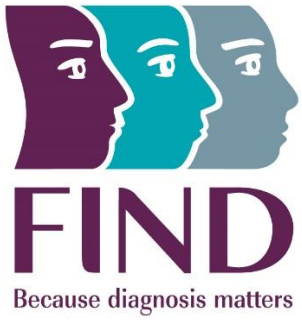

REQUEST FOR PROPOSAL

Diagnostics to Ensure Antibiotic Stewardship for the Treatment of Gonorrhea Infections

STI NG RDT Draft Version 7.0 (v7)

MAY 2019

Table of Contents

1 Acronyms and definitions

For the purposes of the RFP or any document which forms an intrinsic part of the RFP, the definitions set out in this list shall apply.

AMR	Antimicrobial resistance
CAO	Chief Access Officer
CARB-X	Combating Antibiotic Resistant Bacteria
CEO	Chief Executive Officer
CDA	Confidential disclosure agreement
CSO	Chief Scientific Officer
CT	*Chlamydia trachomatis*
DX	Diagnostic test
ESC	Extended-spectrum cephalosporin
FIND	Foundation for Innovative New Diagnostics
GARDP	Global Antibiotic Research and Development Partnership
LMIC	Low- and middle-income countries
NAAT	Nucleic acid amplification test
NG	*Neisseria gonorrhoeae*
NPT	Near-patient platform
POCT	Point of care test
RDT	Rapid diagnostic test
RFP	Request for proposal
STI	Sexually transmitted infection
TPP	Target product profile
WHO	World Health Organization

2 Executive summary

Gonorrhea infection, caused by *Neisseria gonorrhoeae* (NG), is the second most common bacterial sexually transmitted infection with substantial morbidity and economic cost worldwide.[1,2] 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 (ESCs) cefixime and ceftriaxone.

As GARDP drives the development of a new drug for gonorrhea treatment, and WHO simultaneously recommends the AWARE (Access, Watch, and Reserve) approach to antibiotic stewardship, countries will need diagnostic tools to guide treatment choices, ensure current therapies remain effective for as long as possible, and preserve new drugs from rapid development of resistance by overuse. Providing a drug stewardship approach through the use of appropriate diagnostics will allow for controlled introduction of a new drug, preserving its efficacy for as long as possible and ensuring that current therapies are preferentially prescribed in patients who remain treatable with these drugs.

In 2017, WHO published a roadmap for development and implementation of POCTs for STIs with an emphasis on diagnostic development for NG.[3] In support of these initiatives, FIND (finddx.org) is facilitating the development of new diagnostics tools for improved clinical management of NG worldwide, with a particular focus on LMICs. FIND has developed requests for proposals (RFPs) and target product profiles (TPPs) for the highest priority diagnostics for low-and middle-income countries (LMICs) to manage NG infections.

This RFP is to solicit products in development that meet the TPP requirements that describe a rapid, low-cost diagnostic test[a] to diagnose NG or NG and *chlamydia trachomatis* (CT) for use in primary health care settings in LMICs (see Section 5.2 below). Technologies may include lateral flow or molecular diagnostic tools with a high likelihood for successful development, commercialization and implementation within a 3-4 year time frame. RFPs serve to assess prospective development partners for technology readiness, commitment to global access pricing, and feasibility to meet the introduction timeline for LMIC markets in 2023.
Based on the outcomes of this RFP, FIND anticipates a maximum of 5 awards to be offered, including both lateral flow technologies (maximum US$500K per award) and molecular technologies (maximum US$1M per award) to support feasibility assessment. Technologies requiring minimal development to demonstrate applicability to NG detection are eligible for consideration as long as the development and feasibility assessment can be completed in three to four years.

[a] Standalone single-use, disposable diagnostic test; reader optional

Proposals should be submitted to the RFP project manager Cecilia Ferreyra, AMR Medical Officer at FIND, following guidelines described in Section 6 below. **Proposals must be received by 18h00 Central European Time (CET) on 31 May 2019.** Proposals received after the stipulated date and time shall be invalid.

