

## Request for Proposals

# Increasing the temperature stability of COVID-19 and other febrile illnesses rapid tests

### Executive summary

FIND, the global alliance for diagnostics, is leading a Request for Proposals (RFP) to support **the extension of the temperature and humidity stability range on several rapid tests for COVID-19 antigen as well as other febrile illnesses** thus enabling triaging and differential diagnosis in locations with no air conditioning.

- The short-term focus of this RFP is to extend the storage and in-use temperature and humidity range indicated on the rapid test's package and instructions of use. This should be achieved for a bundle of tests comprising of at least one COVID-19 antigen test as well as other tests used for differential diagnosis of febrile illnesses (dengue, typhoid, C-reactive protein, Zika, influenza, etc.) or that identify co-morbidities (e.g. HbA1c).
- A long-term goal of this RFP is to establish the temperature range at 30°C–40°C and the humidity range at 70–90% as a requirement for in vitro diagnostic (IVD) products to enable unrestricted use outside of climate-controlled facilities, particularly in limited resource settings.
- A budget envelope of **US\$1.2 million** is available to selected manufacturers to support R&D expenses and device re-validation studies.
- Suppliers are expected to **commit to supplying an affordable product to the public sector in low- and middle-income countries (LMICs)** and to submit a dossier for regulatory authorization at the end of the program.

## BACKGROUND

Products intended for implementation in health systems in much of the world must be able to withstand high temperatures and humidity when stored and used in laboratories or healthcare facilities. This is due to the harsh conditions during transport or in the intended use setting (fig 1), especially at lower healthcare levels. Despite the clear need for global access, very few diagnostic products, which are assumed to be used at lower-level health facilities (e.g. primary health care), do in fact meet the criteria in the instructions for use (IFU).

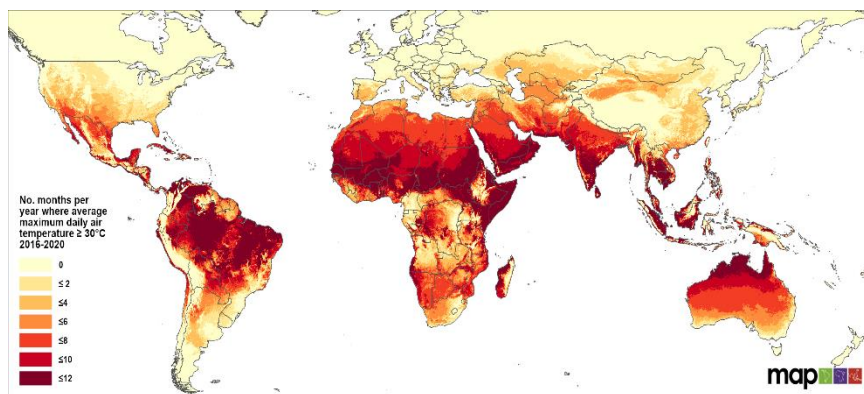


Figure 1: Map showing the number of months/year in which the temperature exceeds 30°C. Source: Malaria Atlas Project.

The ongoing COVID pandemic has underscored the importance of febrile patient management at the first point-of-contact, independent of the health care level. Early identification of COVID-19 positive patients as well as differential diagnosis of COVID-19-negative patients, has proved to be crucial during this pandemic.<sup>1,2</sup>

While all malaria RDTs are required to have higher temperature/humidity stability<sup>3</sup>, most non-malarial rapid diagnostic tools do not permit use and/or storage at temperatures above 30°C, thus limiting their use outside of climate-controlled settings. This includes not only COVID-19 antigen RDTs but also other tests for diseases prevalent in tropical or subtropical areas that are needed for differential diagnosis or identification of comorbidities.

To support and enable access to a wide range of tests to manage febrile illnesses, **FIND is seeking to advance R&D in this field and ensure a variety of relevant tests are available and can be used outside of climate-controlled settings** to allow COVID-19 detection and differential diagnosis.

