REQUEST FOR PROPOSAL (RFP)

SEEKING A MANUFACTURING AND COMMERCIALIZATION PARTNER FOR AN ANTIGEN-BASED RAPID DIAGNOSTIC TEST FOR NEISSERIA GONORRHOEAE INFECTION WITH A FOCUS IN LOW- AND MIDDLE-INCOME COUNTRIES.

PUBLICATION REFERENCE:
RP25-0005

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EXECUTIVE SUMMARY

Background	Gonorrhoea, caused by *Neisseria gonorrhoeae* (NG), is the second most common bacterial sexually transmitted infection (STI) worldwide with considerable morbidity and economic cost. The syndromic approach has been used for decades in the absence of a low-cost rapid test that can differentiate NG from other STIs, such as Chlamydia trachomatis (CT). In the era of the development of new treatments for NG, there is an urgent need for diagnostic solutions that ensure antimicrobial stewardship practices to protect the effectiveness of existing and new antibiotics. To fight this health threat, WHO has been generating evidence for the past two years to support replacing syndromic management with an etiological approach using a point-of-care test (POCT) to detect NG and or CT and has recently launched new guidelines for the management of symptomatic STIs. As part of this effort, FIND and WHO published a target product profile (TPP) describing the features required for a NG only or a NG/CT POCT for use in low- and middle-income countries (LMICs). FIND has in turn developed a low-cost, fluorescence-based antigen rapid diagnostic test to detect NG in urine (for men) and vaginal swab (for women) (NG LFA), which satisfies the TPP requirements. The current NG POCT has now achieved design freeze (final device optimization) and is ready for technology transfer to manufacturing.
Purpose of partner engagement	FIND is issuing a Request for Proposals (RFP) to find a manufacturing and commercialization partner to whom to transfer a fluorescence-based antigen lateral flow assay for *Neisseria gonorrhoeae* infection (NG LFA) for use in LMICs to support the shift from syndromic to etiologic management of STIs in low-resource settings.
Type of partners & Technologies	FIND is inviting companies with capacity to manufacture quality-assured lateral flow assays with a global sales, marketing and distribution network in the IVD market, including a commercial presence in LMICs, to submit a proposal for the tech transfer and commercialization of the NG LFA. A successful partner must possess the resources and skills and demonstrate the necessary commitment to successfully commercialize the NG LFA in LMICs within a 2-year timeframe. For further details, see section “Eligibility criteria”. The partner will conduct a technology transfer, manufacture the product, complete appropriate performance studies and regulatory submissions and provide product demand creation, commercial sales, marketing, and distribution in select LMIC target markets.
Support provided by FIND	FIND offers LFA manufacturers an opportunity to access a high-performing design-frozen (final device optimization) NG LFA ready to be transferred, together with market assessment, insights on the regulatory roadmap for the assay, investment case for a country in Africa, technical support for tech transfer (in-kind and time-limited) and in-kind support for setting-up clinical studies for regulatory submissions.
Expected project timeline	Start of technology transfer activities**: 2025 Q3/Q4**
Application deadline	The deadline for receipt of submissions is **April 9th, 2025, at 23h59 (Geneva time).**
Contact	Please email questions to rfp.bi@finddx.org with the subject line: “**RFP: NG LFA TT 2025**”

SECTION 1: THE PROJECT

1. BACKGROUND & DIAGNOSTIC GAP

Gonorrhoea, caused by *Neisseria gonorrhoeae* (NG), is the second most common bacterial sexually transmitted infection (STI) worldwide with considerable morbidity and economic cost. The World Health Organization (WHO) estimates that in 2020, 82.4 million new cases of NG infection occurred among adolescents and adults aged 15 to 49 years worldwide, with a global incidence rate of 19 per 1000 female and 24 per 1000 male individuals, with the highest magnitude in WHO Western Pacific and African Regions[1]. WHO has also identified NG as a high-priority pathogen because of widespread antimicrobial resistance (AMR) to antibiotics used in the treatment of NG infection. Management of patients with STIs has been based on syndromic treatment for signs such as urethral or vaginal discharge, which results in almost all symptomatic patients being prescribed treatment leading to unnecessary or inappropriate use of antibiotics. The syndromic approach has been used for decades in the absence of a low-cost rapid test that can differentiate NG from other STIs, such as Chlamydia trachomatis (CT). In the era of the development of new treatments for NG, there is an urgent need for diagnostic solutions that ensure antimicrobial stewardship practices to protect the effectiveness of existing and new antibiotics. To fight this health threat, WHO has been generating evidence for the past two years to support replacing syndromic management with an etiological approach using a point-of-care test (POCT) to detect NG and or CT and has recently launched new guidelines for the management of symptomatic STIs[2].