3 About FIND

FIND is an international non-profit organization that enables the development and delivery of much-needed diagnostic tests for poverty-related diseases. FIND acts as a bridge between experts in technology development, policy, and clinical care, reducing barriers to innovation and effective implementation of diagnostic solutions in low- and middle-income countries. FIND fosters global health product development partnerships, engaging in active collaboration with over 150 partners, including health ministries, bilateral and multilateral organizations, research and academic institutes, commercial partners, private-public partnerships, NGOs and over 80 clinical trial sites. In addition to addressing market entry barriers for diagnostics, FIND supports the appropriate use of diagnostics in many countries through training programmes, quality assurance programmes, and laboratory strengthening work.

FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control, and prevention. Since its inception in 2003, FIND has partnered in the delivery of 21 new diagnostic tools used in 150 LMICs. Over 50 million FIND-supported products have been provided to our target markets since the start of 2015. FIND has created an enabling environment for numerous other products through the provision of specimen banks, reagent development, and better market visibility. A WHO Collaborating Centre, FIND works with more than 200 academic, industry, governmental, and civil society partners worldwide on over 70 active projects that cross six priority disease areas. FIND also has active collaborations with bilateral and multilateral organizations and clinical trial sites.

4 Background

4.1 Unmet need

Gonorrhea is the second most common bacterial sexually transmitted infection (STI) and results in substantial morbidity and economic cost globally.[1,2] The WHO estimates that in 2012, 78 million new cases occurred among adolescents and adults aged 15–49 years worldwide with a global incidence rate of 19 per 1000 females and 24 per 1000 males, with the highest magnitude in WHO Western Pacific and African Regions. Co-infection with CT is detected in 10–40% of people with gonorrhea.

The WHO has identified NG as a high-priority pathogen because of widespread AMR to penicillin, tetracyclines, macrolides (including azithromycin), sulphonamides, trimethoprims, and quinolones, including emergent resistance to the “last line” extended-spectrum cephalosporins (ESC) cefixime and ceftriaxone. The emergence of decreased susceptibility of *N. gonorrhoeae* to ESC together with already-existing AMR to other antibiotics, make *N. gonorrhoeae* a multidrug-resistant organism.

Patients with gonorrhea-like symptoms (vaginal and urethral discharge) are mostly seen in primary health care settings, which do not have accessible diagnostics to confirm NG and/or CT infection or provide guidance on effective antibiotic treatment regimens. Many STI treatment guidelines recommend clinical evaluation followed by treatment for both NG and CT infection with a combination of two antibiotics, hence many patients are being treated for NG, for example, even though they are infected with another disease.

Furthermore, STI guidelines assume that NG infections are consistent with symptoms like vaginal and urethral discharge, yet a large percentage of STI infections (including CT and NG) are asymptomatic.[4] To improve case detection rates, high performance tests are required to enable effective screening programs in asymptomatic key populations to i) diagnose what STI the individual has and ii) reduce transmission. New diagnostics are needed to help guide diagnosis and treatment decisions to foster antibiotic stewardship of existing and new antibiotics. If syndromic evaluation remains the primary approach to guide treatment of STIs, there is a significant risk of misdiagnosis and antibiotic overuse, which has been shown to lead to antimicrobial resistance.[5–7] To prevent misuse of antibiotics, a diagnostic-based stewardship strategy is urgently needed, particularly at primary health centers where patients present for treatment. The stewardship strategy must fit within a redefined, WHO-supported clinical algorithm that includes the use of diagnostics for patients presenting to primary health care settings.

Currently, there is no clinically validated POCT widely available for NG identification. One FDA-approved molecular diagnostic test is available to distinguish between CT and NG infections; however, turnaround time to results is too long for use in clinics, the cost remains prohibitive for use in primary health care settings, and uptake remains limited to reference-level laboratories.[8] Recent technology advancements may facilitate development of POCTs for NG. A low-cost rapid diagnostic test for NG detection alone or combined NG/CT detection and differentiation would enable wide scale uptake at primary health care level in LMICs.

4.2 Project objectives

To support a diagnostic stewardship plan for treatment of NG, FIND has identified a critical TPP needed to address accurate NG diagnosis at primary health care setting.

4.3 Project phases

The FIND diagnostic development project phases are as follows:
Phase I – Evaluation: This first phase is focused on assessing the applicant's assay and device data to determine eligibility and define what further development and investment will be needed.
Phase II – Partnership development: This second phase includes review of the applicant's technologies based on the required test specifications, and the establishment of a partnership and business model for the FIND programme, including a site visit and price negotiation for LMICs.

