

Accelerating the development of a point-of-care hematology device adapted to low resource settings

Executive summary

- FIND, the global alliance for diagnostics, is leading a Request for Proposals (RFP) to **accelerate the development of devices capable of 3- or 5-differential white blood cell (WBC) counts** and adapted for use in low- and middle-income countries (LMICs).
- The short-term focus of this RFP is to support triage and referral of **severe patients**, including **COVID-19** patients, in **decentralized settings**
- A long-term goal of this RFP is to increase **access to critical hematology parameters**, such as WBC and hemoglobin, by accelerating the **availability of point-of-care hematology analyzers** in LMICs.
- A budget envelope of **USD\$1.5 million** is available to selected manufacturers to enable development of a device that meets a set of predefined **key product requirements**.
- Suppliers are expected to **commit to supplying an affordable product to the public sector in LMICs** and to submit a dossier for regulatory authorization by the World Health Organization Prequalification Programme.

BACKGROUND

Hematology tests are included in the WHO and national essential diagnostic lists, as key tools to the healthcare systems in Low- and Middle-Income Country (LMIC) settings.^{1,2,3} Currently, however, these tests are generally only available in central laboratories, where high-end instruments capable of high throughput analyses of blood components, such as flow cytometry, can be installed, operated, and serviced. Although smaller point-of-care (POC) hematology analyzers have been commercialized and have the potential to offer quick near-patient screening and guidance on patient management, they are not currently implemented in decentralized healthcare settings (Level 2 and below, included primary healthcare – PHC).

Implementation of such POC hematology devices in level 2 or below could have a major impact in the management of acute febrile illness, such as COVID-19, and other conditions. The on-going COVID pandemic, requiring frequent lockdowns and travel bans, evidences the importance of patient triage and management at the first point of contact. Identification of patients who need referral to a hospital from patients that could be monitored at low-health care levels or at their homes has proved to be key during this pandemic.^{4,5} Total and differential counts of white blood cells (WBC), as well as hemoglobin level measurements, could guide the identification of severe patients for subsequent referral to a hospital, which is key to increase survival rates in COVID-19 severe patients, or support diagnosis of bacterial infection to guide antibiotic therapy.⁶

One of the key challenges to implementation of POC hematology analyzers in decentralized settings is the extreme environmental conditions encountered. Currently, products in the market, have not been designed to withstand challenging transport and operating conditions, including high temperatures, dust, lack of continuous power supply, and low equipment maintenance.^{7,8} In order to support access and broaden the reach of hematology analyzers at first point of contact globally, **FIND is seeking to accelerate the development of devices capable of 3- or 5-differential WBC counts and adapted to low level healthcare settings in LMICs.**

OBJECTIVE AND SCOPE

FIND aims to **accelerate the development, manufacturing, and launch of point-of-care hematology device** for use in LMICs. The main areas of focus for this RFP are:

- ✓ Develop a small, robust, easy-to-use and low-maintenance POC device for 3- or 5-part WBC counting, ideally including hemoglobin and platelets measurements
- ✓ Suitability of the platform for use in decentralized healthcare facilities in LMICs (Level 1 and Level 2), with a specific focus on high operating temperature, ruggedness, and extended assay shelf-life
- ✓ Sample-to-answer systems that can be operated with minimal user training
- ✓ Affordability by LMICs, with a target production COGS for the assay and instrument of less than \$5 and \$2,000, respectively

FIND seeks platforms that closely meet the key product requirements listed in the “**Technical Assessment**” sheet within the **Assessment Matrix** (see **HOW TO APPLY** below for forms and templates). We encourage all applicants to review these target product requirements.

Lastly, preference will be given to applicants with interest in expanding manufacturing capacity in LMICs and platforms that are flexible for further customization and expansion of the menu.

