Request for Proposals

Seeking a manufacturing and commercialization partner for a fluorescence-based antigen rapid diagnostic test for gonorrhoea infection with a focus in low- and middle-income countries

Executive summary

- FIND, the global alliance for diagnostics, is leading a Request for Proposals (RFP) to **find a manufacturing and commercialization partner to transfer a fluorescence-based antigen rapid diagnostic test for gonorrhoea infection** (NG POCT) for use in low- and middle-income countries (LMICs).
- The short-term focus of this RFP is to identify partners with interest in transfer of the technology for manufacture.
- Selected applicants will be required to commit to undertake activities that enable product launch (local registration, service, and distribution activities) and supply to the public sector in LMICs (volume and details to be negotiated), based on FIND's global access policy.

BACKGROUND

Gonorrhoea infection, 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) has identified NG as a high-priority pathogen because of widespread antimicrobial resistance (AMR) to penicillin, tetracyclines, macrolides (including azithromycin), sulphonamides, trimethoprims, and quinolones, including emergent resistance to the "last line" extended-spectrum cephalosporins − cefixime and ceftriaxone. The reason for the increase in antibiotic resistance is the unnecessary use of antibiotics in patients with suspected STIs. 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 wide spectrum 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 (CT), and has led to a significant number of patients being treated with unnecessary antibiotics. 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.[1]

As part of this effort, FIND and WHO published a target product profile[2] (TPP) (see Appendix 1) describing the features required for a NG only or a NG/CT POCT for use in low- and middle-income countries (LMICs). FIND, the Global Antibiotic Research and Development Partnership (GARDP), and WHO have signed a Memorandum of Understanding (MOU) to explore joint initiatives that could improve access to antibiotics while protecting them against the emergence of AMR. The MOU includes development of new POCTs and a campaign for their sustainable use in LMICs under the new WHO guidelines for STI treatment and management of symptomatic patients.

With funding from the Global AMR Innovation Fund (GAMRIF), FIND has supported the development of rapid, low-cost diagnostics for NG and CT. A low-cost, fluorescence-based antigen rapid diagnostic test was developed with DCN Research Group (DCN) to detect NG in urine samples (for men) and vaginal swabs (for women), which satisfies the TPP requirements. The current NG POCT is in late-stage development and is ready for technology transfer to manufacturing. FIND is seeking a manufacturer and commercialization partner who will commit to obtaining regulatory approval for the deployment of the test in LMICs.

FINAL PRODUCT SPECIFICATIONS AND RATIONALE

The key product requirements are shown in Appendix 1.

The NG POCT developed by FIND and DCN meets the TPP requirements for a non-molecular test for use with male urine and female, self-collected vaginal swabs. Preliminary clinical performance shows optimal clinical sensitivity and specificity for the detection of NG in patients with urethral or vaginal discharge. Recent performance in asymptomatic (male) patients suggests that the test could also be used to support screening strategies to reduce NG transmission. As many patients are asymptomatic, screening for NG would be ideal to reduce the circulation of the bacteria in at-risk populations. Testing of additional clinical samples is currently ongoing at a study site in South Africa and in the USA.

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 the sensitivity and consequently requires a fluorescence reader to view the results. FIND

[1] https://www.who.int/publications/i/item/9789240024168

has concurrently developed an LMIC-appropriate companion POCT reader, which meets the TPP requirements (Appendix 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. 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[3]. The use of a POCT can rule out the presence of NG, and thus support antimicrobial stewardship.

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.)[3] The use of a NG POCT in these population can contribute to the reduction in the transmission of NG and other STIs.

The market is currently in its early stage, mainly because this type of POCT for large-scale testing does not exist yet in LMIC markets and WHO only released the new recommendations in July 2021. However, this new tool represents an urgent market opportunity to contribute to the global efforts to reduce STIs by 2030.

