

Request for Proposals

Seeking manufacturers of true point-of-care molecular tests for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* to accelerate product development/evaluation and market entry in low- and middle-income countries.

EXECUTIVE SUMMARY

<p>Background</p>	<p>There is a need for a rapid molecular diagnostic point-of-care test to detect <i>Neisseria gonorrhoeae</i> (NG) and <i>Chlamydia trachomatis</i> (CT) infection to prevent inadequate use of antimicrobials resulting from current WHO syndromic management in low-resource settings. Diagnostic products that meet the existing target product profiles (TPP) requirements for a rapid, low-cost test to diagnose NG and CT for use in primary health care settings in low- and middle-income countries (LMICs) are needed (see section “Product Specification” for further details). To fill this gap, FIND (finddx.org) intends to accelerate the development and market entry for true point-of-care molecular diagnostics (tPOC MDx) for NG/CT in LMICs.</p> <p>The primary objective of this project is to evaluate dual NG/CT tPOC MDx tests in LMICs sites and/or support the development/optimization of tPOC MDx tests for <u>dual</u> NG/CT detection in both genital (e.g. urine, vaginal swab) and extragenital (e.g. pharyngeal and rectal) sample types.</p>
<p>Purpose of partner engagement</p>	<p>FIND is opening a Request for Proposals (RFP) to find developers and manufacturing partners of tPOC MDx for NG/CT to perform an independent performance evaluation in LMICs sites and/or accelerate product development.</p>
<p>Type of partners & Technologies</p>	<p>Eligible developers and manufacturers of tPOC MDx devices must have an existing dual NG/CT molecular assay at a technology level readiness (TRL) of 4 or above.</p> <p>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. For further details, see section “Eligibility criteria”.</p>
<p>Benefits for the applicants</p>	<p>Through this RFP FIND may:</p> <ul style="list-style-type: none"> • Fund an independent evaluation in LMIC sites to assess the performance of TRL7 or above technologies against reference standards in target populations and different specimen types in LMICs • Fund product optimization to meet the operational requirements for a test to be used at primary care settings in LMICs (TRL6 or above) • Fund product development activities of disruptive technologies (TRL4 or above)

Expected project timeline	<ul style="list-style-type: none"> • Start of R&D activity to optimize/develop the tPOC MDx assay: October 2024 • Completion of R&D activities: End 2025/Early 2026 • Start of independent performance evaluation: April 2025 • End of independent performance evaluation: December 2026
Co-funding opportunity	This RFP is released in coordination with the RIGHT Foundation. Korean applicants that meet the scope of both RIGHT Foundation and FIND will be eligible for co-funding (refer to Section “Co-funding opportunity with RIGHT Foundation”).
Application deadline	The deadline for receipt of submissions is May 6th 2024 at 23h59 CEST.
Contact	Please email questions to rfp.bi@finddx.org with the subject line: “CT/NG Molecular tPOC RFP”

SECTION 1: THE PROJECT

BACKGROUND

Sexually transmitted infections (STIs) remain one of the most critical global health challenges of the 21st century.[1,2] In 2006 and again in 2019, the World Health Organization (WHO) highlighted the importance of a comprehensive STI control strategy, which includes the promotion and provision of prevention strategies, targeted community-based interventions, reliable data to guide the response, and effective clinical services for STI patients with a particular focus on primary health care, antenatal, sexual and reproductive health, and HIV prevention and care services. Among the most common and manageable STIs are *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT).[3,4] The 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.[5]

A low-cost molecular diagnostic NG/CT test would be a valuable addition for use in primary healthcare settings in low- and middle-income countries (LMICs).[6] Currently available NG/CT molecular diagnostic tests are not suitable for primary healthcare infrastructure in which true point-of-care molecular diagnostic tests (tPOC MDx) with short turnaround times are necessary; besides their cost remains prohibitive for use in most LMICs. Recent COVID-driven technology advancements may facilitate development of low-cost tPOC MDx tests for NG/CT which can be used at the point of care in primary healthcare settings.