## OBJECTIVE AND SCOPE

With this RFP, FIND aims to **support the extension of the temperature and humidity stability range on rapid tests for febrile illnesses.**

The focus of this RFP is:

- ✓ To extend the storage and in-use temperature and humidity range indicated in the rapid tests package inserts and the instructions of use for a bundle of tests comprising COVID-19 antigen tests and tests for other febrile or respiratory illnesses like dengue, Zika, typhoid, influenza etc. (see Appendix 1 for a non-comprehensive list of in-scope tests)
- ✓ To extend the sample stability for samples requiring additional sample preparation (if applicable)
- ✓ To extend the transport temperature and humidity range (if applicable)
- ✓ To support stability studies in line with current industry guidelines (e.g. CLSI guideline EP25-A) in order to support labelling changes with respect to shelf-life and in-use stability at temperatures  $\geq 35^{\circ}\text{C}$  and humidity  $\geq 70\%$  (in-house or out-sourced)
- ✓ To support the compilation of an updated technical file – ideally compliant with IVDR regulations (see <https://euivdr.com/>) to be submitted to regulatory authorities

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

**FIND will support temperature, humidity and/or sample stability studies (as relevant) for commercialized tests and late-stage development tests (plus related accessories) with the goal of dossier submission to regulatory authorities by December 2022.** Supported activities will vary according to the needs of each applicant and may include, but are not limited to:

- Assay development/adaptation to enable equivalence of performance across the temperature and humidity range
- Extension of sample stability for tests requiring additional sample preparation (e.g. COVID-19 tests)
- Verification and validation studies and clinical performance assessment at  $\geq 35^{\circ}\text{C}$  and  $\geq 70\%$  humidity
- Support for in-country registration, and/or clinical studies/trials
- Quality and regulatory activities related to instructions for use (IFU) modifications

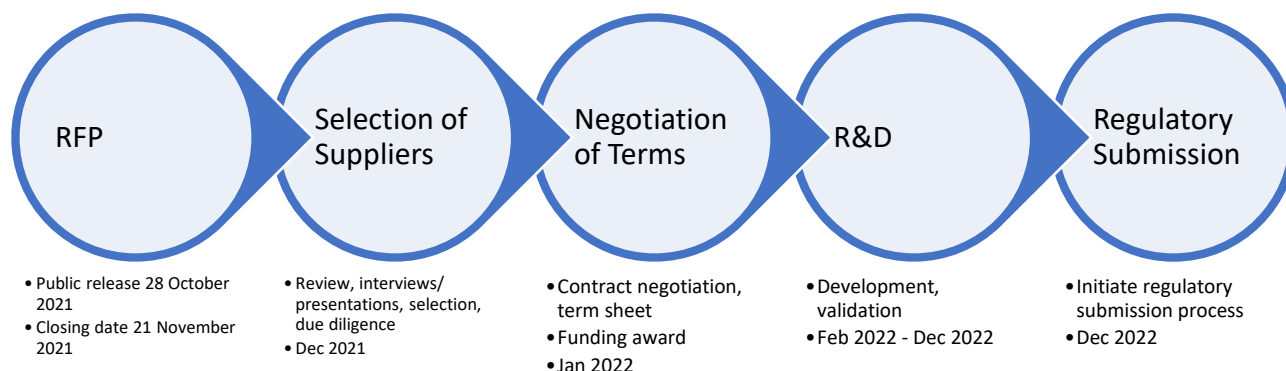
**FIND will not support** market access and post-launch activities (e.g. shipping logistics, procurement, implementation, user training, distributor qualification, post-market surveillance).

## 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 Q4 2022 for at least one test but preferably for a bundle of tests.** The anticipated timeline for this initiative is as follows (may vary depending on applicant):

1. Selection of companies and tests (1 month)
2. Negotiation of terms and financing (1 month)
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 allowed, enabling work under this RFP to begin as early as 1 January 2022.

## FUNDING AWARDS

Funding for the RFP is provided through FIND from a donor grant; a **budget envelope of US\$1.2 million will be available to support 1–5 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. For the latter, a single lead entity shall be designated to assume responsibility of the application and 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 change of the operating and/or storage conditions, to update product launch (e.g. local registration, service, and distribution activities), and to supply to the public sector in LMICs.
- Commit to undertake activities that enable change of the sample stability in transport media or buffers, to update product launch (e.g. local registration, service, and distribution activities), and to supply to the public sector in LMICs (if applicable).
- Commit to clearly state operating and/or storage temperature and humidity claims in the IFU
- Commit to submit a dossier for regulatory authorization
- Commit to and follow [FIND Global Access Policy](#) and [FIND Code of Conduct and Ethics](#)
- Accept the Terms and Conditions of KfW Declaration of Undertaking (**Appendix 3**) since the project is being funded by KfW.