OBJECTIVE AND SCOPE

FIND invites companies with capacity to manufacture quality assured IVDs (manufacturing can also be offered in collaboration with an appropriate partner) with a global sales, marketing and distribution network in the IVD market, including a commercial presence in LMICs, to submit a proposal for the commercialization of the new NG POCT.

The project objectives are designed to enable a partner to commercialize the NG POCT within a 2−3-year timeframe.

- ✓ To conduct a technology transfer from FIND's development partners at the end of the product development phase (July 2021).
- ✓ To complete appropriate regulatory studies and submissions for registration in selected target markets as well as WHO Prequalification (FDA, CE-IVD, WHO PQ).
- ✓ To manufacture the product using their own facilities or in collaboration with an appropriate third party at the required scale to meet market projections while following the necessary quality standards (ISO 13485).
- ✓ To provide product demand creation, commercial sales, marketing, and distribution support in select LMIC target markets. Please note that all sales revenue from the NG POCT would accrue to the commercialization partner.

TIMELINE

The product is expected to be available for transfer to manufacturing by Q4 2021/Q1 2022 with manufacturing processes defined, pilot manufacturing established, and verification testing completed.

SUPPORT PROVIDED

- A **design-locked NG POCT** ready to be transferred to a manufacturer.
- 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 GARDP and WHO, FIND will advocate with donors to accelerate the deployment and access of the test in the most affected countries. Ongoing efforts aim to increase country awareness around the need for STI diagnostics; different modeling options are under development to accelerate policy changes and faster introduction of the test in LMICs.
- Access to FIND's market assessment in six countries potentially interested in a fast introduction of the NG POCT.
- Access to clinical samples for further development, if needed.

ELIGIBILITY CRITERIA

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

- Have gained WHO Prequalification or other stringent regulatory body (e.g. FDA or CE mark) approval for at least one IVD product,
- Be willing to commit to an affordable selling price for LMICs, together with other access conditions, to be negotiated as part of the commercialization agreement.

Proposals are welcome from organizations with existing in-house capacity for large-scale manufacturing, distribution, and marketing, as well as from consortiums of entities with established relationships offering to jointly undertake the work. In the latter case, proposals shall be submitted by the lead organization which will be the main point of contact and responsible for further negotiations.

COMMERCIAL PARTNER INVESTMENT

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

- Fully support the investment required to implement and scale up manufacturing operations (including setting up the manufacturing system, if required).
- Run clinical trials and other studies to obtain regulatory approval in target markets (target markets will be agreed on during contract negotiation process), in addition to WHO Prequalification, or regulatory equivalent.
- Ensure adequate manufacturing capacity to meet demand.
- Promote the product in the public sector in agreed target markets and submit tender offers for appropriate tenders.
- Maintain and manage adequate inventories to meet demand and distribute the product to fulfill orders.

- Provide after-sale support, customer training, complaint management.

SELECTION CONDITIONS

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

- Commit to undertake 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 3**).
- Commit to and follow FIND Global Access Policy and FIND Code of Conduct and Ethics
- See **Appendix 4** for additional information on "Grounds for Exclusion".

SELECTION PROCESS

The deadline for receipt of submissions is 30 November 2021. The selection process is designed to be objective, independent, and transparent to ensure that the most suitable technologies are supported, 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 FIND and specialists with backgrounds in technical R&D, product launch, and implementation. The review panels will use information submitted in the application (see **Application Requirements** below), 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 4**. The list of eligible candidates will advance to Stage 1.
- **Stage 1.** This first evaluation will downselect the long list of candidates to a short list of 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:
    - 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 normalized scores from the Business Assessment (50%), and Alignment Criteria (50%). Short listed candidates will be selected in a consensus call of reviewers and will advance to Stage 2.
- **Stage 2.** This second evaluation will downselect short-listed candidates to a 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.
    - Scores from the Business Assessment (completed in Stage 1) will also be provided to the external review panel.