OBJECTIVE AND SCOPE

A dual NG/CT tPOC MDx test will accelerate the global availability of molecular true point-of-care tests for NG/CT with a particular focus on LMICs. Therefore, **the primary objective of this project is to evaluate dual NG/CT tPOC MDx tests in LMICs sites and/or support the development/optimization of tPOC MDx tests for dual NG/CT detection in both genital (e.g. urine, vaginal swab) and extragenital (e.g. pharyngeal and rectal) sample types.**

Specifically, FIND is willing to support optimization and/or product development activities as well as conduct independent evaluations of test performance. In that context, FIND is seeking eligible¹ developers and manufacturers of tPOC MDx diagnostic devices for dual NG/CT detection to (by order of priority):

- Fund an independent evaluation in LMIC sites to assess the performance of TRL7 or above technologies against reference standards in target populations and different specimen types in LMICs
- Fund product optimization to meet the operational requirements for a test to be used at primary care settings in LMICs (TRL6 or above)
- Fund product development activities of disruptive technologies (TRL4 or above)

Irrespective of the type of partner engagement activities, FIND will request applicants to provide a budget and timeline to bring their dual NG/CT tPOC MDx to TRL7 and ready for an independent evaluation in LMIC sites. **This RFP is released in coordination with the RIGHT Foundation. Korean applicants that meet the scope of both RIGHT Foundation and FIND will be eligible for co-funding (refer to Section “Co-funding opportunity with RIGHT Foundation”).**

¹ See ELIGIBILITY CRITERIA section

PRODUCT SPECIFICATIONS

FIND is seeking tPOC MDx devices and assays that target or already meet the following key product requirements:

	Minimal	Optimal
Target use setting	Primary healthcare settings including health posts (Level 1)	
Test format / Equipment	A single-use, disposable diagnostic consumable combined with a True POC instrument (handheld or portable, battery operated or compatible with external portable power bank to ensure operations for 4-8-hour operation between charges)	A non-instrumented , single-use, disposable (biodegradable or recyclable preferred) diagnostic test
Target users	Health worker with level 1 test training	Community health workers with minimal training
Clinical Sensitivity	≥90%	≥95%
Clinical Specificity	≥95%	≥98%
Specimen	Women: vaginal swab Men: urine (preferred) or urethral swab	Women: vaginal swab, urine Men: urine; urethral, rectal, pharyngeal swab
Specimen collection	Provider-collected vaginal swabs	Self-collected and provider-collected vaginal swabs
Time to result	≤60 minutes	≤20 minutes
Per test price	<\$10 USD	<\$5 USD

The above requirements are based on existing target product profiles for NG/CT:

- Ferreyra C, et al. Developing target product profiles for Neisseria gonorrhoeae diagnostics in the context of antimicrobial resistance: An expert consensus. PLoS One. 2020;15(9):e0237424. Available at: [Developing target product profiles for Neisseria gonorrhoeae diagnostics in the context of antimicrobial resistance: An expert consensus | PLOS ONE](#)
- Point-of-care tests for sexually transmitted infections: target product profiles. Geneva: World Health Organization; 2023. Available at: [9789240077102-eng.pdf \(who.int\)](#)

OPPORTUNITIES AND BENEFITS FOR THE APPLICANTS

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

- Generation of performance data for presentation to WHO, ministries of health and other global health stakeholders.
- Exploration of follow-up project to support market entry in LMICs, such as accelerated development and technology readiness for NG/CT global market.

