNITIES AND BENEFITS FOR THE APPLICANTS

Participating in the independent evaluation of their product, the test developers and manufacturers will:

- **Benefit from evidence generation on performance** data that will be relevant to global health stakeholders, particularly Africa CDC.
- **Contribute to Global Health:** By participating in this project, applicants contribute to advancing diagnostic capabilities for mpox in LMICs.
- **Networking and Collaboration Opportunities:** The project provides a platform for applicants to connect and collaborate with FIND, other stakeholders, and potential partners in the global health community. This can foster valuable relationships, knowledge exchange, and future opportunities for research and development.

Depending on the outcome of the project, additional support to selected manufacturers will be considered, such as:

- **Test optimization** to support market entry in LMICs.

TIMELINE

An overview of key project dates is provided below (tentative dates):

- Start of the independent performance evaluation**: November 2024.**

SUPPORT PROVIDED BY FIND

INDEPENDENT EVALUATION ACTIVITIES

For technologies ready and eligible for independent evaluations, the applicants can expect the following support from FIND in cooperation with study sites (the list provides examples and is not exhaustive):

- FIND will conduct the performance evaluation and may conduct formative research in the target populations (e.g. usability assessment).
- FIND will procure the tests and platforms (or consider loan agreements for platforms) for the evaluation study.
- Assistance with import permit to ship the kits to the evaluation sites.
- Selection of the study sites.
- Study protocol development and submission for IRB approval.
- Study management.
- Data collection and data analysis.
- Study report preparation.
- Dissemination of results to relevant stakeholders.

PRODUCT DEVELOPMENT ACTIVITIES

For technologies that will undergo product optimization/development activities during the project, the applicants can expect to receive the following support from FIND (the list provides examples and is not exhaustive):

- Funding for product optimization to meet the requirements for a test to be used in the community and/or at primary care settings in LMICs. Example: Improve the robustness of the device or assay reagents for LMIC environmental conditions, make the device battery-operated, and simplify the operating steps.
- Funding for product optimization to identify or differentiate between the various MPXV clades.
- Funding for product optimization to withstand environmental conditions in LMICs (extended shelf-life, wider operating conditions).

- In-kind support such as technical guidance, expert consultancy support.
- Access to biobanked samples

COMMERCIAL PARTNER INVESTMENT

The following typical investments will be needed from the selected partners:

INDEPENDENT EVALUATION ACTIVITIES

- Manufacture the number of assays and devices/readers (if applicable) needed for the independent performance evaluation at LMIC sites from 3 different lots (from different critical raw materials).
- Ship a minimum of 150 assays and 3 devices/readers (if applicable) to sites (n=3, 2 in LMICs) for independent studies in less than 30 days.
- Provide instructions for use and training to the evaluation team.
- Provide support during the studies, if necessary.

PRODUCT OPTIMIZATION ACTIVITIES

- Carry out optimization/development activities according to project requirements and timelines within the agreed budget.
- Maintain documentation according to Quality Management System.
- Provide regular technical and financial reports per agreed scope-of-work.
- Co-funding for product development/optimization activities is not compulsory but strongly encouraged.

Irrespective of the type of partner engagement activities, the selected partners commit to a transparent and affordable pricing model by providing relevant COGS for the lowest sustainable pricing for LMICs (i.e., COGs-based pricing).

SECTION 2: INSTRUCTIONS AND PROPOSAL REQUIREMENTS

ELIGIBILITY CRITERIA

Entities responding to this RFP must meet the following criteria for their proposals to be considered.