  The external review panel will score the candidate's alignment to the goals of the RFP (see sheet titled **"Alignment Criteria" in the Assessment Matrix**) – this scoring will be conducted *independently of the candidate's score in the Alignment Criteria from the internal review panel during Stage 1.* Lastly, the **Applicant's Total Score** will be calculated. A finalists will be selected in a consensus call of reviewers and will advance to contract negotiation. 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 conduct of 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 downselect long-listed candidates to short-listed candidates (up to 10)*	*Second evaluation to downselect short-listed candidates to a list of finalists*
• Verification that the contents of the application are in-scope. Applicants that are "out of scope" will be excluded. • Verification of applicant eligibility. Applicants that are not eligible will be excluded.	• Evaluation of long-listed candidates will be performed by an internal review panel. • Candidates will be evaluated based on: 1. Score on the "Business Assessment" within the Assessment Matrix 2. Applicant Presentation • The internal review panel will score the candidate's overall alignment with the goals of the RFP (see sheet titled "Alignment Criteria" within the Assessment Matrix).	• Evaluation of short-listed candidates will be performed by an external review panel. • Candidates will be evaluated based on: 1. Scores on the "Business Assessment" completed in Stage 1. 2. Applicant Presentation 3. Follow-up questions and Live Presentation • The external review panel will score the candidate's overall alignment with the goals of the RFP (see sheet titled "Alignment Criteria" within the Assessment Matrix).

APPLICATION REQUIREMENTS

Applications should include the following:

1. **Applicant presentation**
   - Applicants shall provide a slide deck of **no more than 10 slides** and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms).

2. **Assessment matrix**
   - Applicants are to complete noted sections of the provided spreadsheet titled "Assessment Matrix" (see **HOW TO APPLY** for templates and forms), specifically:
     Business assessment: Please provide evidence and supporting information (column C) regarding each of the criteria. Applicant responses to be supported by/verifiable through corporate documentation and due diligence.
3. **Supporting documents**
   - Aside from the two forms 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.
   - There will not be public opening of awards, or separate technical and financial bidding documents.

HOW TO APPLY

Submit applications via the FIND Technology Scouting Submission Webform. Please select **'AMR'** as the 'Disease Area' and 'RFP: Manufacturing partner Ng LFA' as the 'Disease Area Subtype' and proceed with the online submission. Templates for the Applicant Presentation and Assessment Matrix can be downloaded from the submission portal. Please upload your completed **Applicant Presentation** and **Assessment Matrix,** along with any supporting documents by **30 November 2021**.

QUESTIONS & FURTHER INFORMATION

Please email questions to Ng-LFA-manufacturing-RFP@finddx.org. Questions will be accepted and responded to expediently up to and including **30 November 2021**. 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 a commercial-level contractual mechanism, where the standard Terms and Conditions address the requirements of supplying a product for public health particularly in LMICs, as set forth under **Appendix 5**.

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 (Ng-LFA-manufacturing-RFP@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: Target product profile for a rapid, low-cost diagnostic to distinguish gonorrhoea from chlamydia infection at primary care