As part of this effort, FIND and WHO published a target product profile[3] (TPP) describing the features required for a NG only or a NG/CT POCT for use in low- and middle-income countries (LMICs). FIND has in turn developed a low-cost, fluorescence-based antigen rapid diagnostic test to detect NG in urine (for men) and vaginal swab (for women) (NG LFA), which satisfies the TPP requirements[4].

The NG LFA has undergone evaluations in performance studies in South Africa and Zimbabwe and demonstrated high performance meeting the TPP requirements for the primary use case of detection of NG infection among symptomatic men and women. The assay also demonstrated very good performance, meeting TPP requirements among

[1] WHO. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. https://www.who.int/publications/i/item/9789240027077

[2] WHO. Guidelines for the management of symptomatic sexually transmitted infections. 2021. Guidelines for the management of symptomatic sexually transmitted infections

[3] Ferreyra C, et al. Developing target product profiles for Neisseria gonorrhoeae diagnostics in the context of antimicrobial resistance: An expert consensus. PLoS One. 2020 Sep 1;15(9):e0237424. Developing target product profiles for Neisseria gonorrhoeae diagnostics in the context of antimicrobial resistance: An expert consensus | PLOS ONE

[4] Gleeson B, et al. Development of a Novel Fluorescent-Based Lateral Flow Assay for the Detection of Neisseria gonorrhoeae at the Point of Care. Sex Transm Dis. 2024 Mar 1;51(3):186-191 Sexually Transmitted Diseases

asymptomatic men and non-pregnant women and very high specificity with lower sensitivity among pregnant women[5,6]. Usability studies show high usability and acceptability for the NG-LFA[7].

WHO has recently posted for public comments draft documents for rapid diagnostic tests to detect NG/CT antigen under the technical specifications series (TSS) for submission to WHO prequalification – diagnostic assessment[8].

The current NG LFA has now achieved design freeze (final device optimization) and is ready for technology transfer to manufacturing. In addition, preliminary performance data, cost-effectiveness of such a tool and market size estimates are available. **FIND is seeking a manufacturer and commercialization partner who will commit to obtaining regulatory approval for the deployment of the test in LMICs.**

2. MARKET OPPORTUNITIES

During 2019−2020, FIND conducted deep-dive market studies in six countries in Asia and Africa to understand the current STI landscape, define use cases and identify the potential market for new NG/CT POCTs. The six countries included in this market assessment were Kenya, the Philippines, South Africa, Thailand, Vietnam, and Zambia[9]. Results indicate that global and national STI policies are lacking, with most countries implementing the syndromic approach based on prior WHO guidelines. For gonorrhoea testing to rise in importance among national stakeholders, the priority next steps include raising awareness and building the evidence to support and inform national policy making and funding decisions for gonorrhoea testing to align with the newly launched WHO STI guidelines. Based on the new recommendations, two intended use cases have been identified for the new NG POCT.

1. A diagnostic POCT to support patient management of symptomatic patients: it is estimated that more than 70 million people (per year) are symptomatic and likely to present for NG testing in LMICs[10]. The use of a POCT can rule out the presence of NG, and thus, support antimicrobial stewardship.

[5] Peters RPH, et al.. Novel lateral flow assay for point-of-care detection of Neisseria gonorrhoeae infection in syndromic management settings: a cross-sectional performance evaluation. Lancet. 2024 Feb 17;403(10427):657-664. Novel lateral flow assay for point-of-care detection of Neisseria gonorrhoeae infection in syndromic management settings: a cross-sectional performance evaluation - The Lancet

[6] Martin K, et al. Evaluation of a novel point-of-care lateral flow assay screening for Neisseria gonorrhoeae infection among pregnant women in Zimbabwe. PLOS Glob Public Health. 2025 Feb 11;5(2):e0003839. Evaluation of a novel point-of-care lateral flow assay screening for Neisseria gonorrhoeae infection among pregnant women in Zimbabwe | PLOS Global Public Health