Phase III – Assessment: The third and final phase will include a feasibility assessment at the close of this project. Clinical validation and test performance in settings appropriate to the intended use (primary, community care in LMICs) may be the focus of a secondary programme as needed.
Optional **Phase IV – Optimization:** At FIND's discretion, this optional phase may occur after the minimum diagnostic requirements have been met in order to support limited technology development/optimization.

4.4 Project team

The RFP project manager is Cecilia Ferreyra, AMR Medical Officer at FIND.

Table 1: Project team

Name	Email	Role
Cecilia Ferreyra	cecilia.ferreyra@finddx.org	Project manager
Cassandra Kelly	cassandra.kelly@finddx.org	Project leader
Elisa Baszanger	elisa.baszanger@finddx.org	Technology assessment
Ranga Sampath	Ranga.sampath@finddx.org	CSO

The project team will assess all applications for completeness and to ensure they meet the RFP submission criteria (see Appendix 3). A secondary assessment will be completed by members of FIND's executive team and Scientific Advisory Committee (see Section 7).

4.5 Benefits of working with FIND

FIND intends to catalyse the development of high-priority POC NG diagnostics by establishing the right partnerships and providing assistance and resources in areas such as R&D, product validation, regulatory and clinical affairs, quality systems and processes, manufacturing, and distribution. These activities are primarily donor funded, enabling FIND to partially fund product development programs.

FIND expects a major resource commitment from the selected RFP candidate companies to bring a diagnostic solution to market and make the product accessible in low-resource settings. In some cases, FIND may assist sourcing for diagnostic reagents and commercial partnerships. FIND may also provide implementation support by working closely with national ministries of health in LMICs, as well as assistance/guidance on the WHO endorsement process and/or other international regulatory bodies.

5 Scope of work (NG POCT RFP)

5.1 Objectives

The objective of the FIND STI NG project is the development of the highest priority diagnostics for NG to guide treatment decisions. FIND has identified key test attributes that should serve as success criteria for diagnostic development, with minimal and optimal requirements defined for each criterion. As described below, the TPP defines the intended use, characteristics, and performance of the test for the appropriate setting.

5.2 Diagnostic test and assay specifications

The purpose of this RFP is to catalyse the development of promising technologies that can meet the need to identify NG and CT infection at the primary care level. Historically, CT and NG lateral-flow based technologies have shown considerably poor performance, especially with respect to clinical sensitivity. It is believed that recent advances in lateral flow test development and emerging single-use disposable molecular tests could enable improved sensitivity and performance for NG and CT detection in primary health care settings.

The TPP for a rapid, low-cost diagnostic test to distinguish NG from CT at primary care is presented in detail in Appendix 1 (TPP STI NG), with device performance specifications presented as a range (minimal to optimal). This TPP has intentionally been designed as agnostic to technology approach (e.g. single-use molecular or immunoassay tests),[b] provided the approach is appropriate for use in Level 1 facilities.[9] There is a preference for technologies that can achieve optimal characteristics, while maintain low costs to obtain the list price of the tests as defined in the TPP, with particular emphasis on key criteria identified below.

Table 2: Key device performance criteria (TPP STI NG)

Characteristic	Minimal	Optimal
Intended use	To 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
Target use setting	Primary health care settings including health posts (Level 1); to be used after initial clinical evaluation (referring to Step 2 in the WHO Vaginal/Urethral Discharge Flowchart[10]) to guide treatment decision	
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;	

[b] It is presumed that single-use molecular tests will likely have higher complexity and costs, but also enable improved performance.

	Reader optional and only appropriate if its inclusion supports enhanced test performance (see Appendix 2 for reader requirements)	
Clinical Sensitivity	>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
Characteristic	Minimal	Optimal
Time to result	≤30 minutes	≤10 minutes
Target list price 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

5.3 Responsibilities

FIND will ensure:

- Project and timeline coordination
- Assist with specimens and samples for preliminary validation
- Assist with reagent sourcing, if needed
- Assist with partnership for commercialization, if needed
- Assess project milestones and final technical and performance specifications

The diagnostic developer will ensure:

- Sufficient internal resources (e.g. personnel and facilities) for assay and device development and preliminary analytical data available
- The proper and sufficient collection, analysis, and archiving of data to evaluate the NG Dx test, based on the criteria in TPP STI NG (Appendix 1)
- The appropriate capacity (and certification) for manufacturing, quality control, and anticipate validation and regulatory approval of device