FIND will support pre-market activities for platforms that are in late-stage development and/or commercialized with the goal of dossier submission to regulatory authorities by December 2022, with the aim of enabling market introduction across several LMICs from early 2023. Supported pre-market activities will vary according to the needs of each applicant and may include, but are not limited to:

- Late-stage assay development of platform/device, software, or assay, verification of performance.
- Modification of an assay or instrument to meet critical design specifications (weighted as ‘3’ in column H of the Technical Assessment)
- Validation of system performance in key LMIC markets (e.g. RUO studies, usability studies).
- Support for in-country registration, and/or clinical studies/trials.

FIND will not support market access and post-launch activities (e.g. shipping logistics, procurement, implementation, user training, distributor qualification, post-market surveillance).

In parallel to the activities in this RFP, **FIND can decide to engage in market assessment activities to estimate the demand in the relevant market segments for specific hematology parameters**, and to understand the clinical use of such a device. This information will guide further refinement of final product design specifications. Specifically, FIND’s market research should enable the definition of specific operating conditions, parameters menu and other specifications that are relevant to as many high-priority LMICs as possible.

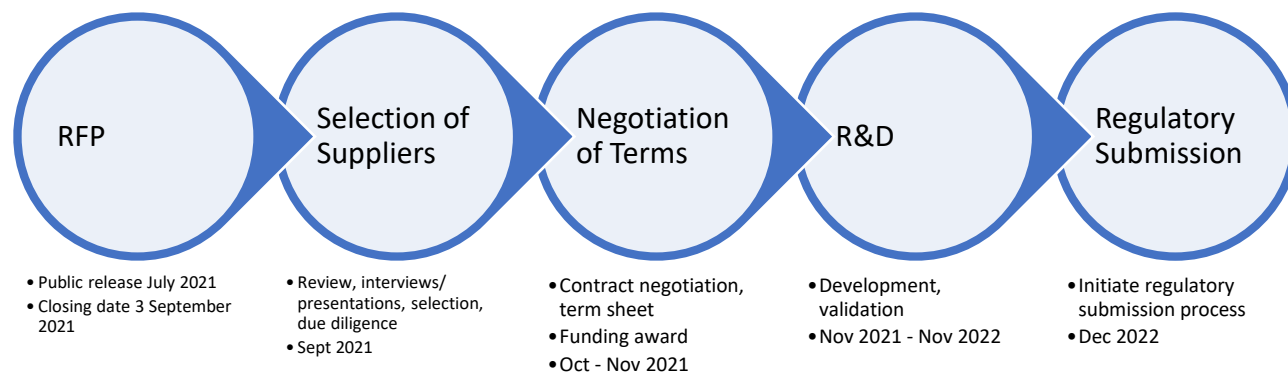
Importantly, the market assessment information generated by FIND in parallel to this RFP may also be used at a later date to secure volume commitments and negotiate pricing in preparation for market introduction of assays and platforms developed through this RFP.

TIMELINE

The expectation is that this RFP will enable manufacturers to submit a dossier to regulatory authorities by the end of Q4 2022. **Priority will be given to applicants who demonstrate a high likelihood to reach validation stage by Q3 2022.** The anticipated timeline for this initiative is as follows (may vary depending on applicant):

1. Selection of suppliers (1 months)
2. Negotiation of terms and financing (2 months)
3. R&D activities and/or clinical validations (12 months)

Timeline



Note that for those suppliers ultimately selected for an award, costs incurred during the negotiation period will be allowable, enabling work under this RFP to begin as early as 1 October 2021.

FUNDING AWARDS

Funding for the RFP is provided through FIND from a donor grant; a **budget envelope of US\$1.5 million will be available to support 1-3 applicants**. Funding negotiations will be conducted independently and confidentially for each proposal; the form and amount of the award will be tailored to the application. Further, FIND can facilitate connections and networking opportunities with a broad ecosystem of partners, working towards support for product procurement, implementation, and scale-up.

Applicants may be public or private entities, institutions, or organizations. Applicants may also be a group or collaboration of public and/or private entities. A single lead entity shall be designated and shall assume responsibility of the application and of negotiations with FIND. Formal written authorizations from partners will only be required of applicants invited to full contract development. FIND reserves the right to request additional information confirming the validity of specific collaboration agreements, i.e., that specific and appropriate contractual agreements either exist or can be established between partners.

