REQUEST FOR PROPOSAL (RFP)

SEEKING A MANUFACTURING PARTNER FOR A LATERAL FLOW TEST READER FOR A MULTIPLEX SEMI-QUANTITATIVE MALARIA TEST WITH A FOCUS IN LOW- AND MIDDLE-INCOME COUNTRIES.

PUBLICATION REFERENCE:
RP25-0011

PUBLICATION DATE
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EXECUTIVE SUMMARY

Background	The PvSeroRDT project has the objective to develop and bring to market a rapid and field-adapted point-of-contact test to identify individuals at risk of a relapse of *P. vivax* malaria. The test will function by detecting serological markers of recent *P. vivax* infection. A multiplexed panel of markers for this purpose has recently been defined and validated in target populations. Sero-positive individuals are likely to be carriers of dormant liver-stage parasites ("hypnozoites") and be at risk of developing clinical relapses in the weeks to months following their initial mosquito-borne infection. The target diagnostic provides a tool to triage community participants for receiving appropriate anti-malarial treatment against relapses in the context of a serological test-and-treat intervention known as "PvSeroTAT". This intervention is currently being assessed for safety and efficacy through the closely linked EU-funded grant ("PvSTATEM"). The PvSeroRDT project aims to develop the field-adapted screening test to make this intervention feasible to implement at scale in the remote settings where transmission of *P. vivax* malaria persists. The envisioned diagnostic comprises a lateral flow assay (LFA) and a digital reader to aid in test interpretation.
Purpose of partner engagement	**FIND is issuing a Request for Proposals (RFP) to identify a manufacturer of a lateral flow assay (LFA) reader** (mobile App or portable standalone device) to be used for a new multiplex, semi-quantitative LFA for malaria detection. The test is currently under development and is intended for use in low- and middle-income countries (LMICs). Upon completion of the PvSeroRDT project in 2030, manufacturing capacity will have been established by the Manufacturing Partner, and the test will be ready for market entry.
Type of partners & Technologies	FIND is inviting companies with capacity to manufacture quality-assured lateral flow assay readers with interest in adapting their reader to a test under development with OEM purposes. A successful partner must possess the resources and skills and demonstrate the necessary commitment to successfully build prototypes that adapt to the need of the test developer within a 6 month timeframe. For further details, see section "Eligibility criteria". The partner will conduct the technology adaptation, manufacture the product and complete appropriate performance studies and regulatory submissions.
Support provided by FIND	FIND will provide financial and technical support to the selected partner in adapting an existing reader solution (either mobile-based or stand-alone) for use with the PvSeroRDT, a multiplex, semi-quantitative rapid diagnostic test. This support includes funding for adaptation to the test format and classification algorithm, and for the development and delivery of prototypes for field study. FIND will also facilitate collaboration with the RDT developer, provide regulatory and market insights, and support the establishment of OEM and licensing agreements.
Expected project timeline	Start of reader adaptation**: 2025 Q3**
Application deadline	The deadline for receipt of submissions is **June 6th, 2025, at 23h59 (Geneva time).**
Contact	Please email questions to rfp.bi@finddx.org with the subject line: "**RFP: PvSeroRDT LFA Reader 2025**"

SECTION 1: ABOUT FIND

1. ABOUT FIND

The Foundation for Innovative New Diagnostics (FIND) is dedicated to ensuring equitable access to reliable diagnosis worldwide. We connect countries and communities, funders, decision-makers, healthcare providers, and developers to promote diagnostic innovation and integrate testing into sustainable and resilient health systems. Established in Geneva, Switzerland, in 2003, we have regional hubs in Kenya, India, South Africa, Vietnam and Indonesia. In partnership with public and private sector organisations, we strive to ensure that everyone who needs a test has access to one. We achieve this by collaborating closely with governments, international organisations, the private sector, civil society, academia, and other key stakeholders. For more information, please visit www.finddx.org.