5.4 Deliverables

The NG Dx program deliverables include:

- Signed partnership between FIND and the NG RDT developer
- Global price and access agreement
- Project Gantt chart timeline for programme management and deliverables schedule
- The generated (raw and analysed) data from the analytical (compulsory) and preliminary performance data (desirable) of the NG RDT
- Quality Assurance/Quality Control SOPs in place
- The generated (raw and analysed) data from the Quality Assurance/Quality Control of the NG RDT manufacturing process

- Prototypes or early-stage (pilot-scale) manufactured NG RDT devices

5.5 Timeline

After contract commencement, preliminary data for the NG RDT device must be generated within 12 months from contract signing. FIND foresees partnership development and device evaluation lasting up to 24 months. Technologies requiring minimal development to demonstrate applicability to NG detection are eligible for consideration as long as the development and feasibility assessment can be completed in 3-4 years.

5.6 Budget

A development budget should be submitted as part of the proposal to include the cost of fully developing the specified NG RDT as described above. Please list self-funded activities and in-kind contributions in the budget. Self-funding of parts of the work is a strong plus as it demonstrates the commitment of the test developer. The final contract will provide additional details on financial terms.

FIND anticipates offering a maximum of 5 awards of up to US$500K (per award) for lateral flow technologies and up to $US1M (per award) for molecular technologies, including NG diagnostic technology development (as needed) and preliminary validation activities.

5.7 Communication plan

FIND proposes bi-weekly or monthly calls throughout the award development timeline to track progress, define action items, and address challenges. Additional meetings will be planned on an as needed basis. Interim and final reports including project and budget narratives to FIND will be required as decided after the award negotiation.

6 Instructions to applicants and proposal requirements

This RFP is an invitation for suitable companies and technology developers to submit a proposal for a diagnostic device to detect NG infection as described in Section 5. Accordingly, this RFP must *not* be construed, interpreted, or relied upon, whether expressly or implied, as an offer capable of acceptance by any person, or as creating any form of contractual, promissory, or other rights.

6.1 Expected proposal content

The submitted proposal should include an executive summary with sections on the company overview, product status including available performance data on NG/CT or appropriate surrogates, proposed work plan and timeline, project risks, proposed budget, commercialization resources, key personnel relevant to this proposal.

Proposals should be submitted in English using a 10 or 12 point font and formatted in Microsoft Word, PDF and/or Excel. Proposals should not exceed 10 pages (see Appendix 3 for more detail).

6.2 Confidentiality

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested developers prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. Review of proposals will be carried out by FIND and FIND's independent Scientific Advisory Committee, all members of which are also under confidentiality and are 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.

6.3 Submission timeline (and deadline)

Proposals should be submitted in English to cecilia.ferreyra@finddx.org, by e-mail, and formatted as described in Appendix 3. The RFP timeline is summarized in the table below; the deadline for full proposal reception is **WEDNESDAY, 05 June 2019.** Proposals received after the deadline of 18h00 Central European Time (CET) shall be invalid.

Table 3: RFP Timelines

Activity	Date
RFP published	02 May 2019
Deadline for questions to be submitted to FIND	17 May 2019
RFP Closing time [18h00 Geneva time]	05 June 2019
Notification of decision	28 June 2019

6.4 Questions and contacts

FIND is available to further discuss this opportunity over the telephone and to answer questions via email. Questions should be submitted in writing to the project manager, Cecilia Ferreyra (cecilia.ferreyra@finddx.org), no later than 17 May 2019.

7 Evaluation and selection criteria

Proposals will be assessed and partners selected through a systematic process designed to be objective, independent, and transparent to ensure that the most suitable technologies are supported, potential conflicts of interest are avoided, and the global community understands and has access to the selection process and its outputs.

The FIND project team will assess all applications for completeness and to ensure they meet the RFP submission criteria. In the first stage of evaluation, any proposal shall be rejected if it is found deficient as per the requirement indicated in the technical specifications (TPP STI NG) for responsiveness of the proposal.

A secondary assessment will be completed by a Selection Committee, comprised of members of the FIND executive team including the CEO, CSO, CAO and subject matter experts, which may be external reviewers and/or members of the FIND Scientific Advisory Committee. A standardized scoring matrix will be used to assess all applications and feedback on the decision will be provided.