## SELECTION AND AWARD PROCESS

**The deadline for receipt of submissions is 10 December 2021.** A commitment to a tight timescale is necessary, 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 tests 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 staff 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** 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 and mid-stage platforms with little/no verification or performance data (at a minimum, platform should be at Technology Readiness Level 7 (TRL 7)<sup>9</sup>). Additional grounds for exclusion of an application at this stage 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 information purposes; signing is not requested at the time of application). A longlist of eligible candidates will advance to Stage 1.
- **Stage 1.** This first evaluation will downselect the longlist of candidates to a shortlist of up to 10 candidates. An internal review panel will evaluate longlisted candidates using the submitted application materials (see **Application Requirements**). More specifically, candidates will be evaluated on:
  - o Existing product specifications scored under "**Technical Assessment**" in the **Assessment Matrix**.
  - o Organizational criteria scored under "**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 "**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%). Shortlisted candidates will be selected during a consensus call of reviewers and will advance to Stage 2.

- **Stage 2.** This second evaluation will downselect shortlisted candidates to a list of finalists. Candidates will be evaluated using:
  - o **Follow-up presentation** (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.
  - 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 "**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 during a consensus call of reviewers and will advance to contract negotiation. Final funding awards and contract execution is expected to be completed by January **2022**. 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 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 longlisted candidates</i>	<i>First evaluation to downselect longlisted candidates to short-listed candidates (up to 10)</i>	<i>Second evaluation to downselect shortlisted candidates to a list of finalists</i>
<ul style="list-style-type: none"> <li>• Verification that the contents of the application are in-scope. Applicants that are “out of scope” will be excluded.</li> <li>• Verification of applicant eligibility. Applicants that are not eligible will be excluded.</li> </ul>	<ul style="list-style-type: none"> <li>• Evaluation of long-listed candidates will be performed by an internal review panel.</li> <li>• Candidates will be evaluated based on:               <ol style="list-style-type: none"> <li>1. Score on the “Technical Assessment” within the Assessment Matrix</li> <li>2. Score on the “Business Assessment” within the Assessment Matrix</li> <li>3. Applicant presentation</li> </ol> </li> <li>• The internal review panel will score the candidate’s overall alignment with the goals of the RFP (see “Alignment Criteria” in the Assessment Matrix).</li> </ul>	<ul style="list-style-type: none"> <li>• Evaluation of short-listed candidates will be performed by an external review panel.</li> <li>• Candidates will be evaluated based on:               <ol style="list-style-type: none"> <li>1. Scores on the “Technical Assessment” and “Business Assessment” completed in Stage 1.</li> <li>2. Applicant presentation</li> <li>3. Follow-up questions and presentation via teleconference</li> </ol> </li> <li>• The external review panel will score the candidate’s overall alignment with the goals of the RFP (see “Alignment Criteria” in the Assessment Matrix).</li> </ul>

## APPLICATION REQUIREMENTS

Applications should include the following:

### 1. Applicant presentation

- Applicants must provide a slide deck of **no more than 20 slides** – using the PowerPoint template provided – with the following information (see **HOW TO APPLY**):
  - Overview of the portfolio of tests targeted
  - Current performance of the test: evidence of the test performance, including but not limited to any existing verification and/or validation studies demonstrating performance (published or internal)
  - Alignment with product requirements: evidence to support claims, particularly for requirements denoted with a Weight of ‘3’ in under “Technical Assessment” in the **Assessment Matrix**
  - Roadmap, including proposed activities to meet the design requirements, where the existing specification does not meet either the Optimal or Acceptable requirements (see “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
  - Commercialization plan for selected 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 IVD, and/or LMIC markets

### 2. Assessment Matrix

- Applicants are to complete indicated sections of the Assessment Matrix spreadsheet (see **HOW TO APPLY** for templates and forms), specifically:
  - Technical Assessment
    - Please describe the system’s **existing** design specifications (column D), and provide evidence and/or data (column E) to support the claims in column D

- If the existing specifications do not fall within the Acceptable and Optimal test performance characteristics of this RFP, please use the Applicant presentation to briefly describe the intended or expected activities planned for modifying the existing specifications
- 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 (Application presentation and Assessment Matrix) listed above, the only additional documents for submission are: instructions for use/product inserts for relevant products, registration/regulatory certificates, QMS/ISO certificates, and CVs from relevant team members and management.
- There will not be any 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 'Fever' as the 'Disease Area' and 'RFP: Extended storage and in-use tests conditions' 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 10 **December 2021**.