SECTION 2: THE PROJECT

2. BACKGROUND & DIAGNOSTIC GAP

Malaria remains a major global health challenge, with over 200 million cases reported annually, primarily in low- and middle-income countries. While much progress has been made in controlling *Plasmodium falciparum*, efforts to eliminate *Plasmodium vivax* have lagged behind due to unique biological features that complicate detection and treatment. *P. vivax* poses a persistent challenge to malaria elimination efforts due to its ability to form hypnozoites, dormant liver-stage parasites that cannot currently be detected with available diagnostic tools. These hypnozoites may reactivate weeks or months after the initial infection, causing relapses and continuing transmission even in the absence of new mosquito bites. In endemic settings, relapses account for 60–90% of recurrent *P. vivax* cases. Addressing this silent reservoir is essential for elimination. At present, no diagnostic test exists that can directly detect hypnozoites. This diagnostic gap severely limits the ability of national malaria programs to target asymptomatic carriers, who contribute significantly to ongoing transmission.

FIND, in collaboration with a well-established consortium partner (Institut Pasteur , Abingdon Health, Institut Pasteur Dakar, WEHI, LSHTM), is supporting the development of a novel, field-deployable rapid diagnostic test (RDT) to fill this gap. Rather than detecting the parasite directly, the test uses a serological approach to measure IgG antibody responses to a multiplex panel of *P. vivax* antigens. These antibodies serve as biomarkers of recent infection (within the previous 9 months, corresponding to the lifespan of hypnozoites) and allow for the identification of individuals likely to carry dormant parasites.

The test is designed as a multiplex, semi-quantitative lateral flow assay (LFA) that can detect multiple antibody responses from a finger-prick blood sample. Signal intensities from the test lines are interpreted using a classification algorithm that outputs a binary result (sero-positive or sero-negative). This algorithm-based analysis will be embedded in a reader (either a mobile application or a standalone device) to support standardized result interpretation.

The RDT will form the basis of the PvSeroTAT (P. vivax Serological Testing and Treatment) intervention, which aims to identify asymptomatic individuals at risk of relapse and treat them with appropriate anti-malarial drugs. By enabling targeted treatment in community settings, this strategy provides a safer and more effective alternative to mass drug administration and traditional screen-and-treat approaches based solely on blood-stage diagnostics.

This project responds directly to a critical need identified by the WHO and malaria control stakeholders for tools that can detect individuals at risk of *P. vivax* relapse. The successful development of this RDT and reader system will represent a breakthrough for targeted elimination strategies in endemic regions.

3. MARKET OPPORTUNITIES

The PvSeroRDT and its reader will be developed to meet a well-defined need within national malaria programs and elimination strategies. The primary buyers are expected to include ministries of health, implementing partners, and international donors supporting test-and-treat interventions in *P. vivax*-endemic countries. Use cases will range from community-based campaigns to targeted sub-national elimination efforts.

Initial demand is anticipated from countries in the Asia-Pacific region, Latin America, and the Horn of Africa, settings with ongoing *P. vivax* transmission and active investment in elimination. Early modelling study projects an annual requirement of 500,000 to 1,000,000 test units (the associated reader units will depend on site demand) with further growth possible as the PvSeroTAT strategy is integrated into national programs. Procurement agencies are increasingly seeking diagnostic solutions aligned with global policy recommendations. As part of this project, a comprehensive market assessment will be conducted in conjunction with the product development project to inform go-to-market strategy and support product introduction beyond the life of this funded project.

By participating in this RFP, manufacturers have the opportunity to engage in an innovative public health product with strong alignment with donor priorities and the potential for sustained demand over the coming decade.

4. OBJECTIVE AND SCOPE

The primary objective of this RFP is to identify and subcontract a qualified company to adapt, customize a reader (either mobile app-based or portable standalone device) for a new semi-quantitative, multiplex lateral flow test (PvSeroRDT) for *P*. *vivax*. This reader will be an essential component of the diagnostic system, responsible for interpreting multiple test line intensities and applying a predefined algorithm to generate a binary output (sero-positive or sero-negative). The test cannot be assessed by the naked eye and thus the reader is required for all intended use scenarios.

