

Request for Proposals

Seeking manufacturers of multiplex rapid diagnostic tests for HIV/HCV/HBV and HIV/HCV self-testing who are willing to undergo usability and performance evaluation

EXECUTIVE SUMMARY

Background	In 2015, the WHO endorsed HIV self-testing as a supplementary method to broaden the reach of HIV testing services. Since then, substantial evidence has emerged demonstrating the various advantages of HIV self-testing. Now, FIND wants to accelerate the availability of diagnostic solutions intended for self-testing in low- and middle-income countries (LMICs) and is leading a project to evaluate HIV/HCV/HBV multiplex self-testing rapid diagnostic tests. FIND will also facilitate the development of the Target Product Profile (TPP) draft.
Purpose of partner engagement	FIND is opening a Request for Proposals (RFP) to find manufacturing partners of multiplex rapid diagnostic tests (RDT) for HIV/HCV/HBV and HIV/HCV self-testing with the purpose of performing manufacturer-independent usability assessment and performance laboratory evaluation.
Type of partners & Technologies	Developers/Manufacturers of multiplex blood-based RDT for HIV/HCV/HBV and HIV/HCV self-testing. Tests must be commercialized or near design-locked and ready for supply upon FIND procurement. Applicants must be willing to commit to an affordable selling price for LMICs, together with other access conditions, to be negotiated as part of the partner agreement.
Benefits for the applicants	Generation of a body of usability and performance data for presentation to the WHO, ministries of health and other global health stakeholders to support future product registration and market entry.
Expected project timeline	Usability and acceptability assessments: June 2024. Performance evaluation: Aug 2024.
Application deadline	The deadline for receipt of submissions is March 15, 2024 by 23h59 CET .
Contact	Please email questions to multiplex.st@finddx.org with the subject line: "RFP Multiplex ST"

SECTION 1: THE PROJECT

BACKGROUND

Self-care strategies for health represent some of the most innovative and significant contributions to achieving universal health coverage (UHC). The World Health Organization (WHO) defines self-care as the capability of individuals, families, and communities to enhance health, prevent diseases, sustain health, and manage illness and disability with or without the aid of a healthcare provider. Self-care is increasingly recognized for its potential to supplement and improve conventional healthcare approaches.

In 2015, the WHO endorsed HIV self-testing as a supplementary method to broaden the reach of HIV testing services. Since then, substantial evidence has emerged demonstrating the various advantages of HIV self-testing. The widespread adoption of self-testing for the SARS-CoV-2 antigen during the COVID-19 pandemic made testing more accessible, quick, and private for millions, while also heightening awareness about the feasibility of using straightforward tools for at-home infection status checks. Home testing addresses the stigma often associated with clinic-based testing and circumvents challenges like transportation and competing priorities that could hinder timely access to healthcare services.

FIND, through its work on Hepatitis C (HCV) and COVID-19 self-testing, has amassed considerable experience in orchestrating and executing a comprehensive range of tasks necessary to deliver affordable, effective self-testing solutions and to introduce innovative service delivery models. This includes conducting feasibility studies, generating evidence for policy-making, and launching self-testing products in the market.

Combination tests for HIV, HCV, and Hepatitis B (HBV) are essential for self-testing due to their comprehensive coverage, environmental benefits, and logistical advantages. Their ability to screen for multiple infections that share similar transmission routes—blood and bodily fluids—makes testing more efficient and encourages broader participation. These tests also utilize less plastic in production, aligning with efforts to reduce environmental impact. Additionally, the simplified logistics of distributing and managing a single type of test enhances accessibility, especially in resource-limited settings, and streamlines public health initiatives. By offering a sustainable, practical, and accessible testing option, combo tests play a crucial role in early detection, treatment, and control of these infections.

OBJECTIVE AND SCOPE

To accelerate the availability HIV/HCV/HBV multiplex self-testing rapid diagnostic tests (RDT) in LMICs, FIND will conduct laboratory evaluations of test performance and usability assessments. In that context, FIND is seeking manufacturers who are willing to undergo performance evaluation of these combo tests and formative research in target populations to assess usability and acceptability.

The partner would need to provide blood-based multiplex RDT HIV/HCV/HBV and/or HIV/HCV intended for self-testing use for:

- ✓ lab evaluation of the test performance using stored samples
- ✓ usability and acceptability assessment of the test in target populations

Through the support of our donors, FIND has funding to procure the company's tests and prototype assays (see numbers below) for assessment and evaluation at the study sites.