AWARD CONDITIONS

For this RFP, applicants who are selected for final awards 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 to LMICs (i.e., COGS-based pricing).
- Commit to and follow [FIND Global Access Policy](#) and [FIND Code of Conduct and Ethics](#)
- See **Appendix 2** for additional information on "Grounds for Exclusion".
- Accept the Terms and Conditions of KfW Declaration of Undertaking (**Appendix 3**).

SELECTION AND AWARD PROCESS

The deadline for receipt of submissions is 3 September 2021. A commitment to a compressed timescale is required, and we anticipate funding awards and contract execution within 2 months. 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 are 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 global experts with backgrounds in technical R&D, product launch, and implementation. The review panels will use information submitted in the application (see **Application Requirements** section 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 (see Table below):

- **Stage 0.** All applicants' eligibility will be verified and those that are "out of scope" will be excluded. Out of scope applications may include, but are not limited to, organizations with no quality management processes in place, or early-stage platforms with little/no verification or performance data (at a minimum, platform should be at Technology Readiness Level 6 (TRL 6)⁹). Additional grounds for exclusion of an application at this Stage 0 are detailed in **Appendix 2**. Finally, applicants should review **Appendix 3** and verify that they will be eligible to sign at the time of contract execution (please note that Appendix 3 is only provided at this time for informational purposes; signing is not requested at the time of application). A long 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 to 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:
 - o Existing product specifications, scored in the sheet titled "**Technical Assessment**" in the **Assessment Matrix**.
 - o Organizational criteria, scored in the sheet titled "**Business Assessment**" in the **Assessment Matrix**.
 - o **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 Technical Assessment (25%), Business Assessment (25%), 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:
 - o **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.
 - o Applicant Presentation, which details specific topics described in the Application Requirements.
 - o Scores from the Technical Assessment and 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. Finalists will be selected in a consensus call of reviewers and will advance to contract negotiation. Final funding awards and contract execution is expected to be completed by November 2021. Note: Applicants not selected will be notified; however, the details regarding non-selection will not be provided for every applicant.

- **Due diligence:** Given the tight timelines for this RFP, 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
<i>Initial screening of all applicants to a set of long-listed candidates</i>	<i>First evaluation to downselect long-listed candidates to short-listed candidates (up to 10)</i>	<i>Second evaluation to downselect short-listed candidates to a list of finalists</i>
<ul style="list-style-type: none"> • Verification that the contents of the application are in-scope. Applicants that are “out of scope” will be excluded. • Verification of applicant eligibility. Applicants that are not eligible will be excluded. 	<ul style="list-style-type: none"> • Evaluation of long-listed candidates will be performed by an internal review panel. • Candidates will be evaluated based on: <ol style="list-style-type: none"> 1. Score on the “Technical Assessment” within the Assessment Matrix 2. Score on the “Business Assessment” within the Assessment Matrix 3. Applicant Presentation • The internal review panel will score the candidate’s overall alignment with the goals of the RFP (see sheet titled “Alignment Criteria” within the Assessment Matrix). 	<ul style="list-style-type: none"> • Evaluation of short-listed candidates will be performed by an external review panel. • Candidates will be evaluated based on: <ol style="list-style-type: none"> 1. Scores on the “Technical Assessment” and “Business Assessment” completed in Stage 1. 2. Applicant Presentation 3. Follow-up questions and Live Presentation • The 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 20 slides** that must include the following information, and must use the provided PowerPoint template (see **HOW TO APPLY** for templates and forms):
 - Overview of the platform and assay.
 - Current performance of the system: evidence of the system performance, including but not limited to any existing verification and/or validation studies demonstrating performance (published or internal).
 - Alignment with Product Requirements. Provide evidence to support performance claims, particularly for requirements denoted with a Weight of ‘3’ in the sheet titled “Technical Assessment” in the **Assessment Matrix**.
 - Roadmap, including current stage of development and proposed activities to meet the design requirements, where the existing specification does not meet either the Optimal or Acceptable specification (in sheet titled “Technical Assessment” in the **Assessment Matrix**).
 - Description and timeline of activities proposed under this award. Please also include estimated funding need, and other support required to meet product requirements and/or pricing and supply in LMICs.
 - Proposed pricing model: describe a COGS-based pricing model and expected business model. Include the pricing structure, indicating the expected cost of manufacture, markup, royalties, expected distributor margin, and budget for service & maintenance. See **Appendix 1** for additional considerations.
 - Commercialization plan for select LMICs (including service and distribution plans, if applicable). Indicate where additional funding or assistance, beyond this award, may be required from FIND or global partners.
 - Organizational strength: Evidence of institutional commitment and/or track record of the organization or key personnel with experience in hematology analyzers, in vitro diagnostics (IVD), and/or LMIC markets.