Characteristic	Minimal	Optimal	Current characteristics of the developed product at DCN by FIND
1. Intended use	Detect *Neisseria gonorrhoeae* (NG) only or NG and *chlamydia trachomatis* (CT) infection to improve syndromic patient management and to facilitate appropriate antibiotic use	Same as minimal, plus to support public health management to assist in screening to identify previously undetected NG or NG and CT infections	Detect *Neisseria gonorrhoeae* (NG) only
2. Target use setting	Primary health care settings including health posts (Level 1[2]); to be used after initial clinical evaluation (referring to Step 2 in the WHO Vaginal/Urethral Discharge Flowchart[3]) to guide treatment decision		Primary health care settings
3. Test format / Equipment	A non-instrumented, single-use, disposable diagnostic test preferred; Ideally no additional power required for operation, but if required, battery power with 8-hour operation between charges; Reader optional and only appropriate if its inclusion supports enhanced test performance (see Appendix 2)		Single-use, disposable diagnostic with a battery-operated POC fluorescent reader
4. Target users	The target users include community health workers with minimal training and any health worker with a similar or superior training level		community health workers
5. Target analytes	Identification of NG or NG AND CT	Same as minimal, plus detection of additional sexually transmitted infections (e.g. Mycoplasma & trichomonas) ideal	Identification of NG
6. Clinical Sensitivity[4]	>80% – required to achieve the minimal intended use for a non-molecular test; >95% – required to achieve the minimal intended use for a molecular test	>90% – required to achieve the minimal intended use for a non-molecular test; >95% – required to achieve the minimal intended use for a molecular test	95% sensitivity (58/61), on frozen clinical samples (male urine)
7. Clinical Specificity[5]	>95% – required to achieve the minimal intended use	>98% – required to achieve the optimal intended use	95% specificity (78/82), on frozen clinical samples (male urine)
8. Specimen[6]	Women: self-collected and provider-collected high vaginal swabs Men: urethral swab acceptable, urine preferred Same test format able to accept multiple specimen types to achieve results for men and women	Women: urine preferred, self-collected and provider-collected high vaginal swabs acceptable Men: urine, and rectal and pharyngeal swabs Same test format able to accept multiple specimen types to achieve results for men and women	Women: provider-collected vaginal swabs Men: first-catch urine
9. Analytical Inclusivity	Assay detects geographically and genetically representative *N. gonorrhoeae* strains		Detects 14/14 NG strains

[2] Ghani AC et al. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. Nature 2015.
[3] WHO. Training modules for the syndromic management of sexually transmitted infections. World Health Organization: Geneva, 2007
[4] In genital specimens with performance verified as compared to nucleic acid reference standard
[5] Ghani AC et al. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. *Nature* 2015.
[6] Sensitivity and specificity for rectal and pharyngeal swabs is not yet determined

10. Analytical Exclusivity	No cross-reactivity with >95% of non-chlamydial and non-gonococcal pathogens and other microorganisms that frequently colonize and/or infect the genital tract especially non-gonorrhoeal *Neisseria*	No cross-reactivity with >99% of non-chlamydial and non-gonococcal pathogens and other microorganisms that frequently colonize and/or infect the genital tract especially non-gonorrhoeal *Neisseria*	Cross reactivity detected with N. *meningitidis*, *N. lactamica* and *N. polysaccharea* No cross reactivity with CT
11. Specimen preparation	Minimal sample processing; no more than one operator step	Integrated; no sample preparation required by user	Minimal sample processing (single extraction buffer step)
12. Steps performed by healthcare worker between specimen preparation and result	No more than three operator steps, none of which is timed or labour intensive	One operator step (none of which has a timed interval), excluding waste disposal	Three operator steps (add specimen, add buffer, mix)
13. Additional consumables required but not provided within the test kit	None, except for specimen collection		Specimen collection
14. Cold chain	None required at any point		none
15. Test kit	All materials required for test procedure, including devices, reagents or other consumables to diagnose one individual, included in packaged, self-contained kit (either packaged individually as one test per test kit or sufficient to perform the number of tests packaged in the test kit box – e.g. 20, 50 or 100 tests)		TBD (include preferred vaginal swab)
16. Test kit stability and storage conditions	12 months, stable between 2−35°C, 70% humidity, 3000 meters altitude	18 months, stable between 0−50°C, 90% humidity, 3000 meters altitude	Cassette stable for 12 months evaluated at 4°C, 25°C, and 55°C; storage at 55°C is equivalent to 24 months at 35°C.
17. Environmental tolerance of packaged test kit	Transport stress (48 hours with fluctuations up to 50°C and down to 0°C) Tolerate exposures between 2°C−45°C at an altitude up to 3000 meters, up to and including condensing humidity		TBD
18. Operating conditions	Operation between 15°C and 40°C at an altitude up to 2000 meters Extremely low relative humidity to condensing humidity Result interpretation in low light settings	Same as minimal, plus operation between 10°C and 45°C at an altitude up to 3000 meters preferred	TBD
19. Training required	< 90 minutes	30 minutes	30 minutes
20. Clean water	None required		
21. Time to result	≤30 minutes	≤10 minutes	20 minutes
22. Duration of sample stability (time from specimen collection to insertion into test cartridge)	Immediate testing of the sample		TBD – preferred <4 hours