During the assessment, a particular focus will be put on:

- **Technology:** 1) Current performance of any relevant technology (device, assay), 2) capability to develop the NG RDT to meet the success criteria, 3) affordability of the technology, and 4) strength of the data.
- **Partnership opportunity:** 1) Company resources and capability, 2) business model and commitment to global health, and 3) technology maturity.

The project team will also conduct site visits or phone discussions with top candidates to further assess their fit with FIND and the scope of work prior to final selection of the awards.

This selected awardees will be invited for negotiations, if considered necessary. Representatives conducting negotiations on behalf of the awardee must have written authority to negotiate and conclude a contract. Technical negotiations will include a discussion of the proposed technical approach and methodology, work plan, and organization and staffing, and any suggestions to improve the Terms of Reference. Special attention will be paid to clearly defining the technical and pricing milestones required to ensure satisfactory implementation of the development programme. Financial negotiations will then reflect the scope of work for the development program agreed to during the technical negotiations.

8 References

1 World Health Organization, Reproductive Health and Research. *WHO guidelines for the treatment of Neisseria gonorrhoeae. 2016.* 2016http://www.ncbi.nlm.nih.gov/books/NBK379221/ (accessed 18 Feb2019).

2 WHO | Global action plan on AMR. WHO. http://www.who.int/antimicrobial-resistance/global-action-plan/en/ (accessed 18 Feb2019).

3 WHO | Point-Of-Care Diagnostic Tests (POCTs) for Sexually Transmitted Infections (STIs). WHO. http://www.who.int/reproductivehealth/topics/rtis/pocts/en/ (accessed 18 Feb2019).

4 Unemo M, Bradshaw CS, Hocking JS, de Vries HJC, Francis SC, Mabey D *et al.* Sexually transmitted infections: challenges ahead. *Lancet Infect Dis* 2017; **17**: e235–e279.

5 Antibiotic resistance. https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance (accessed 19 Feb2019).

6 CDC. What Exactly is Antibiotic Resistance? Cent. Dis. Control Prev. 2018.https://www.cdc.gov/drugresistance/about.html (accessed 19 Feb2019).

7 Aslam B, Wang W, Arshad MI, Khurshid M, Muzammil S, Rasool MH *et al.* Antibiotic resistance: a rundown of a global crisis. *Infect Drug Resist* 2018; **11**: 1645–1658.

8 Wilson SP, Vohra T, Goldberg J, Price C, Calo S, Mahan M *et al.* Reliable Rapid Assay for Gonorrhea and Chlamydia in the Emergency Department. *J Emerg Med* 2017; **53**: 890–895.

9 Ghani AC, Burgess DH, Reynolds A, Rousseau C. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. *Nature* 2015; **528**: S50-52.

10 WHO. *Training modules for the syndromic management of sexually transmitted infections*. World Health Organization: Geneva, 2007.

9 Supplementary material

9.1 Appendix 1: TPP STI NG

Target product profile for a rapid, low-cost diagnostic to distinguish gonorrhea from chlamydia infection at primary care:

Characteristic	Minimal	Optimal
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
2. Target use setting	Primary health care settings including health posts (Level 1c); to be used after initial clinical evaluation (referring to Step 2 in the WHO Vaginal/Urethral Discharge Flowchart[d]) to guide treatment decision	
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)	
4. Target users	The target users include community health workers with minimal training and any health worker with a similar or superior training level	
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
6. Clinical Sensitivity[e]	>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
7. Clinical Specificity[f]	>95% -required to achieve the minimal intended use	>98% -required to achieve the optimal intended use
8. Specimen[g]	Women: self-collected and provider-collected high vaginal swabs Men: urethral swab acceptable, urine preferred	Women: urine preferred, self-collected and provider-collected high vaginal swabs acceptable Men: urine, and rectal and pharyngeal swabs