- Original developers/manufacturers of antigen-based lateral flow tests or point-of-care molecular tests capable of detecting MPXV clades 1 (including Clade 1b) and 2, and being suitable for primary and community care levels (see Health Levels table).
- Geography: We invite developers/manufacturers from around the globe and also strongly encourage applications from LMICs.
- Willing to participate in an independent performance evaluation.
- Stage of development: commercially available. If in development, the system must be design-locked and ready for independent evaluation (including manufacturing and shipping), defined as TRL7 or above (see TRL table).
- Commit to supply assay kits and devices for manufacturer-independent performance evaluation upon FIND procurement.
- At minimum, the following key technical requirements must be met:
    1. Technology: Lateral flow test (antigenic immunoassay) or point-of-care molecular tests
    2. Inclusivity: Able to detect MPXV clades Ia, Ib, IIa and IIb (at least, coverage). Differentiation between the clades is strongly preferred for point-of-care molecular tests.
    3. No cross-reactivity with endogenous substances and other human non-OPXV, especially those causing similar signs and symptoms as MPXV (e.g., VZV, HSV).
    4. Compatible with operations in decentralized testing and operated by lay users or health workers with limited training on laboratory practices.
    5. No laboratory equipment is required with all necessary materials and reagents included in the kit.
    6. In case of a device/reader, it must be handheld, portable or small footprint device (usually below < 10kg) and battery operated or compatible with external portable power bank to ensure operations for 4-8 hours between charges.

Table: Description of Technology Readiness Level (TRL).

Technology Readiness Level	Description	Detail
TRL 1	Basic technology principles	Scientific literature reviews and market surveys; unmet need and potential solutions articulated
TRL 2	Technology concept formulated	Potential applications identified, research plans and protocols developed
TRL 3	Experimental proof-of-concept	Preliminary demonstration of scientific principles using laboratory models and methods
TRL 4	Technology components validated in laboratory	Component validation in laboratory environment *Some laboratory practices (e.g. kit extraction) still used*
TRL 5	Technology validated in operational environment	Component/breadboard validation for target setting (e.g. LMIC, POC) *All components for device are developed and demonstrated*
TRL 6	Technology demonstrated in operational environment	Prototype demonstration: full process but not final integration *Appropriate for in-house alpha testing*
TRL 7	Integrated system demonstration in target setting	Prototype demonstration: fully integrated system *Appropriate for beta-testing; can be sent out for evaluation*
TRL 8	System complete and qualified	Validation studies completed; in process for regulatory approval
TRL 9	Commercial system ready for operation	System can be marketed

Table: Definition of health system infrastructure levels according to Ghani et al. and the Maputo Declaration[2]

Characteristics	Level 0	Level 1	Level 2	Levels 3 and 4
Description	In the community or home	Lowest level of healthcare system with a laboratory	First level of referral healthcare and laboratories	Second and higher levels of referral healthcare and laboratories
Examples of locations	In homes, health fairs, health posts, clinics with no lab, pharmacies	Health centres (Africa), rural health centres (Asia and Latin America)	Hospitals (Africa), urban health clinics (Asia and Latin America), clinical labs in the developed world	Hospitals (Latin America and Asia), national clinical/reference laboratories (Africa), surveillance laboratories, research laboratories
Electricity	Not reliably available	Not reliably available	Available, expected to have refrigeration	Available
Clean water	Not reliably available	Not reliably available	Available	Available
Physical lab infrastructure and lab equipment	No laboratory	Not all facilities have labs. If present, minimal lab (e.g. microscope, centrifuge) or moderate lab (see level 2 description)	Moderately equipped lab (e.g. additional equipment for basic chemistry and manual immunoassays)	Well-equipped laboratories (e.g. automated and advanced equipment)
Personnel	Community healthcare worker, nurse, family member, pharmacist, traditional medicine practitioner	Nurses, sometimes physicians, laboratorians with a range of training	Nurses, physicians, moderate and well-trained laboratorians	Nurses, physicians, well-trained laboratorians

OUT OF SCOPE

The following categories of entities and products are not in the scope of this RFP:

- × Distributors
- × Academic teams
- × Antibody-detecting lateral flow tests
- × Products that are not compatible with decentralized testing, such as molecular kits, large automates
- × Prototype tests (e.g. tests still in early development and not design-locked)
- × Tests currently not available for supply or procurement for independent evaluation

SELECTION CONDITIONS

For this RFP, applicants who are part of the final selection are expected to:

- Commit to and follow FIND Global Access Policy and FIND Code of Conduct and Ethics
- See **Appendix 3** for additional information on "Grounds for Exclusion".