TIMELINE

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

- Start of R&D activity to optimize/develop the tPOC MDx assay: **October 2024**
- Completion of R&D activities: **End 2025/Early 2026**
- Start of independent performance evaluation: **April 2025**
- End of independent performance evaluation: **December 2026**

SUPPORT PROVIDED BY FIND

PRODUCT DEVELOPMENT ACTIVITIES

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

- Funding for product optimization to meet the operational requirements for a test to be used at primary care settings in LMICs. Example: Improve robustness of the device or assay reagents for LMIC environmental conditions, making the device battery operated, simplification of the operating steps.
- Funding for product development activities of disruptive technologies. Example given: Integrate innovative sample preparation and/or detection technologies to adapt the MDX tPOC to new, not-yet validated specimen types including extragenital sample types such as pharyngeal and rectal swabs.
- In-kind support such as technical guidance, expert consultancy support.

INDEPENDENT EVALUATION ACTIVITIES

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

- Selection of the study sites.
- Study protocol development and submission for IRB approval.
- Study management.
- Data collection and data analysis.
- Study report preparation.
- Dissemination of results to relevant stakeholders.

CO-FUNDING OPPORTUNITY WITH RIGHT FOUNDATION

This RFP is released in coordination with the RIGHT Foundation, a Korean non-profit organization supported by the Korean Ministry of Health and Welfare, Korean life science companies, and the Bill & Melinda Gates Foundation. Applicant teams that include *at least one Korean entity* with R&D expertise and with proposals that meet [RIGHT's RFP criteria](#) are encouraged to **apply to both RIGHT and FIND for co-funding**. The benefits of co-funding include increased project funding.

Co-funding eligibility:

- Proposals meet RIGHT Foundation RFP eligibility criteria
- Proposals meet FIND RFP eligibility criteria
- Proposals comply with the review procedures for both RIGHT Foundation and FIND

Terms and conditions:

- All proposals will be reviewed by RIGHT Foundation and FIND independently, and the selection status of one funder does not impact eligibility for funding by the other.
- Proposals may be selected for funding by RIGHT Foundation, FIND, or by both funders.
- Co-funded projects will be awarded funding for two-thirds of total project costs (i.e. one-third contributions from each of RIGHT Foundation, FIND, and grantee) or up to the maximum award amount of each funder, respectively.
- Co-funded projects must adhere to the project reporting requirements of both RIGHT Foundation and FIND, respectively.

COMMERCIAL PARTNER INVESTMENT

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

PRODUCT DEVELOPMENT ACTIVITIES

- Co-funding for product development / optimization activities is not compulsory but strongly encouraged.

INDEPENDENT EVALUATION ACTIVITIES

- Manufacture and ship devices and assays for independent evaluation at LMIC sites.
- Provide after-supply support, such as customer training and complaint management.

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

SECTION 2: INSTRUCTIONS AND PROPOSAL REQUIREMENTS

ELIGIBILITY CRITERIA

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

- ✓ Original developers/manufacturers of a MDx tPOC diagnostic devices with an existing dual NG/CT assay at a technology level readiness (TRL) of 4 or above (refer to the TRL table below).
- ✓ The MDx tPOC diagnostic devices and assays must target or meet the following key requirements of a molecular true point-of-care test that enable molecular testing at the lowest level healthcare settings such as primary care, as well as community and at-home testing (for those specifications that not met yet, the applicant will be requested to describe the activities and budget to meet the specification and reach TRL 7 within the timeframe of the project):
 - Handheld or portable (i.e. can be carried, usually below < 5kg).
 - No laboratory equipment required with all necessary materials and reagents included in the kit.
 - Operated by lay users or health workers with limited training on laboratory practices.
 - Short turn-around-time, below 60 min.
 - Battery operated (platforms that come with a battery, either integrated (e.g. Li-ion), disposable (e.g. AA cell) or removable (plug and play)) or compatible with external portable power bank (low power consumption that allows operations with a portable charger / power bank that needs to be purchased separately) to ensure operations for 4-8 hours.
 - 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.

