

EXPRESSION OF INTEREST (EOI)

FIND IS SEEKING AN IN-VITRO DIAGNOSTIC (IVD) PARTNER TO APPLY TO A HORIZON EUROPE CALL FOR THE TRANSLATION OF A HOST-RESPONSE mRNA SIGNATURE TO A PORTABLE POINT-OF-CARE MOLECULAR DIAGNOSTIC PLATFORM AND ADVANCING THE ASSAY TO MARKET IN LMICs.

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EXECUTIVE SUMMARY

Background	FIND is a global non-profit organisation dedicated to accelerating the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases. Over the past few years, FIND has been involved in accelerating the development and implementation of innovative antimicrobial resistance (AMR) solutions (e.g. diagnostic technologies, digital solutions, AMR data) relevant in the context of antimicrobial stewardship. As part of its strategic priorities, FIND has been focusing on diagnostics that are capable of distinguishing viral or bacterial infections for use at the lower levels of the health systems in low- and middle-income countries (LMICS). Acute febrile illness is among the most common clinical presentations worldwide. In many settings, particularly in LMICs, the lack of access to diagnostics leads to overuse and misuse of antimicrobials which contributes to AMR. A diagnostic assay capable of differentiating between bacterial and viral infections at the point-of-care (POC) represents an important step toward improving patient management and antimicrobial stewardship. A target product profile (TPP) was developed by global health stakeholders defining minimal performance requirements of $\geq 90\%$ sensitivity and $\geq 80\%$ specificity for such tools intended for use in resource-limited settings.¹ The DIAMONDS consortium (https://www.diamonds2020.eu) is an EU Horizon-funded consortium with partners in 12 EU countries, UK, Taiwan, Nepal, Gambia and South Africa. The consortium has identified host blood RNA signatures for diagnosis and monitoring of treatment for a number of globally important infections. DIAMONDS has built on 4 previous EU program grants, which have recruited over 20,000 patients, and undertaken RNA and protein expression analysis on 10,000 patients. RNA signatures comprising 4-20 genes have been identified for distinguishing bacterial and viral infection, predicting severity of illness, and diagnosis of various febrile illnesses, such as tuberculosis, Rheumatic fever, Kawasaki disease, and multiclass distinction of TB/Bacterial and Viral infections and Malaria. The signatures and technologies have reached a stage where translation onto a scalable POC diagnostic platform is required to enable manufacturing and commercialisation in LMICs.
Purpose of partner engagement	FIND, in collaboration with the DIAMONDS consortium, is issuing an EOI to identify potential manufacturing and commercialization partner that have the capacity to integrate this host-response mRNA signature onto their existing POC or near-patient molecular platforms. Identified partners will work with FIND and DIAMONDS members to jointly pursue funding through the HORIZON-HLTH-2027-02-IND-02 “Portable and versatile point-of-care diagnostics” call and to advance the assay to market in LMICs. HORIZON Europe co-funding will support the translation, product optimisation, evidence generation, and manufacturing required to advance the assay toward market entry in LMICs.

¹ <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0161721>

Type of partners & Technologies	FIND is inviting companies with proven experience in multiplex molecular biomarker point-of-care diagnostics, the capacity to manufacture quality-assured diagnostics, and a global sales, marketing, and distribution network in the IVD market, including a commercial presence in LMICs, to submit a proposal for the transfer and commercialisation of the mRNA expression signature. Applicants should possess a near-market-ready or commercially available molecular diagnostic platform with demonstrated feasibility for point-of-care or near-patient use, transcriptomic read-out and a clear pathway to regulatory approval and scalable manufacturing. The successful partner must demonstrate the resources, expertise, and commitment required to bring the product to LMICs markets within the timeframe of the HORIZON project. Applicants must also be willing to commit to an affordable selling price for LMICs, together with other access conditions, to be negotiated as part of the collaboration agreement. For further details, see section “Eligibility criteria”.
Benefits for the applicants	• Potential funding opportunity via HORIZON Europe • Access and commercial license to clinically validated host-response signature • Support for regulatory, market access and policy engagement • Entry into a high-priority AMR diagnostic market
Application deadline	The deadline for receipt of submissions is November 6th 2026, at 23h59 (Geneva time).
Contact	Please email questions to rfp.bi@finddx.org with the subject line: “EOI: DIAMONDS_2026”