Relevant for product optimization activities only:

- Commit to undertaking activities that enable product launch (e.g., local registration, service, and distribution activities) and to supply to the public sector in LMICs (volume and details to be negotiated).
- Commit to a pricing model that is transparent and affordable for LMICs (i.e. COGS-based pricing) (see **Appendix 2**).

[2] Ghani AC, Burgess DH, Reynolds A, Rousseau C. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. Nature. 2015;528:S50–52. The Maputo Declaration on strengthening of laboratory systems. Geneva: World Health Organization; 2008 (http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf, accessed 27 December 2019).

APPLICATION DEADLINE

The deadline for receipt of submissions is **20th September 2024 at 23h59 CEST.**

APPLICATION REQUIREMENTS

To be complete, applications must include the following:

- **Applicant presentation:** Applicants shall provide a slide deck of **no more than 30 slides** and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms).
- **Assessment matrix:** Applicants are to complete noted sections of the provided spreadsheet titled "Assessment Matrix" (see **HOW TO APPLY** for templates and forms).
- **Self-declaration:** Applicants are to complete the self-declaration form (see Appendix 3)
- **Supporting documents:** Aside from the documents listed above, the only additional documents allowed for submission are registration/regulatory certificates, QMS/ISO certificates, instructions for use/product inserts for existing or relevant products, if available, and CVs from relevant team members and management.

HOW TO APPLY

Submit applications via the FIND Technology Scouting Submission Webform. Templates for the documents requested for the application can be downloaded from the submission portal. An incomplete dossier will not be considered for review.

SELECTION PROCESS

Preamble: Below is a description of the selection process. For the PHASE 1 activity (i.e. the independent evaluation), only the Stages 0 and 1 are applicable. For the PHASE 2 activity (i.e. the product optimization), the Stage 2 and Due diligence will be applicable.

The selection process is designed to be objective, independent, and transparent to ensure that the most suitable partner is selected, and potential conflicts of interest avoided. Candidates will be evaluated by an internal review panel comprised of staff at FIND and possibly FIND's project partners, and by an external review panel comprised of specialists with backgrounds in technical R&D, product launch, and implementation. The review panels will use information submitted in the application (see **Application Requirements**), as well as publicly available information. The review panels may request additional information or clarifications, if needed, in writing.

Applications will be evaluated in stages, as follows:

- **Stage 0.** All applicants' eligibility will be verified, and those that are "out of scope" or incomplete will be excluded. Additional grounds for exclusion of an application at this stage are detailed in **Appendix 3**. The list of eligible candidates will advance to Stage 1.
- **Stage 1.** This first evaluation will shortlist up to 10 candidates. An internal review panel will evaluate long-listed candidates using the submitted application materials (See **Application Requirements**). More specifically, candidates will be evaluated on:
    - Existing product specifications, scored in the sheet titled "**Technical Assessment**" in the **Assessment Matrix**.
    - Organizational criteria, scored in the sheet titled **"Business Assessment"** in the **Assessment Matrix.**
    - **Applicant Presentation,** which details specific topics described in the **Application Requirements**.

  The internal review panel will then score the candidate's alignment to the goals of the RFP (see sheet titled **"Alignment Criteria"** in the **Assessment Matrix**). The **Applicant's Total Score** will then be calculated as a weighted sum of the scores from the Technical Assessment, Business Assessment, and Alignment Criteria. Short-listed candidates will be selected in a consensus call of reviewers and will advance to Stage 2.

- **Stage 2.** This second evaluation will define the list of finalists. Candidates will be evaluated using:
    - **Follow-up live presentation** (by teleconference): short-listed candidates will be invited to make a follow-up presentation to address a set of questions provided to the candidates in advance.
    - Applicant presentation, which details specific topics described in the application requirements.

  Note: Applicants not selected will be notified; however, the details regarding non-selection will not be provided for every applicant.
- **Due diligence:** The due diligence (DD) to verify the applicant submissions and claims will proceed in parallel with contract negotiations. The DD process may include site visits and/or phone/video conferencing, as well as requests for additional information. Should the DD reveal any unresolvable inconsistencies with this RFP and/or donor requirements and restrictions, applicant exclusion at this late stage is still possible. FIND may outsource the conduct of DD to an independent third party, following FIND procedures.