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

	Same test format able to accept multiple specimen types to achieve results for men and women	Same test format able to accept multiple specimen types to achieve results for men and women
9. Analytical Inclusivity	Assay detects geographically and genetically representative Neisseria gonorrhoea strains	
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*
11. Specimen preparation	Minimal sample processing; no more than one operator step	Integrated; no sample preparation required by user
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
13. Additional consumables required but not provided within the test kit	None, except for specimen collection	
14. Cold chain	None required at any point	
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)	
16. Test kit stability and storage conditions	12 months, stable between 2-35ºC, 70% humidity, 3000 meters altitude	18 months, stable between 0-50ºC, 90% humidity, 3000 meters altitude
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 and 45 °C at an altitude up to 3000 meters, up to and including condensing humidity	
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
19. Training required	< 90 minutes	30 minutes
20. Clean water	None required	
21. Time to result	≤30 minutes	≤10 minutes
22. Duration of sample stability (time from specimen collection to	Immediate testing of the sample	

insertion into test cartridge)		
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
24. Safety precautions (bio-safety requirements)	Closed, self-contained system; unprocessed sample transfer only; no open handling of biohazardous material	
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
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
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
28. Patient identification capability	Yes – simple, self-contained way to indicate a patient identifier	
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 1) that supports enhanced test performance	
30. Target list price[h] 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
31. Regulatory requirements	WHO PQ or other stringent regulatory body (e.g. FDA or CE mark)	

[h] 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[i] (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 key pad 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

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

		standards, where appropriate; instrument tracks and transmits quality assurance data over time (e.g. identify shifts or trends)
10. Regulatory requirements	GMP compliant, ISO 13485:2016 certified and authorized for use by a stringent regulatory authority	
11. Cost of reader	Reader cost included in the list price of the test	

9.2 Appendix 3: Proposal template for STI NG RFP response (table format)

The proposal should provide a clear description for how the diagnostic developer intends to carry out the scope of work for the project described in the RFP. The application must address the key sections below and should reflect the applicant's clear understanding of the nature of the work and eligibility.

Proposals should be submitted in English using a 10 or 12 point font and formatted in Microsoft Word, PDF and/or Excel. Proposals should not exceed 10 pages (annex exceptions noted below).

#	Section	Description	Page limit	FIND RFP Assessment
1	**Executive summary**	Provide a brief summary of the company, the technology platform and any relevant assays for review, and how the company plans to work with FIND.	500 words	Understanding of the project needs.
2	**Product status**	Provide a description of the platform for use based on the requirements (see Section 5.2 of the RFP), including: • Detailed status of the device technology to be used in the program • List of current assays, devices that are on the market and in development • List of relevant clinical data (supporting data provided as annex, which is not included in the 10-page limit) • Detailed country list of placement of devices(s) to date	2	Current performance of technology, including device and assay capacity. Strength of the data.
3	**Work plan and timeline**	Provide a description of the work plan and timeline for the following: • Propose and justify the main activities of the development process, their content and duration, phasing and interrelations • Product development milestones (including interim approvals by FIND and delivery dates for interim and final reports • Work plan for product development; R&D, deliverables, validation • Project timeline chart (provided as annex, which is not included in 10-page limit)	2	Capacity and expertise to provide the services needed.
4	**Project risks**	Identify and briefly describe potential project risks and plans for mitigation.	1	Understanding of the project needs.

5	**Budget**	Provide a detailed budget for the following: • Product development, manufacturing, and validation • Material, reagent, and sample requirements • Self-funded/"in-kind" contributions should be included	2	Company resources and capabilities. Affordability of the technology and project.
6	**Commercialization**	Provide a high-level description of the commercialization strategy of the device, covering manufacturing and distribution aspects for LMICs as well as cost estimates to expand the platform.	1	Business model and commitment to global health. Affordability of technology.
7	**Key personnel**	Provide a list of personnel expected to be involved in the project: • Description of expertise, roles and responsibilities • CVs of key personnel (provided as annex, which is not included in 10 page limit)	1	Capacity and expertise to provide the defined services and products.
8	**Company overview**	Provide a brief description of the company organization, business & operations, and technology available. The description should briefly cover: Company/Organization: • Brief history of the company and key achievements in the context of the project • Total number of employees • Locations of facilities and subsidiaries relevant to the project • Annual financial turnover • Financial statements from the last 3 month (provided as annex, which is not included in 10 page limit) Business & Operations: • Geographic presence • Resources in R&D, manufacturing, and distribution to the project • Outsourced activities related to project • Quality system(s) in place Technology Overview: • Principle of operation • Freedom-to-operate (IP and IP licenses related to the project) • Regulatory status of the product/assay used in the project	1	Company resources and capabilities. Technology maturity and time to market.