SECTION 1: THE PROJECT

1. BACKGROUND

Fever is one of the leading causes of healthcare visits globally. In LMICs, antibiotics are prescribed for up to 75% of children presenting with fever, even though many of these infections are viral². Limited access to diagnostic testing results in the widespread use of empiric antibiotic use, which contributes to AMR. Host-response diagnostics that distinguish bacterial from viral infections have been identified as a high-priority intervention to improve treatment decisions and reduce inappropriate antimicrobial use³. The intended use of the assay is to support clinical decision-making at primary healthcare and community levels where diagnostic access is limited, and the burden of febrile illness is high. Deployment of such a tool is expected to improve patient outcomes, reduce inappropriate antibiotic prescription and support antimicrobial stewardship strategies. As part of this effort, FIND and global health stakeholders published a target product profile describing the features required for a viral vs bacterial test for use in LMICs⁴.

The DIAMONDS consortium (<https://www.diamonds2020.eu>) has discovered and developed a host-response mRNA expression signature that distinguishes bacterial from viral infections using a 12-gene signature. The signature has been translated to RT-PCR technology and validated on over 3000 children presenting to medical care with febrile illness. While the 12-gene signature provides optimal performance, in a multi-ethnic, multi-country study, similar sensitivity and specificity can be achieved with smaller numbers of genes. DIAMONDS has also identified host response signatures that distinguish bacterial and viral infection, tuberculosis, and malaria with less than 20 genes, opening the way to multiclass diagnosis of common febrile illnesses in malaria endemic regions (other examples include the diagnosis of Rheumatic fever and Kawasaki disease). The host-response 12-gene signature has reached an advanced stage of development, and good clinical performances were demonstrated, but further work is required to optimise, industrialise, and integrate the signature onto a scalable, point-of-care or near-patient platform suitable for use in LMICs.

To fill this diagnostics gap, FIND, in collaboration with the DIAMONDS consortium, intends to accelerate the development and market entry for a POC or near-patient affordable, high-performing test for viral and bacterial biomarkers in LMICs. The selected partner will participate as an industrial partner in a consortium submission to HORIZON Europe, support assay translation and optimization, evidence generation, manufacturing and preparation for regulatory approval and market launch.

² <https://pmc.ncbi.nlm.nih.gov/articles/PMC10230568/>,
<https://journals.plos.org/globalpublichealth/article?id=10.1371%2Fjournal.pgph.0002134>
[https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(23\)00232-8/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(23)00232-8/fulltext)

³ <https://academic.oup.com/cid/article/82/2/215/8301044>

⁴ <https://pmc.ncbi.nlm.nih.gov/articles/PMC4999186/>

2. OBJECTIVE AND SCOPE

The primary objective is to translate the host-response mRNA signature onto a commercially available POC or near-patient use, affordable platform and enable use of the test at the lower level of the health system in LMICs.

Specifically, FIND is seeking a partner to:

- Collaborate with FIND and DIAMONDS consortium members to jointly develop and submit a proposal for HORIZON Europe funding (HORIZON-HLTH-2027-02-IND-02)
- Integrate the signature onto an appropriate diagnostic POC or near-patient molecular platform
- Conduct analytical and clinical performance evaluations
- Support scale-up and preparation for regulatory approval and market entry

3. PRODUCT SPECIFICATIONS

The 12-gene signature distinguishing bacterial and viral infection has been validated on 3,900 participants from 11 countries and has been shown to have an area under the curve (AUC) of 91.6%, 87.8% sensitivity and 82.6% specificity.

The final assay is intended to meet key TPP characteristics for bacterial versus non-bacterial differentiation. Below is a set of characteristics that are used as guiding principles. Given the complexity of the project, the consortium will also consider near-patient platform for use at level 2 (district hospital labs).