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

1

OUT OF SCOPE

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

- ✗ Distributors
- ✗ Academic teams
- ✗ Non-molecular-based technologies, such as immunoassays, lateral flow assays
- ✗ Molecular solutions that cannot meet the true point-of-care requirements (according to the above requirements), such as lab-based solutions, open-PCR kit.

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 to the public sector in LMICs (volume and details to be negotiated).
- Commit to a pricing model that is transparent and affordable for LMICs (i.e. COGS-based pricing) (see **Appendix 2**).
- 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 **May 6th 2024, 23h59 CEST**.

APPLICATION REQUIREMENTS

To be complete, applications must include the following:

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

HOW TO APPLY

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

SELECTION PROCESS

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 by an external review panel comprised of specialists with backgrounds in technical R&D, product launch, and implementation. The review panels will use information submitted in the application (see **Application Requirements**), as well as publicly available information. The review panels may request additional information or clarifications, if needed, in writing. Applications will be evaluated in stages, as follows:

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

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

Short-listed candidates will be selected in a consensus call of reviewers and will advance to Stage 2.

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

Note: Applicants not selected will be notified; however, the details regarding non-selection will not be provided for every applicant.

- **Due diligence:** The due diligence (DD) to verify the applicant submissions and claims will proceed in parallel with contract negotiations. The DD process may include site visits and/or phone/video conferencing, as well as requests for additional information. Should the DD reveal any unresolvable inconsistencies with this RFP and/or donor requirements and restrictions, applicant exclusion at this late stage is still possible. FIND may outsource the conduct of DD to an independent third party, following FIND procedures.

Stage 0	Stage 1	Stage 2
<i>Initial screening of all applicants to a set of long-listed candidates</i>	<i>First evaluation to short-list candidates (up to 10)</i>	<i>Second 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). 	<ul style="list-style-type: none"> • Evaluation of the finalists will be evaluated based on: <ol style="list-style-type: none"> 1. Scores on the “Technical Assessment” and “Business Assessment” completed in Stage 1. 2. Applicant Presentation 3. Follow-up questions and Live Presentation • The review panel will score the candidate’s overall alignment with the goals of the RFP (see sheet titled “Alignment Criteria” within the Assessment Matrix).

SUMMARY OF SELECTION TIMELINE

RFP Issued	April 15th 2024
Deadline for questions	April 29th 2024
Application deadline	May 6th 2024
Notification of short-listed candidates (end of Stage 1, tentative timeline)	June 10th 2024
Start of due diligence and contract negotiation (end of Stage 2, tentative timeline)	July 15th 2024
Start of project (tentative timeline)	October 2024

QUESTIONS & FURTHER INFORMATION

Please email questions to rfp.bi@finddx.org with the subject line: “CT/NG Molecular tPOC RFP”. Questions will be accepted and responded to expediently up to and including **29th April 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 (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 <i>production</i> ;

“Manufacturer of Record” <i>(if applicable)</i>	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” <i>(if applicable)</i>	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” <i>(if applicable)</i>	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;

- 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
- 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 settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The number of arbitrators shall be three (3). The place of arbitration shall be Geneva, Switzerland. The language of the arbitration shall be English.

References

1. Global health sector strategy on Sexually Transmitted Infections, 2016-2021. Accessed March 20, 2024. <https://www.who.int/publications-detail-redirect/WHO-RHR-16.09>
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3. *WHO Guidelines for the Treatment of Neisseria Gonorrhoeae*. World Health Organization; 2016. Accessed August 30, 2023. <http://www.ncbi.nlm.nih.gov/books/NBK379221/>
4. Global action plan on antimicrobial resistance. Accessed March 20, 2024. <https://www.who.int/publications-detail-redirect/9789241509763>
5. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accessed March 20, 2024. <https://www.who.int/publications/i/item/9789240027077>
6. Point-of-care tests for sexually transmitted infections: Target product profiles. World Health Organization; 2023. Accessed March 20, 2024. <https://www.who.int/publications/i/item/9789240077102>