Stage 0	Stage 1	Stage 2 (for product optimization only)
Initial screening of all applicants to a set of long-listed candidates	*First evaluation to short-list candidates (up to 10)*	*Second evaluation to define a list of finalists.*
• Verification that the contents of the application are in-scope. Applicants that are "out of scope" will be excluded. • Verification of applicant eligibility. Applicants that are not eligible will be excluded.	• Evaluation of long-listed candidates will be performed by an internal review panel. • Candidates will be evaluated based on: 1. Score on the "Technical Assessment" within the Assessment Matrix 2. Score on the "Business Assessment" within the Assessment Matrix 3. Applicant Presentation • The internal review panel will score the candidate's overall alignment with the goals of the RFP (see sheet titled "Alignment Criteria" within the Assessment Matrix).	• Evaluation of the finalists will be evaluated based on: 1. Scores on the "Technical Assessment" and "Business Assessment" completed in Stage 1. 2. Applicant Presentation 3. Follow-up questions and Live Presentation • The review panel will score the candidate's overall alignment with the goals of the RFP (see sheet titled "Alignment Criteria" within the Assessment Matrix).

SUMMARY OF SELECTION TIMELINE

RFP Issued	3rd September August 2024
Deadline for questions	10th September 2024
Application deadline	20th September 2024
Notification of short-listed candidates (end of Stage 1, tentative timeline)	1 October 2024
Start of evaluations (tentative timeline)	05 November 2024

For PHASE 2 (product optimization), the timeline for Stage 2 review, Due Diligence and contract negotiation will be communicated later to selected candidates.

QUESTIONS & FURTHER INFORMATION

Please email questions to rfp.bi@finddx.org with the subject line: "RFP MPOX EVALUATION AUG2024". Questions will be accepted and responded to expediently up to and including **10 September 2024**. Submitted questions (and corresponding answers) will be publicly available on the Calls for Partners page.

CONFIDENTIALITY

All information supplied to the applicant by FIND, including the RFP and all other documents relating to the RFP process, must be treated as confidential, and not disclosed to any third party unless the information is already in the public domain or is required to be disclosed by law *and vice versa*. FIND considers all application and supporting documents received under the RFP as confidential. FIND shall communicate the application and supporting documents only to its employees, consultants, agents, actual and potential donors, advisors, actual and potential partners (together "Representatives") who: (a) need to know such application and supporting documents, and (b) such Representative has agreed to be bound by confidentiality and non-use restrictions, and (c) shall be recused if found to have a potential conflict of interest (which they are obliged to disclose).

CONTRACTUAL TERMS AND CONDITIONS

FIND will use binding agreements containing commercial-level contractual clauses and FIND standard Terms and Conditions to address the requirements of supplying a product for public health particularly in LMICs, as set forth under **Appendix 4**.

COMPLAINTS

Applicants who disagree with any actions or decisions taken in the course of the RFP evaluation may file a complaint in writing to FIND (rfp.bi@finddx.org), detailing the grounds for the complaint and making reference to the applicable provisions in the RFP or other regulations. The complainant may also use FIND's Ethics Hotline as a channel for raising complaints anonymously. FIND shall acknowledge the complaint within three (3) days of receipt and respond within ten (10) working days thereafter.

Appendix 1:

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Appendix 2: Pricing considerations

FIND is committed to assisting research and development for innovative diagnostics that have the potential to ultimately be delivered to LMICs. Special consideration will be given to applicants who are able to demonstrate their **commitment to marketing their system in LMICs.**

Transparency

FIND recognizes not only the urgent market need for an affordable point-of-care system but also the need for a sustainable business model. In the spirit of collaboration, FIND aims to strike a balance where the needs of both the market and the applicant are met. In the context of confidential discussions, FIND expects applicants to provide transparency around the COGS-based price. This price should allow companies to cover their expenses and enable long-term support and supply of the product while remaining accessible to the public sector in LMICs. Ultimately, applicants are encouraged to **explore pricing models that will enable them to sustain a long-term commitment to supply in LMICs**. Pricing models include, but are not limited to, a capital purchase agreement (upfront payment for the instrument with contracted price per test), or a "reagent-rental" model, which is an all-inclusive price that includes an amortized instrument cost, all necessary reagents or consumables, and service and maintenance.