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:
 - Technical Assessment

- Please describe the system’s **existing** Design Specifications (column D), and provide supporting evidence and/or data (column E) to support the claims in column D.
 - If the Existing Specification does not fall within the Acceptable and Optimal Specifications, please use the Applicant Presentation to briefly describe the plan or expected activities required to modify the existing specification into a proposed acceptable specification.
- 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 2 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’s [Technology Scouting Submission Webform](#). Please, select ‘**Hematology**’ as the ‘Disease Area’ and ‘**RFP: POC hematology device**’ 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 **3 September 2021**.

FIND intends to use the information on technologies submitted in response to this RFP to update the community’s understanding of the POC Hematology pipeline. All tests submitted to this RFP will automatically be included in the Hematology technologies pipeline tracker which may be published on FIND’s website. If you do not want your product to be included, please mention it in the application or at poc_hematology_rfp@finddx.org.

QUESTIONS & FURTHER INFORMATION

Please email questions to: poc_hematology_rfp@finddx.org. Questions will be accepted and responded to expediently until 27 August 2021. Submitted questions (and corresponding answers) will be publicly available at: <https://www.finddx.org/poc-hematology-qa/>.

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 4**.

COMPLAINTS

Applicants who consider that actions or decisions taken in the course of the RfP result in an unfair dis/advantage may file a related complaint. Such a complaint shall be addressed in writing to FIND (at poc_hematology_rfp@finddx.org), detailing the grounds for the complaint and making reference to the applicable provisions in the RfP or other applicable 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 with results of the complaint handling within ten (10) working days thereafter.

Appendix 1: 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 also remain 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 2: 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, the European Union or the German Government applies.

Applicants/Bidders shall not be awarded 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 3: Declaration of Undertaking

Accelerating the development of a point-of-care hematology device adapted to low resource settings (the "Contract")