[7] de Vos L, et al. Usability of a novel lateral flow assay for the point-of-care detection of Neisseria gonorrhoeae: A qualitative time-series assessment among healthcare workers in South Africa. PLoS One. 2023 Jun 2;18(6):e0286666. Usability of a novel lateral flow assay for the point-of-care detection of Neisseria gonorrhoeae: A qualitative time-series assessment among healthcare workers in South Africa | PLOS ONE

[8] Technical Specifications Series | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

[9] Market and landscape insights - FIND
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20221213_rep_market_viet_nam_FV_EN.pdf
20221213_rep_market_philippines_FV_EN.pdf
20221213_rep_market_thailand_FV_EN.pdf
20221213_rep_market_south_africa_FV_EN.pdf
20221213_rep_market_kenya_FV_EN.pdf

[10] Cecilia Ferreyra, et al. Barriers to Access to New Gonorrhea Point-of-Care Diagnostic Tests in Low- and Middle-Income Countries and Potential Solutions: A Qualitative Interview-Based Study. Sex Transm Dis. 2020. Oct;47(10):698-704. Sexually Transmitted Diseases

2. A screening POCT to identify NG infection in asymptomatic at-risk populations: the size of the high-risk and vulnerable populations for asymptomatic NG/CT screening in LMICs is large, with estimates up to 100 million people (per year) that could benefit from NG screening. This estimate comprises many different high-risk populations, including an estimated 4 million female sex workers, 4.9 million men who have sex with men, 130,000 people enrolled in HIV pre-exposure prophylaxis (PrEP), 107 million pregnant women seen at antenatal care clinics, and 500 million young women/adolescents (although only a fraction of these young women would be considered high risk). The use of a NG POCT in these populations can contribute to the reduction in the transmission of NG and other STIs.

Additional market insights and market size estimates generated for additional countries are available.

3. OBJECTIVE AND SCOPE

The primary objective is to transfer the technology for manufacture and commercialization in LMICs. Specifically, FIND is inviting companies with capacity to manufacture quality-assured IVDs with a global sales, marketing and distribution network in the IVD market, including a commercial presence in LMICs, to submit a proposal for the tech transfer and commercialization of the NG LFA.

The RFP aims to identify a partner that has the resources, skills and the necessary commitments to successfully commercialize the NG LFA in LMICs within a 2-year timeframe. In that context, FIND is seeking eligible manufacturers to:

- conduct a technology transfer of the assay from FIND's development partner.
- manufacture the product using their own facilities, or in collaboration with an appropriate third party, for testing in clinical studies and to scale up to meet market projections while following the necessary quality standards (ISO 13485).
- complete appropriate performance studies and submissions for registration in selected target markets in addition to WHO Prequalification or from a mature regulatory authority (for example US FDA, CE marking under IVDR, Australia TGA, Japan PMDA, UK MHRA, Health Canada).
- provide product demand creation, commercial sales, marketing, and distribution in select LMIC target markets.

4. PRODUCT SPECIFICATIONS

The NG LFA developed by FIND meets the TPP requirements for a non-molecular test for use with male urine and female self-collected vaginal swabs. Clinical performance shows optimal clinical sensitivity and specificity for the detection of NG in patients with urethral or vaginal discharge. Performance in asymptomatic male and non-pregnant female patients suggests that the test could also be used to support screening strategies to reduce NG transmission. The test is easy to use, with a time to result of 20 min, and an LMIC-appropriate shelf life.

This test uses fluorescent europium labels to increase sensitivity and consequently requires a fluorescence reader to analyze the results. FIND has concurrently developed an LMIC-compatible companion POCT reader.

Technical files and performance reports, among other key documents for the tech transfer, will be provided to the successful applicant.

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

In the technology transfer and commercialization agreement, FIND will grant the selected manufacturer a worldwide non-exclusive, royalty-free license over FIND assay technology. FIND has negotiated access to a critical antibody reagent for the assay and will be able to sublicense the reagent to the selected manufacturer on favorable LMIC terms.

The agreement will contain requirements for the manufacturer for best commercial efforts that the final product, as manufactured by the manufacturer will meet requirements as outlined in the TPP, particularly the performance and price requirements. Commitment by the manufacturer will also be required to meet Global Access terms and conditions in line with the FIND Global Access policy (FIND Global Access Policy) and that an appropriate and affordable reader (fluorescent reader) will be manufactured and commercialize as part of the product offer, and any decisions on the selection of this device and its commercialization conditions will be mutually agreed by FIND and the selected manufacturer.