Characteristic	Acceptable	Desired
Goal	Rapid, biomarker-based testing to differentiate between bacterial and non-bacterial infections to guide antimicrobial treatment	
Target population	Febrile population (including neonates/children) presenting with acute fever at health facilities	Total febrile population (including neonates) presenting with fever.
Target level of health system	Level 1, passive case finding	Level 0
Target user	Healthcare worker	Trained lay person
Price per individual test (ex-works)	The ex-work price of the test and the platform must be transparent and affordable for LMIC markets and comply with access conditions.	
Analytical sensitivity / limit of detection	Limit of detection should be such that it allows clinically relevant performance as defined below.	
Diagnostic sensitivity (bacterial vs non-bacterial differentiation)	≥90%	≥95%
Diagnostic specificity (bacterial vs non-bacterial differentiation)	≥80%	≥90%

Sample type	Capillary blood	
Sample volume	100 ul	25 ul

Kit configuration	No additional reagents outside of the kit required (including gloves)	
Process control	Internal control to provide test validity and acceptance	
Reagent preparation	Minimal of one additional step to prepare prior to use No (precise) measuring required.	No additional reagents required, everything is provided ready-to-use
Equipment	Small, robust, dust-resistant, portable or hand-held integrated instrument that must operate on battery or be compatible with external power banks.	Reusable instrumentation not required
Data interpretation	Minimal interpretation required	No interpretation required

4. OUTLINE OF TERMS OF THE TECHNOLOGY AND COMMERCIALISATION AGREEMENT

Under the collaboration agreement, the DIAMONDS consortium partners will provide access to the host-response signature and the associated supporting data necessary for assay development and validation. Commercial licensing terms (such as a non-exclusive license), including provisions consistent with FIND's/DIAMONDS consortium access principles, will be agreed to ensure equitable, affordable, and sustainable access in LMICs.

5. SUPPORT PROVIDED BY CONSORTIUM PARTNERS

FIND will lead the development of the joint funding proposal for the 2027 Horizon Europe Health Industry call. Actively engaging with WHO, donors, and national programmes to facilitate the adoption and access of the assay. The organization will provide regulatory pathway insights, facilitate access to clinical evaluation networks, and support the generation of evidence needed to inform policy updates and guideline inclusion, ensuring that the product meets both technical and global access objectives. FIND will also provide technical support for tech transfer.

DIAMONDS consortium members will provide specific information on the genes in the RNA signatures, and optimised targets for the RT-PCR assays. They will provide well-characterized samples from DIAMONDS biobank (including samples from both LMIC and Europe) for cross platform validation of each gene and the combined signature on the candidate platform. They will also provide samples from the DIAMONDS biobank for large scale validation of prototype tests on >5000 well-characterized patients with febrile illness. DIAMONDS can also provide access to prospective collection of samples for field evaluation of prototype tests.

6. COMMERCIAL PARTNER COMMITMENT AND INVESTMENT

The selected partner will be expected to use the funding from the 2027 Horizon Europe Health Industry call to invest in platform integration and scale-up manufacturing, conduct performance and clinical studies, obtain regulatory approvals from a mature regulatory authority, ensure adequate manufacturing capacity to meet demand and price requirements of the TPP.

7. TIMELINE

- HORIZON call opens: **10 February 2027.**
- Stage 1 submission: **13 April 2027, 17:00 Brussels time.**
- Stage 2 submission: **22 September 2027, 17:00 Brussels time.**
- Project duration (if funded): Up to **48 months.**

Indicative Project Timeline

Within approximately **36 months** of partner agreement (post-Horizon funding award, ~Q1 2028):

Activity	Duration	Achieved by
Integration & analytical validation	6 months	Month 6
Clinical performance studies	12 months	Month 18
Pilot manufacturing	9 months	Month 9
Regulatory submissions (IVDR/WHO PQ)	12 months	Month 30
GoToMarket strategies and market entry	12 months	Month 36

SECTION 2: INSTRUCTIONS AND PROPOSAL REQUIREMENTS

8. ELIGIBILITY CRITERIA

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

- ✓ **Type of entities:** Company that is the original developer/manufacturer of the POC or near-patient molecular diagnostic platforms (i.e. be in the molecular POC platform business). *Note: Applications from academic teams may also be considered on a case-by-case basis where they can demonstrate a path to market (e.g. assay and platform development under design controls, manufacturing and distribution capacity, partnership with industry).*
- ✓ **Commercial stage:** Mature company with at least one in-vitro diagnostic (IVD) product (platform or assay) being commercially available with active sales, either as RUO or regulatory approved (in the field of molecular POC is a plus but not compulsory).
- ✓ **Technology & Readiness:** The proposed molecular platform must be compatible with point-of-care or near-patient use and must be commercially available or in late-stage development (in V&V phase / TRL 6 and above). Furthermore, the platform must have a proven capacity to provide transcriptomic read-out.
- ✓ **Tech transfer:** The company must demonstrate capacity to integrate/transfer multi-gene mRNA signatures onto a POC molecular platform (track record through a past project is a plus).
- ✓ **Manufacturing capacity:** The company must have a commercial production line. Entities with only small-scale manufacturing lines to support R&D activities are not eligible, unless a clear and committed plan for scale-up is provided.
- ✓ **LMICs markets:** The company must be actively serving a LMICs market or have a clear and committed plan for entering such market within the timeframe of the HORIZON project.