PRODUCT SPECIFICATIONS

FIND is willing to evaluate multiplex blood-based RDT for HIV/HCV/HBV and HIV/HCV self-testing that meet or target the following key product requirements:

Category	Minimum requirements
Intended use	Rapid diagnostic tests (RDT) intended for self-test use to detect the following combination from a single sample: HIV/HCV/HBV and/or HIV/HCV
Target population	General population seeking to learn HIV/HCV/HBV status through nonclinic/provider/assisted based testing.
Target technology	Immunoassay
Infrastructure / Instrumentation / Additional third-party consumables	None. Disposable test only. No electricity or clean water requirements.
Sample type / Collection method	Finger-prick capillary whole blood with lancet.
Sample volume	50 µl
Type of analysis	Qualitative
Result interpretation	High contrast, clear result for naked eye
Clinical sensitivity	HIV >99 % HCV >97 % HBV >97
Clinical specificity	HIV >99 % HCV >98 % HBV > 98
Target analytes	HIV: HIV-1 and HIV-2 antibodies HCV: HCV antibodies HBV: HB surface antigens
Time to results	< 20 minutes to develop test result
Ease of use	Easy to use for self-test use in private settings (outside the healthcare facilities). Minimal hands-on time and low number of manual steps Clear and user-friendly instructions.
Packaging	Individually packaged, self-contained kit. All reagents and supplies included in test kit to test one self-test user, with minimal import restrictions
Target shelf-life/stability	Stable for 12 months at 2-40°C, 70% humidity
Operating temperature	Operation between 15°C and 40°C; ability to tolerate extremely low relative humidity to condensing humidity.
Target price (ex-works)	2 USD.

OPPORTUNITIES AND BENEFITS FOR THE APPLICANTS

Depending on the outcome of the project, the following opportunities could be considered for the selected partners:

- Generation of a body of usability and performance data for presentation to the WHO, ministries of health and other global health stakeholders.
- Exploration of follow-up project to support market entry in LMICs

TIMELINE

The usability and acceptability assessment activities are planned to start in June 2024.

The laboratory performance evaluation is planned to start in August 2024.

SUPPORT PROVIDED BY FIND

The selected applicants can expect to receive the following support from FIND:

- Funding (secured) to conduct performance evaluation using laboratory-stored blood samples and to conduct formative research in the target populations
- Funding to procure the tests or for the production of a pilot lot for the evaluation study
- Assistance with import permit to ship the kits to the evaluation sites
- Selection of the study sites
- Study protocol development
- Study Protocol submission for IRB approval
- Management of the study
- Data collection and data analysis
- Report preparation
- Results dissemination
- Draft of the TPP

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 the following multiplex immunoassay rapid diagnostic tests: HIV/HCV/HBV and/or HIV/HCV
- ✓ Stage of development: commercially available. If in development, the test must be design-locked or near design-locked. In such a case, the developer/manufacturer must provide evidence that it can produce pilot lots in time for the planned assessment and evaluation.
- ✓ At minimum, the following key technical requirements must be met:
 - Technology is based on immunoassay.
 - Use fingerprick whole blood.
 - Detect HIV-1/HIV-2 antibodies.
 - Detect HCV antibodies.
 - If the assay is capable of detecting HBV, HBV surface antigens must be the target analyte.
 - The assay is fully disposable and does not require any instrumentation, any electricity or clean water.
 - The assay shall be readable by naked eye and thus not require any external instruments, readers or machines for interpreting the test.
- ✓ Commit to supply 600 assay kits¹ for HIV/HCV/HBV and 400 assay kits for HIV/HCV by May 31, 2024 for manufacturer-independent usability and acceptability assessments upon FIND procurement. The provided assay kits should include samples/examples of positive and negative test results.
- ✓ Commit to supply 400 assay kits² by July 31, 2024 for manufacturer-independent performance laboratory evaluation upon FIND procurement.
- ✓ Be willing to commit to an affordable selling price for LMICs (i.e. below or equal to 2 USD ex-work price), together with other access conditions, to be negotiated as part of the partner agreement.

OUT OF SCOPE

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

- ✗ Distributors
- ✗ Academic teams
- ✗ Products that are not immunoassays, such as molecular-based assay
- ✗ Rapid diagnostic tests that require readers or other equipment for results interpretation

SELECTION CONDITIONS

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

- Fulfill eligibility criteria
- Commit to a pricing model that is transparent and affordable for LMICs (i.e. COGS-based pricing) (see **Appendix 2**).
- 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".