23. Stability of valid result (read window)	At least 30 minutes (after which results may be *false* or *invalid*); Clear language in the instructions for use regarding test reading	≥1 hour (after which results give *invalid* rather than *false* results); Clear language in the instructions for use regarding test reading	TBD (note: label can photobleach)
24. Safety precautions (bio-safety requirements)	Closed, self-contained system; unprocessed sample transfer only; no open handling of biohazardous material		Minimal sample extraction process, cartridge is closed system
25. Waste/disposal requirements	Standard biohazardous waste disposal or incineration of consumables, no high temperature incineration required	Small environmental footprint; recyclable or compostable plastics for test cartridges and other materials after decontamination, no incineration required	TBD Standard biohazardous waste disposal
26. Internal QC – reagents	Procedural (reagent-addition) control internalized in cartridge for each individual test run; positive and/or negative control for internal QC available for purchase separately	Procedural (specimen-addition/sample adequacy) control internalized in cartridge for each individual test run; positive and/or negative control for internal QC provided in each box of test kits	TBD Internal flow control, external positive and negative reagents can be supplied
27. Device control	Indicator of instability or expiration	Indicator of instability, expiration, inadequate sample and incorrect procedure and/or use but not as an additional component	Yes, Internal flow control only
28. Patient identification capability	Yes – simple, self-contained way to indicate a patient identifier		yes
29. Result display and interpretation	Result can be read with the naked eye with minimal instructions for interpretation required by user, or with an integrated reader (See Appendix 2) that supports enhanced test performance		External fluorescent reader display: yes/no/invalid
30. Target list price[7] per test (excluding the cost of a reader)	<$3 USD for a low complexity test (e.g. rapid diagnostic test) that meets the minimal intended use and clinical sensitivity and specificity TPP specifications	<$12 USD for a moderate/high complexity test (e.g. disposable single-use molecular test) that meets the optimal intended use and clinical sensitivity and specificity TPP specifications	<$3 USD
31. Regulatory requirements	WHO PQ or other stringent regulatory body (e.g. FDA or CE mark)		

[7] List Price– the price the manufacturer has arrived at for the product, taking into account the cost of goods and other factors (e.g., margin); the list price does not include any volume or other discounts or potential markup for distribution or other costs, including freight, taxes, etc. This cost is assumed a volume production and the prices listed in the TPP are considered for public health preferential pricing in low- and middle-income countries only.

Appendix 2: Requirements for RDT reader[8] (if required)

Characteristic	Minimal	Optimal
1. Ease of use	No more than 3 operator steps (position RDT (cassette/strip) as required by the reader; take image or scan; read result); simple test menu; integrated LCD screen; simple keypad or touchscreen with icons	
2. Size	Small, portable table-top or hand-held device; or disposable reader	
3. Power requirements	Standard AA/AAA batteries or rechargeable battery with 8-hour operation between charges. Rechargeable battery lifetime > 2 years	
4. Service, maintenance and calibration	Routine preventive maintenance no more than 30 minutes 1x per week (with hands on time <10 minutes). Mean time between failures of at least 36 months or 30,000 tests, whichever occurs first. Self-check alerts operator to reader errors or warnings; and ability to be calibrated remotely, or no calibration needed	
5. Patient identification capability	Manual entry of alphanumeric patient identifier keypad or touchscreen compatible with protective gloves	Same, plus bar code, RFID or other reader
6. Result display; result interpretation	Easy pictorial display: positive, negative, or invalid for each target analyte; no instructions for interpretation required	
7. Data acquisition and display	Able to add information (patient ID, operator ID, date, location, etc.); able to store patient results; able to print out results utilizing commoditized paper products (i.e. standard paper specifications and sizes)	
8. Connectivity	Reader has integrated global positioning system (GPS) module	If combined with a reader, internally integrated GPS/ general packet radio service (GPRS) module and conformity with HL7 messaging standards
9. Data export	Full data export over mobile phone network	Full data export over mobile phone network (data transmission can automatically select between GPRS or more advanced networks and global system for mobile communication (GSM), based on available coverage); GPRS should be able to utilize the internet file transfer protocol to transmit data: data transfer should be initiated every 6–12 hours automatically by the reader; data can be exported in a format compatible with HL7 standards, where appropriate; instrument tracks and transmits quality assurance data over time (e.g. identify shifts or trends).