IMPORTANT. Participation beyond this Horizon Europe call: While Horizon Europe eligibility rules may restrict the participation of entities established in or controlled from China in this project, FIND encourages interested Chinese organizations to submit an expression of interest. This will allow FIND to understand relevant capabilities and technologies and, where appropriate, consider potential collaboration under future initiatives not subject to the eligibility requirements of this Horizon Europe call.

9. OUT OF SCOPE

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

- ✗ Distributors
- ✗ Academic teams without a clear path to market
- ✗ Companies without relevant diagnostic experience or not active in the molecular POC business
- ✗ Early-stage companies with longer runway needed to launch on the market their first product

10. SELECTION CONDITIONS

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

- Supply at least the public sector in LMICs (volume and details to be negotiated).
- Commit to undertaking activities that enable product launch (e.g., local registration, service, and distribution activities).
- 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".

11. APPLICATION REQUIREMENTS

To be complete, applications must include the following:

- **Online questionnaire:** Applicants shall fill out and submit the online questionnaire, available here: <https://forms.cloud.microsoft/e/XVanjgVjFn>
- **Mandatory supporting documents - Applicant presentation:** Applicants shall provide a slide deck of **no more than 10 slides** and must use the provided PowerPoint template, available here: https://www.finddx.org/wp-content/uploads/2026/10/EI26-0001_DIAMONDS-mRNA-TT_PPT-Template.pptx
- **Optional supporting documents:** The applicant can provide:
 - A company presentation, covering topics relevant for this EOI.
 - Instructions for use/product insert or user manual for the proposed platform
 - Evidence of work with transcriptomic signature

Name your documents as follows: NAME OF THE COMPANY_NAME OF PLATFORM_DOCUMENT SHORT TITLE

12. HOW TO APPLY

Submit applications by:

1. completing the online questionnaire
2. emailing the mandatory supporting documents to rfp.bi@finddx.org.

An incomplete dossier will not be considered for review.

13. APPLICATION DEADLINE

The deadline for receipt of submissions is **November 6th, 2026, at 23h59 (Geneva time)**.

SECTION 3: SELECTION PROCESS

14. SELECTION PROCESS

The selection process is designed to be objective, independent, and transparent to ensure that the most suitable partner is selected, and potential conflicts of interest avoided. Candidates will be evaluated by an internal review panel comprised of staff at FIND, and whenever needed, by an external review panel comprised of specialists with backgrounds in R&D, manufacturing and commercialization. The review panels will use information submitted in the application (see **Application Requirements**), as well as publicly available information. The review panels may request additional information or clarifications, if needed, in writing.

Applications will be evaluated in stages, as follows:

- **Stage 0: Completeness and eligibility review.** All applicants' eligibility will be verified and those that are "out of scope" or incomplete will be excluded. The list of eligible candidates will advance to Stage 1.
- **Stage 1: Definition of shortlisted candidates.** This evaluation will define the list of shortlisted candidates. A review panel will evaluate the eligible candidates using the submitted application materials (See **Application Requirements**). Candidates will be evaluated on:
 - **Questionnaire**, which provides responses to specific topics pertinent to the EOI.
 - **Applicant presentation**, which provides additional details on the molecular platform and its workflow.
 Shortlisted candidates will be selected in a consensus call of reviewers and will advance to Stage 2. Shortlisted candidates will be asked to complete a self-declaration form sent by the FIND team prior to the stage 2. Additional grounds for exclusion of an application at this stage are detailed in Appendix 3.
- **Stage 2: Definition of the finalist(s).** This second evaluation will define the list of finalist(s). Shortlisted candidates will be evaluated using:
 - **Interviews** (by teleconference): shortlisted candidates will be invited to make a follow-up presentation to address a set of questions provided to the candidates in advance.
 Finalist(s) will be selected in a consensus call of reviewers and will advance to collaboration agreement discussion.
 The assessment may include external expertise. Shortlisting and selection are at FIND's discretion; selection does not by itself constitute a contract, endorsement, purchase order or promise of exclusivity.
 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 the collaboration agreement. 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 EOI and/or donor requirements and restrictions, applicant exclusion at this late stage is still possible. FIND may outsource the DD to an independent third party, following FIND procedures.