1. We recognize and accept that KfW only finances projects of the Foundation for Innovative New Diagnostics ("FIND") subject to its own conditions, which are set out in the Funding Agreement it has entered with FIND. As a matter of consequence, no legal relationship exists between KfW and our company, our Joint Venture¹ or our Subcontractors under the Contract. FIND retains exclusive responsibility for the preparation and implementation of the RFP and the performance of the Contract.
2. We hereby certify that neither we nor any of our board members or legal representatives nor any other member of our Joint Venture, including Subcontractors under the Contract, are in any of the following situations:
 - 2.1) being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganization or being in any analogous situation;
 - 2.2) convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union 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;
 - 2.3) having been convicted by a final court decision or a final administrative decision by a court, the European Union, national authorities in Switzerland or in Germany for Sanctionable Practice in connection with a Tender Process or the performance of a Contract or for an irregularity affecting the EU's financial interests (*in the event of such a conviction, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this conviction is not relevant in the context of this Contract and that adequate compliance measures have been taken in response*);
 - 2.4) having been subject, within the past five years to a contract termination fully settled against us for significant or persistent failure to comply with our contractual obligations during such Contract performance, unless this termination was challenged, and dispute resolution is still pending or has not confirmed a full settlement against us;
 - 2.5) not having fulfilled applicable fiscal obligations regarding payments of taxes either in the country where we are constituted or in Switzerland;
 - 2.6) being subject to an exclusion decision of the World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank (*in the event of such exclusion, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this exclusion is not relevant in the context of this Contract and that adequate compliance measures have been taken in reaction*); or
 - 2.7) being guilty of misrepresentation in supplying the information required as a condition to participation in this Request for Proposals (RFP).
3. We hereby certify that neither we, nor any of the members of our Joint Venture or any of our Subcontractors under the Contract are in any of the following situations of conflict of interest:
 - 3.1) being an affiliate controlled by FIND or a shareholder controlling FIND, unless the stemming conflict of interest has been brought to the attention of KfW and resolved to its satisfaction;
 - 3.2) having a business or family relationship with FIND's staff involved in the RFP or the supervision of the resulting Contract, unless the stemming conflict of interest has been brought to the attention of KfW and resolved to its satisfaction;
 - 3.3) being controlled by or controlling another Applicant or Bidder, or being under common control with another Applicant or Bidder, or receiving from or granting subsidies directly or indirectly to another Applicant or Bidder, having the same legal representative as another Applicant or Bidder, maintaining direct or indirect contact with another Applicant or Bidder which allows us to have or give access to information contained in the respective Applications or Offers, influencing them or influencing the decisions of FIND;
 - 3.4) being engaged in a Consulting Services activity, which, by its nature, may be in conflict with the assignments that we would carry out for FIND;
 - 3.5) in the case of procurement of Works, Plant or Goods:
 - i. having prepared or having been associated with a Person who prepared specifications, drawings, calculations and other documentation to be used in the Tender Process of this Contract;
 - ii. having been recruited (or being proposed to be recruited) ourselves or any of our affiliates, to carry out works

¹ In the context of this "Declaration of Undertaking", Joint Venture is given to mean collaboration between parties. For clarity, it is not intended in the common contractual sense where two parties share assets and benefits, in addition to risks, in a defined business venture.

supervision or inspection for this Contract.

4. If we are a state-owned entity, and compete in a Tender Process, we certify that we have legal and financial autonomy and that we operate under commercial laws and regulations.
5. We undertake to bring to the attention of FIND, which will inform KfW, of any change in the situation with regard to points 2 to 4 above.
6. In the context of the RFP and performance of the corresponding Contract:
 - 6.1) neither we nor any of the members of our Joint Venture, nor any of our Subcontractors under the Contract, have engaged or will engage in any sanctionable practice during the RFP process and, in the case of being awarded a Contract, will not engage in any sanctionable practice during the performance of the Contract;
 - 6.2) neither we nor any of the members of our Joint Venture or any of our Subcontractors under the Contract shall acquire or supply any equipment nor operate in any sectors under an embargo of the United Nations, the European Union or Germany; and
 - 6.3) we commit ourselves to complying with and ensuring that our Subcontractors and major suppliers under the Contract comply with international environmental and labour standards, consistent with laws and regulations applicable in the country of implementation of the Contract and the fundamental conventions of the International Labour Organization² (ILO) and international environmental treaties. Moreover, we shall implement environmental and social risks mitigation measures when specified in the relevant environmental and social management plans or other similar documents provided by FIND and, in any case, implement measures to prevent sexual exploitation and abuse and gender-based violence.In the case of being awarded a Contract, we, as well as all members of our Joint Venture partners and Subcontractors under the Contract, will (i) upon request, provide information relating to the RFP application and the performance of the Contract, and (ii) permit FIND and KfW or an auditor appointed by either or both of them, and in the case of financing by the European Union also to European institutions having competence under European Union laws, to inspect the respective accounts, records and documents, to permit on the spot checks and to ensure access to sites and the respective project.
7. In the case of being awarded a Contract, we, as well as all our Joint Venture partners and Subcontractors under the Contract, undertake to preserve the above-mentioned records and documents in accordance with applicable laws, but in any case, for at least six years from the date of fulfillment or termination of the Contract. Our financial transactions and financial statements shall be subject to auditing procedures in accordance with applicable laws. Furthermore, we accept that all data (including personal data) generated in connection with the preparation and implementation of the RFP and the performance of the Contract are stored and processed according to the applicable law by FIND and KfW.