[8] Adapted from RDT reader TPP prepared by the Murtagh Group, LLC (2014)

* Price target for reader: around 30 USD

Appendix 3: 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** – this includes an emphasis on the cost of goods sold (COGS) and the marketed price of the system.

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 4: 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 judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union and/or Germany 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 Germany 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.

Appendix 5: 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
"Manufacturing Cost of Goods Sold" or "COGS"	all the direct costs such as labour, material, and allocated overhead costs in Product *production;*
"Ex Works" or "EXW"	based on the meaning under INCOTERMS 2020 and on XYZ COGS;
"**Eligible Purchasers**"	all Public Health Sectors in LMICs and other private (ie non-governmental) health care providers not defined under PHS 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**"	based on Article [●].
"**Intellectual Property**" or "**IP**"	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**"	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;
"**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**" or "**PHS**"	(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;
"Stringent Regulatory Authority" or "SRA"	based on WHO list of SRAs: https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs
"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.

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 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 centres 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 sufficient supply of products to LMICs which 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" [●].

Technology Licence Agreement – in the case of a Technology Transfer ***(if applicable)***

XYZ shall enter into a Technology Licence Agreement with ABC, based on the following terms, comprising the following key definitions and "flow-through" obligations:

a. **Field** shall mean the detection of *N. gonorrhoeae* infection in humans, or as mutually further agreed with respect to other infectious disease agents by the Parties.
b. **Territory** shall include all LMICs as defined by the World Bank, as amended from time to time.
c. **Global Access** key terms regarding the Affordable Price and other key access terms to be an obligation under the Licence.
d. **Scope of the Licence**: XYZ to be granted, a non-exclusive, non-sublicensable (only to Affiliates), royalty-free, fully paid up and perpetual licence under the ABC IP to develop, make, or have made, use, offer for sale, sell, have sold, export or import the Product anywhere in the world for the purpose of its use in the Field and in the Territory. As per Article [●], the Field definition may be extended by mutual agreement of the Parties.
e. **Background IP**: Such Licence shall include the right to use any pre-existing (Background) ABC IP at zero (or minimal) royalty rates as long as it is required for the commercialisation of the Product.

f. **Technology Transfer**: Such Licence shall include appropriate technology transfer obligations under which XYZ and the Manufacturer of Record shall develop a mutually agreed plan of activities and deliverables to ensure such successful Technology Transfer (the **"Transfer Plan"**) in order to ensure that the Manufacturer of Record will be able to produce and commercialize the Product. The Transfer Plan shall be agreed within [●] weeks of the Effective Date.

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.

References

1. https://www.who.int/publications/i/item/9789240024168
2. Ferreyra C, Osborn J, Moussy F, Alirol E, Lahra M, Whiley D, Shafer W, Unemo M, Klausner J, Kelly Cirino C, Wi T. 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.
3. Cecilia Ferreyra, Maël Redard-Jacot, Teodora Wi , Jennifer Daily , Cassandra Kelly-Cirino. 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.