Stage 0	Stage 1	Stage 2
<i>Initial screening of all applicants to a set of long-listed candidates</i>	<i>First evaluation to shortlist candidates.</i>	<i>Second evaluation to define a list of finalist(s).</i>
• 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 a review panel. • Candidates will be evaluated based on: 1. Questionnaire 2. Applicant presentation	• Evaluation of the shortlisted candidates after stage 1 will be evaluated based on: 1. Follow-up live presentation

15. SUMMARY OF SELECTION TIMELINE

	Activity	Expected date
1	Publication of RFP	October 14 th 2026
2	Deadline for questions	November 2 nd 2026
3	Application deadline	November 6 th 2026
4	Notification of short-listed candidates (end of Stage 1, tentative timeline)	November 20 th 2026
5	Interview period	November 30 – December 11 2026
6	Notification of finalist(s) (end of Stage 2, tentative timeline)	December 18 th 2026
7	Project planning and collaboration agreement (tentative timeline)	Jan 2027

Dates are indicative and may change. FIND will communicate material changes to respondents.

16. QUESTIONS & FURTHER INFORMATION

Please email questions to rfp.bi@finddx.org with the subject line: “EOI: DIAMONDS_2026”. Questions will be accepted until **November 2nd 2026**. Submitted questions (and corresponding answers) will be publicly available on the [Calls for Partners](#) page.

17. CONFIDENTIALITY

FIND acknowledges that the information received from Applicants under the EOI may be of a confidential nature. “Confidential Information” means non-public information submitted by an Applicant, whether in written, oral, electronic or other form, that is clearly marked or identified as confidential at the time of submission, or that by its nature and the circumstances of disclosure would reasonably be understood to be confidential. Confidential Information does not include information that: (i) is or becomes publicly available; (ii) was already lawfully known to FIND or a Representative or an Authorized Recipient before disclosure; (iii) is lawfully received from a third party without confidentiality restrictions; (iv) is independently developed without use of the Applicant’s Confidential Information; or (v) is required to be disclosed by law, regulation, court order or applicable institutional requirement. Applicants are responsible for clearly identifying any information they consider confidential. Information not so identified may be treated as non-confidential, unless it is clearly confidential by nature.

FIND shall use the same degree of care with Applicant’s confidential information as it uses to protect its own confidential information. If required by Applicant, FIND can sign a separate CDA with interested Applicants prior to proposal submission.

FIND may communicate the Confidential Information to its employees, independent contractors, institutional donors and other financial sponsors, legal, financial, scientific or technical advisors (together “Representatives”) and also to the members of the consortium under which this EOI is conducted (together the “Authorized Recipients”) who:

- (a) need to know such confidential information for reviewing the EOI submissions, and for other related purposes connected with this EOI, and
- (b) bound by terms and conditions substantially similar to those contained in this EOI, including but not limited to confidentiality and non-use restrictions.

Review of proposals will be carried out by an internal FIND team as well as consortium members, evaluation partners and/or a team of external experts (which may or may not include members of FIND’s independent Scientific Advisory Committee). All such reviewers shall be subject to confidentiality obligations and shall be required to disclose any actual, potential or perceived conflict of interest and to recuse themselves where needed.

Confidential information may be shared across jurisdictions as required for the evaluation activities described in this EOI, subject to the safeguards set out above.

The submission of information under this EOI does not restrict the consortium’s ability to publish or share evaluation results in accordance with the terms of this EOI.

Any specific questions concerning confidentiality should be addressed to the FIND team.

18. 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**.

19. COMPLAINTS

Applicants who disagree with any actions or decisions taken in the course of the EOI 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 EOI 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.

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

Appendix 3: Grounds for exclusion

Country of origin is not generally an exclusion criterion, **except** where an international embargo or sanction by the United Nations applies. Furthermore, participation in funded projects is subject to any eligibility requirements, geographic restrictions, sanctions, or other conditions imposed by the relevant donor or granting agency. Organizations that are not eligible for a specific funding opportunity may still express their interest for consideration in other or future FIND initiatives.

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 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.