## QUESTIONS & FURTHER INFORMATION

Please email questions to: [rfp\\_temp\\_stability@finddx.org](mailto:rfp_temp_stability@finddx.org). Questions will be accepted and responded to expediently until 8 October 2021. Submitted questions (and corresponding answers) will be publicly available at: <https://www.finddx.org/temp-stability-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 advantage or disadvantage may file a complaint in writing to FIND (at [rfp\\_temp\\_stability@finddx.org](mailto:rfp_temp_stability@finddx.org)), detailing the grounds for the complaint and making reference to the applicable provisions in the RFP or other source. 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.

## REFERENCES

1. Rawaf et al. Lessons on the COVID-19 pandemic, for and by primary care professionals worldwide. European Journal of General Practice. 2020
2. World Health Organization. Operational considerations for case management of COVID-19 in health facility and community. 2020
3. World Health Organization. Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment: Malaria rapid diagnostic tests. 2017



## Appendix 1: In-scope tests, technologies, and accessories\*

<b>Pathogens</b>	<b>Host markers</b>	<b>Technologies/Accessories</b>
SARS-CoV-2	HbA1c	Lateral flow assay (strip, cartridge)
Influenza A/B	D-dimer	Other rapid tests
Strep A	Procalcitonin	POC RDT reader
S. pneumonia	C-Reactive Protein	Reagents and buffers
RSV		
Dengue		
Malaria		
Leptospira		
Filariasis		
Zika		
Chikungunya		
O. tsutsugamushi		
Yellow Fever		
Hepatitis B / C		
HIV		
Typhoid		
Syphilis		

\*The list is not comprehensive and aims to mainly include tests for febrile or respiratory illnesses

## 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

### **Increasing the temperature stability of COVID-19 and other febrile illnesses rapid tests (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 Venture<sup>1</sup> 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;

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<sup>1</sup> 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.

- 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 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 Organization<sup>2</sup> (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<sup>3</sup>: \_\_\_\_\_

Signature:

Dated:

<sup>2</sup> 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.

<sup>3</sup> 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

This is 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

<b>“Manufacturing Cost of Goods Sold” or “COGS”</b>	all of the direct costs such as labour, material, and allocated overhead costs in Product <i>production</i> ;
<b>“COVID-19”</b>	coronavirus disease caused by SARS-COV-2, declared by the World Health Organization (WHO) on 30 January 2020 as a Public Health Emergency of International Concern;
<b>“Ex Works” or “EXW”</b>	defined under INCOTERMS 2020 and based on XYZ COGS;
<b>“Eligible Purchasers”</b>	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;
<b>“Global Access”</b>	definition as set out under Article [●];
<b>“Intellectual Property” or “IP”</b>	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 IP may be encompassed in part or in whole under the deliverables and/or Product;
<b>“Know-how”</b>	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;
<b>“Licence Agreement” or “Licence” (if applicable)</b>	licence as further set out under Article [●];
<b>“LMICs” or the “Territory”</b>	countries defined by the World Bank as having “low-income economies”, “lower middle-income economies” or “upper middle-income economies”, and may be amended from time to time;
<b>“Manufacturer of Record” (if applicable)</b>	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;
<b>“Priority Countries”</b>	definition set forth under Article [●];
<b>“Product”</b>	the XYZ assay 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;
<b>“Private Health Sector”</b>	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;
<b>“Public Health Sector” or “PHS”</b>	(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, WHO, UNICEF, Save the Children Fund, and Médecins Sans Frontières;
<b>“Stringent Regulatory Authority” or “SRA”</b>	definition given by WHO ( <a href="https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs">https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs</a> ), and may be updated from time to time;
<b>“Technology Transfer”</b> <i>(if applicable)</i>	activities required to successfully transfer and validate such transfer of required manufacturing processes, procedures, and Know-how, to a Manufacturer of Record;
<b>“Technology Licence” or “Licence”</b> <i>(if applicable)</i>	the licence to use ABC IP and Know-how required to commercialize a Product, and as further set out under Article [●];
<b>“Target Product Profile” or “TPP”</b>	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 Article [●] to this Agreement;
<b>“Test Unit”</b>	the specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen;

## 2. QUALITY REQUIREMENTS *(if applicable)*

Quality Management Systems (“QMS”). XYZ shall ensure compliance at all times with the following;

- a) Ensure an appropriate QMS covering *in vitro* diagnostic products, is in place and compliant with SRA and/or WHO Pre-qualification (“PQ”) requirements; and
- b) Ensure any Product obtains and maintains appropriate SRA and/or WHO PQ authorization or approval, as appropriate, for the duration of this Agreement or its market availability in LMICs, whichever is longest.