APPLICATION DEADLINE

The deadline for receipt of submissions is **March 15, 2024 by 23h59 CET**.

¹ Tentative numbers. Could be amended as part of the study design.

² Tentative numbers. Could be amended as part of the study design.

APPLICATION REQUIREMENTS

To be complete, applications must include the following:

- **Applicant presentation:** Applicants shall provide a slide deck of **no more than 20 slides** and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms).
- **Assessment matrix:** Applicants are requested to complete noted sections of the provided spreadsheet titled “Assessment Matrix” (see **HOW TO APPLY** for templates and forms)
- **Self-declaration:** Applicants are requested 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 (IFU)/product inserts or at least a draft for tests that are not commercialized, 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.

IMPORTANT: If you aim to submit both the HIV/HCV/HBV and the HIV/HCV tests, please apply only once, but provide the information of both tests in the Applicant Presentation (PPT document) and fill twice the Technical Tab in the Assessment Matrix (Excel file).

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 with backgrounds in technical R&D and disease area. 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 finalists. An internal review panel will evaluate long-listed candidates using the submitted application materials (See **Application Requirements**). More specifically, candidates will be evaluated on:
 - o Existing product specifications, scored in the sheet titled “**Technical Assessment**” in the **Assessment Matrix**.
 - o Organizational criteria, scored in the sheet titled “**Business Assessment**” in the **Assessment Matrix**.
 - o **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. 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:

$$\begin{aligned} \text{Applicant's Total Score} = & \\ & (\text{Technical Assessment}) * 0.25 + \\ & (\text{Business Assessment}) * 0.25 + \\ & (\text{Alignment Criteria}) * 0.50 \end{aligned}$$

Finalists will be selected in a consensus call of reviewers and will advance to Due Diligence and Contract Negotiation.

- **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
<i>Initial screening of all applicants to a set of long-listed candidates</i>	<i>Evaluation to define a list of finalists</i>
<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Evaluation of long-listed candidates will be performed by an internal review panel. • Candidates will be evaluated based on: <ol style="list-style-type: none"> 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).

SUMMARY OF SELECTION TIMELINE

RFP Issued	March 04, 2024
Deadline for questions	March 08, 2024
Application deadline	March 15, 2024
Notification of finalists (end of Stage 1, tentative timeline)	March 29, 2024
Start of due diligence and contract negotiation (tentative timeline)	April 01, 2024
Start of project (tentative timeline)	June 01, 2024

QUESTIONS & FURTHER INFORMATION

Please email questions to multiplex.st@finddx.org with the subject line: "RFP Multiplex ST". Questions will be accepted and responded to expediently up to and including **March 08, 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 and vice versa. FIND considers any application and supporting documents received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement with interested applicants prior to proposal submission. FIND shall not disclose the proposal to third parties without the prior written agreement of the proposal submitter. All members of the review panel shall also be under confidentiality and shall be 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.

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 (multiplex.st@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:

None.

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.

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

Please note that due to the existence of third-party Intellectual Property rights, for the distribution of the SCH CAA RDT into High-Income Countries, a royalty of up to 2% of the Ex-works Price (Incoterms 2020) will apply.

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 DoJ, 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.

1. 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;

<p>“Manufacturing Cost of Goods Sold” or “COGS”</p>	<p>means all the direct costs such as labour, material, and allocated overhead costs in Product <i>production</i>;</p>
<p>“Manufacturer of Record” (if applicable)</p>	<p>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.</p>
<p>“Priority Countries”</p>	<p>based on Article [●];</p>
<p>“Private Health Sector”</p>	<p>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;</p>
<p>“Public Health Sector”</p>	<p>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;</p>
<p>“Technology Transfer” (if applicable)</p>	<p>those activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;</p>
<p>“Technology Licence” or “Licence” (if applicable)</p>	<p>the licence to use ABC IP and Know-how required to commercialise a Product, and as further set out under the Article [●];</p>
<p>“Target Product Profile” or “TPP”</p>	<p>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;</p>
<p>“Test Unit”</p>	<p>the specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen.</p>

2. 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.

3. 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.

4. 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” [●].

5. 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.

6. 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.

7. 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.