Ex works Price to LMIC markets = (manufacturing cost) + (mark-up) +
(royalties, if applicable) + (distributor mark-up, if applicable)

Appendix 3: Grounds for exclusion

Country of origin is not an exclusion criterion for this call, **except** where an international embargo or sanction by the United Nations applies.

Applicants/Bidders shall not be selected for a Contract if, on the date of proposal submission or the intended date of award, they:

- are bankrupt, being wound up or ceasing their activities, are having their activities administered by courts, have entered into receivership, or are in any analogous situation;
- have been:
  - convicted by a final judgment or a final administrative decision or subject to financial sanctions by the United Nations, the European Union and/or Switzerland for involvement in a criminal organization, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons who themselves are subject to such convictions or sanctions;
  - convicted by a final court decision or a final administrative decision by a court, the European Union or national authorities in the Partner Country or in Switzerland for sanctionable practice during any Tender Process or the performance of any Contract or for an irregularity affecting the EU's financial interests;
- have been subject, within the last five years to a Contract termination fully settled against them for significant or persistent failure to comply with their contractual obligations during Contract performance, unless (i) this termination was challenged and (ii) dispute resolution is still pending or has not confirmed a full settlement against them;
- have not fulfilled applicable fiscal obligations regarding payments of taxes either in the country where they are constituted or in Switzerland (governing law will be Switzerland);
- are subject to an exclusion decision of the World Bank, or any other multilateral development bank, and are listed in the respective table with debarred and cross-debarred firms and individuals available on the World Bank's website or any other multilateral development bank, and cannot demonstrate, with supporting information along with their DoU, that the exclusion is irrelevant in the context of this RFP;
- have given a misrepresentation in supplying the information requested by FIND as a condition to participate in this RFP.

Kindly complete the self-declaration form provided in the submission portal (see HOW TO APPLY). To note: "yes" answers to these questions should indicate, preferably with accompanying evidence, what remedial measures have been taken by the entity to resolve the issue in question. FIND will not exclude Applicants where we consider the measures to be sufficient and appropriate, and where Applicant reliability can be clearly demonstrated.

Appendix 4: Related Terms & Conditions for LMIC public sector

A list of certain key terms and conditions to be addressed in any contractual agreement executed by FIND for investment and support of successful project applications to the RFP. The below language is given for guidance purposes only. Final language to be agreed between the parties to this agreement.

- **SOME KEY DEFINITIONS**

TERM	DEFINITION
"Ex Works" or "EXW"	shall have the meaning as set out under INCOTERMS 2020 and on XYZ COGS;
"**Eligible Purchasers**"	means all Public Health Sectors in LMICs and other private (ie non-governmental) health care providers not defined under the Public Health Sector but which may have access to preferential access conditions to a Product for use in a public health setting, and as further set out under Global Access Article [●], and as determined on a case-by-case basis by FIND;
"**Global Access**"	means the principles according to which diagnostic products shall be available, affordable and appropriate for use in Territory, as further set forth in FIND's Global Access Policy available at FIND | Policy - Global Access - July 2021 (finddx.org), as amended from time to time.
"**Intellectual Property**" or "**IP**"	means patents, rights to inventions, copyright and related rights, moral rights, trademarks, trade names and domain names, rights in get-up, rights in goodwill or to sue for passing off, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which may now or in the future subsist in any part of the world. Such IPR may be encompassed in part or in whole under the deliverables and/or Product;
"**Know-How**"	means all technical and other information which is not in the public domain (other than a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, relating to but not including Foreground Intellectual Property or Intellectual Property, as previously defined in this Agreement;
"**Licence Agreement**" or "**Licence**" ***(if applicable)***	based on Article [●];
"**LMICs**" or the "**Territory**"	those countries defined by the World Bank as having "low-income economies", "lower middle-income economies" or "upper middle-income economies", as may be amended from time to time;
"Manufacturing Cost of Goods Sold" or "COGS"	means all the direct costs such as labour, material, and allocated overhead costs in Product *production;*