## 3. ADDITIONAL THIRD PARTIES

General. XYZ may use Third Parties as subcontractors in the performance of its activities undertaken in connection with this Agreement, provided; a) FIND is informed and agrees in advance in writing to such subcontractor, and; b) XYZ must obtain each subcontractor’s written agreement to comply with all the applicable terms and conditions of this Agreement. In addition, FIND may require reviewing the relevant sections of any agreement between XYZ and the Third Party in question, solely to ensure compliance with this Article [●]. For the sake of clarity any activity and/or obligation assigned to a Third Party under this Article [●] of this Agreement shall be considered nonetheless as being assigned to XYZ and XYZ shall be wholly held accountable for the fulfilment of such activity/obligation and any failure by the Third Party to execute their obligations shall be considered the full and direct responsibility of XYZ.

## 4. GLOBAL ACCESS AND GENERAL PRODUCT SUPPLY CONDITIONS

General. Each Party recognizes the requirements in accordance with the Global Access to ensure that any Product arising from the Agreement, will be made accessible and affordable to people living in the LMICs. Both Parties will take all reasonable and diligent actions necessary, within their scope and freedom to operate, that any Product arising from the Agreement will be made available broadly in a manner that meets their respective Global Access requirements, including but not limited to; a) provide access to the Product on an affordable basis, and including required in-country registrations as agreed with FIND, and local service and support. In addition, the Parties subscribe to the concept and implementation of Global Access as set out under the FIND policy at [www.finddx.org/policies](http://www.finddx.org/policies) whereby, subject to the terms and conditions of this Agreement, specified results, data, generated pursuant to this Agreement shall be made broadly and publicly available to any and all entities including any Public Sector bodies, as well as for-profit and not-for-profit organizations, and research centres working in healthcare in, or for, resource-limited settings.

Eligible Purchasers and Affordable Price. XYZ agrees to the following:

- a. In particular, with respect to pricing, under the TPP, the Affordable Price shall be determined as an EXW price, currently as a target of US\$ per Test Unit, including sample preparation or results reader (if required);
- b. Affordable Price to be available to Eligible Purchasers looking to supply Product to LMICs, including the Private Sector.
- c. Other Countries. Notwithstanding the above, XYZ shall make its commercial best efforts to ensure sufficient supply of products to LMICs which are not Priority Countries.

#### Priority Countries

In general, the Parties agree that the Eligible Purchasers should be the main focus for Product supply and have the right to the Global Access terms set out under this Article [●]. In addition, the following countries shall be considered as the “Priority Countries” [●].

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

XYZ shall enter into a Technology Licence Agreement with ABC, based on the following terms, comprising the following key Definitions and “flow through” obligations:

- a. **Field** shall mean the detection of 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-sublicensable (only to Affiliates), royalty-free, fully paid up and perpetual licence under the ABC IP to develop, make, or have made, use, offer for sale, sell, have sold, export or import the Product anywhere in the world for the purpose of its use in the Field and in the Territory. As per Article [●], the Field definition may be extended by mutual agreement of the Parties.
- e. **Background IP:** Such Licence shall include the right to use any pre-existing (Background) ABC IP at zero (or minimal) royalty rates as long as it is required for the commercialisation of the Product.
- f. **Technology Transfer:** Such Licence shall include appropriate technology transfer obligations under which XYZ and the Manufacturer of Record shall develop a mutually agreed plan of activities and deliverables to ensure such successful Technology Transfer (the “**Transfer Plan**”) in order to ensure that the Manufacturer of Record will be able to produce and commercialize the Product. The Transfer Plan shall be agreed within [●] weeks of the Effective Date.

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 against "Trafficking in Persons" including, but not limited to the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime.

Specific warranty regarding tobacco and arms. XYZ has, and currently has not had during the past four (4) years, any relations or linkages, with the tobacco or arms industry, or any subsidiary of a tobacco or arms company or commercial entity involved with the manufacture, sale, or distribution of tobacco/arms or tobacco/arms products, including, but not limited to, financial interests, controlling interests, or commercial relations resulting in licensing agreements, programmes, initiatives, research, or projects funded by the tobacco/arms industry, jointly administered with tobacco/arms-affiliated entities, or done for the tobacco/arms industry.

## **7. GOVERNING LAW AND DISPUTE RESOLUTION**

This Agreement shall be governed by and construed in accordance with the laws of Switzerland.

The Parties hereto undertake to settle any dispute concerning the validity, interpretation, and/or performance of this Agreement in an amicable manner. To the extent practical, the Parties shall continue to work under the Agreement pending the 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.