The scope of work includes:

- Adaptation of a reader platform (mobile or hardware-based) compatible with the PvSeroRDT multiplex format in close collaboration with the LFA developer
- Integration of an interpretation algorithm (to be provided by the consortium partner) capable of processing line intensities and classifying results.
- Undertake comprehensive testing of the reader and include consortium members in the process. The testing should cover wide aspects such as functionality/performance and usability.
- Provision of reader units for test development, field evaluation, and verification & validation (V&V) phases
- Contribution to documentation for regulatory approval and preparation for commercialization

5. PRODUCT SPECIFICATIONS

The reader solution, either a mobile application or a standalone portable device, must be capable of interpreting a multiplex, semi-quantitative lateral flow assay for the detection of recent *P. vivax* infection. The reader will be used by community healthcare workers with minimal training, in remote low-resource settings.

Key specifications and requirements include:

Minimal requirements:

- Colorimetric detection
- Accurately read and quantify (semiquantitative) multiple test lines (≥4) and a control line on a lateral flow strip
- Apply a classification algorithm (provided) to generate a binary result: sero-positive or sero-negative
- Cost-effective (preferable Ex-work <100 USD, minimal <500 USD)
- Operable offline (no internet connection required for core functionality)
- Ease of use for a community health worker on the field or a lay person
- Low maintenance (must be designed to require no routine servicing or complex calibration under normal field conditions)

Mobile App-specific requirements:

- Compatible with common Android smartphones found in the target settings (Android 13 or higher)
- Can securely integrate and communicate with other allowed mobile apps installed in the same device through mechanisms such as Intent.

Portable Standalone Reader specific requirement:

- Battery-operated (not AAA) or USB-powered, durable for field use (at least 8 hours autonomy)
- Handheld size device

6. OUTLINE OF TERMS OF THE TECHNOLOGY AND COMMERCIALISATION AGREEMENT WITH FIND

The specific terms and structure of the Technology and Commercialisation Agreement will be defined during discussions with the selected manufacturer(s) and in alignment with the lateral flow assay developer. However, the agreement is expected to cover key aspects such as licensing arrangements, potential OEM models, and other commercialization mechanisms that ensure affordability, equitable access, and sustainability of supply, particularly for low- and middle-income countries (LMICs). The manufacturer will be expected to commit to the commercialization of the reader or mobile App either directly, in collaboration with the assay developer, or via an OEM partnership model, depending on what best supports widespread and sustainable access. The agreement will also include provisions to support timely scale-up, long-term availability, and pricing strategies appropriate for the target markets.

7. SUPPORT PROVIDED BY FIND

FIND will support the selected subcontractor throughout the adaptation or development of the reader solution to ensure alignment with the PvSeroRDT diagnostic system and broader access goals. Support will include both financial and technical assistance across development stages, as well as guidance to prepare for long-term sustainability.

FIND will provide

- Funding for reader adaptation to the PvSeroRDT multiplex format and integration of the provided classification algorithm to generate the final binary result (sero-positive or sero-negative).
- Financial support for prototype development, including:
    - prototypes for assay optimization and internal testing
    - prototypes for field evaluation and verification/validation (V&V)
- Close coordination with CRO and Manufacturing partners to ensure compatibility between reader and RDT and performance alignment
- Regulatory guidance, including mapping of relevant pathways
- Market access support, such as:
    - Facilitation of an OEM agreement with manufacturing partner
    - Market assessment analysis, including country prioritization, stakeholder interviews, and willingness-to-pay studies to inform go-to-market strategy

8. COMMERCIAL PARTNER COMMITMENT AND INVESTMENT

FIND seeks to engage a committed commercial partner that can not only deliver on the technical scope of this project but also contribute to the long-term viability and accessibility of the PvSeroRDT reader platform.

Applicants are expected to demonstrate:

- Organizational and technical capacity to adapt reader solutions to required specifications, including in-house technical expertise (software/hardware engineering, QA, user interface design).
- A clear plan for allocating resources, personnel, infrastructure, and project management to meet timelines and quality expectations.
- Willingness to enter into an OEM agreement with LFA Manufacturer for integration of the reader into the final diagnostic product.
- Openness to support regulatory documentation and certification processes, as required by the selected pathway

FIND is particularly interested in engaging partners who view this initiative not only as a development contract, but as a strategic opportunity to contribute to an impactful diagnostic solution with long-term market relevance in the global health space.