"**Manufacturer of Record**" ***(if applicable)***	the named legal entity legally responsible for placing a Product on the market as recognized by the appropriate in country regulatory authority. For the purposes of this Agreement the Manufacturer of Record shall be the Third Party which is the recipient of the Technology Transfer.
"**Priority Countries**"	based on Article [●];
"**Private Health Sector**"	any non-governmental institute which operates on a for-profit basis but which may have access to preferential access conditions to a Product such as set out under Global Access, and as determined on a case-by-case basis by FIND;
"**Public Health Sector**"	means (i) any government in the LMICs, including any government ministry of health, department or agency, or any local or regional governmental body, authority or entity, and (ii) any officially recognized, not-for-profit organization including private not-for-profit organizations, or funds, that pursue activities to relieve suffering, promote the interests of the poor, provide basic social services, or undertake community development, including, but not limited to, the World Health Organization, UNICEF, Save the Children Fund, and Médecins Sans Frontières, Unitaid, PEPFAR, the Global Fund, FIND or its authorised designee and other funding organizations;
"Technology Transfer" ***(if applicable)***	those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
"Technology Licence" or "Licence" ***(if applicable)***	the licence to use ABC IP and Know-how required to commercialise a Product, and as further set out under the Article [●];
"Target Product Profile" or "TPP"	characteristics of a target product that is aimed at a particular disease or diseases, including intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics, and as specifically referenced under the Article [●] to this Agreement;
"Test Unit"	the specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen.

- **QUALITY REQUIREMENTS *(if applicable)***

Quality Management Systems ("QMS"). XYZ shall ensure compliance at all times with the following;

a) Ensure an appropriate QMS covering *in vitro* diagnostic products, is in place and compliant with Stringent Regulatory Authority (SRA) and/or WHO Pre-qualification ("PQ") requirements; and
b) Ensure any Product obtains and maintains appropriate SRA and/or WHO PQ authorization or approval, as appropriate, for the duration of this Agreement or its market availability in LMICs, whichever is longest.

- **ADDITIONAL THIRD PARTIES**

General. XYZ may use Third Parties as subcontractors in the performance of its activities undertaken in connection with this Agreement, provided; a) FIND is informed and agrees in advance in writing to such subcontractor, and; b) XYZ must obtain each subcontractor's written agreement to comply with all the applicable terms and conditions of this Agreement. In addition, FIND may require reviewing the relevant sections of any agreement between XYZ and the Third Party in question, solely to ensure compliance with this Article [●]. For the sake of clarity any activity and/or obligation assigned to a Third Party under this Article [●] of this Agreement shall be considered nonetheless as being assigned to XYZ and

XYZ shall be wholly held accountable for the fulfilment of such activity/obligation and any failure by the Third Party to execute their obligations shall be considered the full and direct responsibility of XYZ.

- **GLOBAL ACCESS AND GENERAL PRODUCT SUPPLY CONDITIONS**

General. Each Party recognizes the requirements in accordance with the Global Access to ensure that any Product arising from the Agreement, will be made accessible and affordable to people living in the LMICs. Both Parties will take all reasonable and diligent actions necessary, within their scope and freedom to operate, that any Product arising from the Agreement will be made available broadly in a manner that meets their respective Global Access requirements, including but not limited to; a) provide access to the Product on an affordable basis, and including required in-country registrations as agreed with FIND, and local service and support. In addition, the Parties subscribe to the concept and implementation of Global Access as set out under the FIND policy at www.finddx.org/policies whereby, subject to the terms and conditions of this Agreement, specified results, data, generated pursuant to this Agreement shall be made broadly and publicly available to any and all entities including any Public Sector bodies, as well as for-profit and not-for-profit organizations, and research centers working in healthcare in, or for, resource-limited settings.