6. SUPPORT PROVIDED BY FIND

- A design-frozen (final device optimization) NG LFA ready to be transferred to a manufacturer under an Agreement with FIND including Global Access terms.
- A low-cost POCT reader at an advanced stage of development, developed by a third party. Please note that FIND will let the manufacturer choose another reader provided it is compatible with the TPP and global access.
- Within the context of the MOU with WHO and other key stakeholders, FIND will advocate with donors to accelerate the deployment and access of the test in the most affected countries and work closely with WHO to update the testing guidelines and accelerate policy changes.
- Access to FIND's market assessment (developed in 2023), in addition to the published markets assessments, for countries where a fast introduction of the NG POCT would be possible.
- Insights on the regulatory roadmap for the assay.
- Access to a recently developed investment case for a country in Africa.
- In-kind support for setting-up clinical studies, such as identification and connection with potential clinical sites.
- Technical support for tech transfer (in-kind and time-limited).

7. COMMERCIAL PARTNER COMMITTMENT AND INVESTMENT

The following typical tech transfer and commercialization, investments will be needed from the selected commercial partner to bring the product to market:

- Fully support the investment required to transfer the technology for commercial production, including the implementation and scale up of the manufacturing operations.
- Run clinical studies and other performance studies to obtain regulatory approval in target markets (target markets will be agreed on during contract negotiation process), in addition to WHO Prequalification, or from a mature regulatory authority (for example US FDA, CE marking under IVDR, Australia TGA, Japan PMDA, UK MHRA, Health Canada).
- Ensure adequate manufacturing capacity to meet demand and price requirements of the TPP.
- Maintain and manage adequate inventories to meet demand and distribute the product to fulfill orders.
- Provide after-sale support, customer training, complaint management.

8. TIMELINE

The product is available for technology transfer from FIND Development Partner to the selected manufacturer. The selected manufacturer is expected to complete the following steps within a 2-year timeframe: manufacturing processes defined, pilot manufacturing established, lab verification and validation testing completed, commercial manufacturing established, regulatory approval in target markets in addition to WHO Prequalification or regulatory equivalent obtained (via clinical studies and other studies), distribution channels and after-sale support established.

SECTION 2: INSTRUCTIONS AND PROPOSAL REQUIREMENTS

9. ELIGIBILITY CRITERIA

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

- ✓ Type of Entities: Original developers/manufacturers of lateral flow assays (i.e. be in the lateral flow assay business).
- ✓ Technology: Have proven experience with fluorescence-based lateral flow assays, as demonstrated by a commercial product or a product in development.
- ✓ Regulatory experience: Have gained WHO Prequalification, or other regulatory approval for at least one of the following markets (United States of America, Canada, Europe, United Kingdom, Brazil, Japan, Australia, South Korea) for at least one in-vitro diagnostic product based on lateral flow assay.
- ✓ Manufacturing capacity: Has a commercial production line. Entities with only small-scale manufacturing lines to support R&D activities are not eligible.
- ✓ Commercial stage: Have at least one in-vitro diagnostic product based on lateral flow assay being commercially available with active sales.
- ✓ Distribution channel: Have at least one in-vitro diagnostic product based on lateral flow assay being sold in LMICs.
- ✓ Cost structure: Have a manufacturing cost and pricing model that can meet the price requirements specified in the TPP.

10. OUT OF SCOPE

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

- × Distributors
- × Academic teams
- × IVD manufacturers not active in the lateral flow assay business

11. 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**).
- 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".

12. APPLICATION DEADLINE

The deadline for receipt of submissions is **April 9th, 2025, at 23h59 (Geneva time).**

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	March 12th 2025
2	Deadline for questions	March 24th 2025
3	Application deadline	April 9th 2025
4	Notification of short-listed candidates (end of Stage 1, tentative timeline)	Beginning of May 2025
5	Notification of finalist(s) (end of Stage 2, tentative timeline)	End of June 2025
6	Start of project (tentative timeline)	2025 Q3/Q4

17. QUESTIONS & FURTHER INFORMATION

Please email questions to rfp.bi@finddx.org with the subject line: "RFP: NG LFA TT 2025". Questions will be accepted and responded to expediently up to and including **March 24th 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**" ***(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.