9. PROJECT TIMELINES

The selected manufacturer is expected to complete development of the reader solution within a 6-month timeframe. This includes adapting the reader to the PvSeroRDT format and algorithm, delivering prototypes, and undertaking further refinements based on feedback from field testing and evaluation. The envisaged timeline is as follows:

Activity	Duration
Adaptation and development of the reader	4 months
Testing of the reader	1 month
Update the reader based on the testing feedback – field ready version of reader available with accompanying documentation	1 month

SECTION 2: INSTRUCTIONS AND PROPOSAL REQUIREMENTS

10. ELIGIBILITY CRITERIA

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

- ✓ **Type of Entities:** Be a legally registered entity with the capacity to manufacture reader solutions (mobile app or stand-alone device).
- ✓ **Technology:** Have proven prior experience developing/adapting readers for LFAs (based on colorimetric detection), as demonstrated by a commercial product or a product in development.
- ✓ Have in-house capacity to support software and/or hardware development/adaptation, including quality control and system integration.
- ✓ Be willing to collaborate under an OEM and/or licensing framework that ensures affordability and accessibility in LMICs

11. OUT OF SCOPE

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

- × Distributors
- × Manufacturers not active in the lateral flow assay business

12. SELECTION CONDITIONS

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

- Commit to undertaking activities that enable product launch (e.g., local registration, service, and distribution activities) and to supply at least 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**).
- Sign a declaration confirming no Conflict of Interest.
- Sign the Due Diligence Self Declaration form.
- Commit to and follow FIND Global Access Policy.
  Commit to and sign the FIND Code of Conduct and Ethics.
- See **Appendix 3** for additional information on "Grounds for Exclusion".

13. APPLICATION REQUIREMENTS

To be complete, applications must include the following:

- **Applicant questionnaire (compulsory)**
  Applicants are requested to complete a questionnaire. (see **HOW TO APPLY** for templates and forms)

- **Self-declaration (compulsory)**
  Applicants are requested to complete the self-declaration form. (see Appendix 3)

- **Supporting documents (optional)**
  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.

14. HOW TO APPLY

Submit applications via the FIND 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.

SECTION 3: SELECTION PROCESS

15. SELECTION PROCESS

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 whenever needed, by an external review panel comprised of specialists with backgrounds in R&D, manufacturing and commercialization. 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 evaluation will define the list of shortlisted candidates. An internal review panel will evaluate the eligible candidates using the submitted application materials (See **Application Requirements**). Candidates will be evaluated on:
    - **Questionnaire,** which provides responses to specific topics pertinent to the RFP.

  Shortlisted 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 finalist(s). Candidates will be evaluated using:
    - **Follow-up live presentation** (by teleconference): shortlisted candidates will be invited to make a follow-up presentation to address a set of questions provided to the candidates in advance.

  Finalist(s) will be selected in a consensus call of reviewers and will advance to Due Diligence and Contract Negotiations.

  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 DD to an independent third party, following FIND procedures.

Stage 0	Stage 1	Stage 2
Initial screening of all applicants to a set of long-listed candidates	*First evaluation to shortlist candidates.*	*Second evaluation to define a list of finalist(s).*
• 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. Questionnaire	• Evaluation of the shortlisted candidates after stage 1 will be evaluated based on: 1. Follow-up live presentation

16. SUMMARY OF SELECTION TIMELINE

	Activity	Expected date
1	Publication of RFP	May 16th, 2025
2	Deadline for questions	May 25th, 2025
3	Application deadline	June 06th 2025, at 23h59 (Geneva time)
4	Evaluation of applications	June 7th – June 31st, 2025
5	Notification of short-listed candidates (end of Stage 1, tentative timeline)	Mid-June 2025
6	Notification of finalist(s) (end of Stage 2, tentative timeline)	End of June 2025
7	Start of project (tentative timeline)	2025 Q3

17. QUESTIONS & FURTHER INFORMATION

Please email questions to rfp.bi@finddx.org with the subject line: "**RFP: PvSeroRDT LFA Reader 2025** ". Questions will be accepted and responded to expediently up to and including **May 25th, 2025**.
Submitted questions (and corresponding answers) will be publicly available on the Calls for Partners page.

18. 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).

19. 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**.

20. 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**"	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

(if applicable)	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.