Name: _____ In the capacity of: _____

Duly empowered to sign in the name and on behalf of ³: _____

Signature: _____ Dated: _____

² In case ILO conventions have not been fully ratified or implemented in the Employer's country, the Applicant/Bidder/Contractor shall, to the satisfaction of the Employer and KfW, propose and implement appropriate measures in the spirit of the said ILO conventions with respect to a) worker grievances on working conditions and terms of employment, b) child labour, c) forced labour, d) worker's organizations and e) non-discrimination.

³ In the case of a Joint Venture, insert the name of the JV. The person who will sign the application, bid or proposal on behalf of the Applicant/Bidder shall attach a power of attorney from the Applicant/Bidder.

Appendix 4: Access & related Terms & Conditions for the public sector & LMICs

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 each agreement.

1. SOME KEY DEFINITIONS

“Manufacturing Cost of Goods Sold” or “COGS”	means all of the direct costs such as labor, material, and allocated overhead costs in Product <i>production</i> ;
“COVID-19”	means the coronavirus disease caused by SARS-COV-2, declared by the World Health Organisation on 30 th January 2020 as a Public Health Emergency of International Concern;
“Ex Works” or “EXW”	Shall have the meaning under INCOTERMS 2020 and shall be based on XYZ COGS;
“Eligible Purchasers”	means 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”	shall have the meaning as set out under the Article [●].
“Intellectual Property” or “IP”	means patents, rights to inventions, copyright and related rights, moral rights, trade marks, 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” <i>(if applicable)</i>	Means that licence as further set out under the Article [●];
“LMICs” or the “Territory”	means 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” <i>(if applicable)</i>	means 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”	shall have the meaning set forth under the Article [●];
“Product”	means the XYZ assay for the POC Hematology device and the materials provided with the Product as explicitly listed in the associated instructions for use, and all subsequent versions, and subsequent assays to be mutually agreed and documented as an amendment to this Agreement;
“Private Health Sector”	means 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”	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;
“Stringent Regulatory Authority” or “SRA”	Means that definition given by WHO under the url; https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs , as may be updated from time to time;
“Technology Transfer” <i>(if applicable)</i>	means 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>	Means 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”	means that desired ‘profile’ or 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”	means 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, which ever 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 to review 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 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 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 SARS-CoV-2 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-sublicenseable (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.

As the principal funding partner under this Agreement, FIND reserves the right to participate in the licence negotiations between XYZ and ABC. The final Licence Agreement will fully reflect and incorporate the terms for such Licence as set out in this Agreement. XYZ will provide to FIND copies of such final Licence Agreement prior to execution, for FIND’s review and comments and final acceptance, and a final copy of the fully executed agreement for its records.

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 againsts “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 final 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

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2. India National Essential Diagnostics List. 2019
3. World Health Organization. The selection and use of essential in vitro diagnostics. 2021
4. Rawaf et al. Lessons on the COVID-19 pandemic, for and by primary care professionals worldwide. *European Journal of General Practice*. 2020
5. World Health Organization. Operational considerations for case management of COVID-19 in health facility and community. 2020
6. Fernandez-Carballo BL et al. Distinguishing bacterial versus non-bacterial causes of febrile illness –a systematic review of host biomarkers. *Journal of infection*. 2020
7. Obeidi N et al. Evaluation of the effect of temperature and time of incubation on complete blood count (CBC) tests. *African Journal of Biotechnology*. 2012
8. Kaur A et al. Effect of temperature fluctuation and transport time on complete blood count parameters. *American journal of clinical pathology*. 2019.
9. <https://tier7.us/biomedical-dod-trls-medical-devices/>