Eligible Purchasers and Affordable Price. XYZ agrees to the following:

a. In particular, with respect to pricing, under the TPP, the Affordable Price shall be determined as an EXW price, currently as a target of US$ per Test Unit, including sample preparation or results reader (if required);
b. Affordable Price to be available to Eligible Purchasers looking to supply Product to LMICs, including the Private Sector.
c. Other Countries. Notwithstanding the above, XYZ shall make its commercial best efforts to ensure a sufficient supply of products to LMICs that are not Priority Countries.

Priority Countries

In general, the Parties agree that the Eligible Purchasers should be the main focus for Product supply and have the right to the Global Access terms set out under this Article [●]. In addition, the following countries shall be considered as the "Priority Countries" [●].

- **INDEMNIFICATION**

XYZ will be responsible for the manner in which all activities performed under or as a result of this Agreement are carried out and will indemnify and hold harmless FIND for any and all claims and liabilities (including legal fees and costs) arising or resulting from such activities carried out by XYZ, its employees, authorized agents, and subcontractors.

- **COMPLIANCE WITH FIND POLICIES**

Code of Conduct and Ethics: FIND has established a Code of Conduct and Ethics (the "Code") as set forth under the FIND site at https://www.finddx.org/policies. By executing this Agreement, XYZ acknowledges it has read and understood the contents of the Code, has informed the appropriate personnel of the Code's existence, and agrees to abide with the Code terms and conditions, or warrants that it has its own code of conduct which is substantially equivalent and that such own code of conduct is currently applied to XYZ.

Anti-Terrorism: XYZ will not participate, directly or indirectly, in support of activities (a) related to terrorism; (b) with persons or entities that appear on the United Nations Security Council Consolidated List; or the sanctions list of donor

countries including the UK, The Netherlands, Germany, USA, Canada and Australia; (c) with countries or territories against which the U.N. maintains comprehensive sanctions, under applicable law unless specifically approved by FIND in writing, at FIND's sole discretion.

Anti-Corruption & Anti-Bribery: XYZ will not offer or provide money, gifts, or any other things of value directly or indirectly to anyone in order to improperly influence any act or decision by FIND, including by assisting any party to secure an improper advantage.

Political Activity & Advocacy: XYZ may not use funds to influence the outcome of any election for public office in any country, or to carry on any voter registration drive.

Child Safeguarding: XYZ is committed to comply with all relevant local law on child rights and welfare in order to provide what is in 'best interest of the child' including employment law that apply to children and shall not use any funds under this Agreement to support the contrary.

Anti-Trafficking: XYZ is committed to comply will all relevant local, national, and international laws and regulations to prevent and fight against "Trafficking in Persons" including, but not limited to the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime.

Specific warranty regarding tobacco and arms. XYZ has, and currently has not had during the past four (4) years, any relations or linkages, with the tobacco or arms industry, or any subsidiary of a tobacco or arms company or commercial entity involved with the manufacture, sale, or distribution of tobacco/arms or tobacco/arms products, including, but not limited to, financial interests, controlling interests, or commercial relations resulting in licensing agreements, programmes, initiatives, research, or projects funded by the tobacco/arms industry, jointly administered with tobacco/arms-affiliated entities, or done for the tobacco/arms industry.

- **GOVERNING LAW AND DISPUTE RESOLUTION**

This Agreement shall be governed by and construed in accordance with the laws of Switzerland.

The Parties hereto undertake to settle any dispute concerning the validity, interpretation, and/or performance of this Agreement in an amicable manner. To the extent practical, the Parties shall continue to work under the Agreement pending the outcome of any dispute. If the Parties fail to resolve such dispute, controversy or difference through good faith negotiations, any dispute, controversy, or claim arising under, out of, or relating to this Agreement or any task and any subsequent amendments of this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach, or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the ICC Mediation Rules. The commencement of proceedings under the ICC Mediation Rules shall not prevent any disputing party from commencing arbitration in accordance with the following paragraph. All disputes arising out of or in connection with the present contract shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The number of arbitrators shall be three (3). The place of arbitration shall be Geneva, Switzerland. The language of the arbitration shall be English.

References

- Target product profiles for tests used for mpox (monkeypox) diagnosis (who.int)
- Mpox global strategic preparedness and response plan (who.int)