

Request for Proposals

Accelerating the development of molecular diagnostic platforms for decentralized diagnosis of acute respiratory illness

Executive summary

- FIND, the global alliance for diagnostics, is leading a Request for Proposals (RFP) to **accelerate the development, manufacturing, and launch of point-of-care, multi-pathogen, molecular diagnostic platforms** (“POC MDx”) for use in low- and middle-income countries (LMICs). This RFP has been prepared in the context of the Access to COVID-19 Tools Accelerator (ACT-A) Diagnostics Pillar*.
- The short-term areas of focus for this RFP are: (1) suitability of the platform for use in **decentralized settings**, and (2) **differential detection** of respiratory pathogens, including COVID-19.
- A long-term goal of this RFP is to increase **access to critical molecular tests**, such as HIV viral load and detection of tuberculosis, by accelerating the **availability of POC MDx** in LMICs.
- A budget envelope of **USD\$25 million** is available to selected manufacturers to enable development of a platform 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.

*ACT-A is a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. It was set up in response to a call from G20 leaders and launched by the World Health Organization (WHO), European Commission, government of France and the Bill & Melinda Gates Foundation in April 2020. The Diagnostics Pillar of ACT-A is co-chaired by FIND and The Global Fund. ACT-A is a framework for collaboration designed to bring key players around the table with the goal of ending the pandemic as quickly as possible by reducing COVID-19 mortality and severe disease through the accelerated development, equitable allocation, and scaled-up delivery of tests, treatments, and vaccines, thereby protecting health systems and restoring societies and economies in the near term. It draws on the experience of leading global health organizations that are tackling the world’s toughest health challenges, and which, by working together, are unlocking new and more ambitious solutions for COVID-19. Its members share a commitment to ensure all people have access to all the tools needed to defeat COVID-19 and to work with unprecedented levels of partnership to achieve it.

BACKGROUND

From January 2020 to June 2021, nearly 170 million COVID-19 cases and more than 3.5 million deaths have been reported globally^{1,2}. Significant advances in the prevention and treatment of COVID-19 have been achieved with unprecedented speed – vaccinations, tests, and treatments are now available³. However, while the number of global cases and deaths are decreasing in some regions, case detection and rates of death remain at high levels, and the rise of more transmissible variants is threatening progress in the fight against COVID-19. It remains critical to continue to identify cases – this enables isolation, contact tracing, and ultimately reduction in the virus’ ability to replicate, mutate, and accumulate variants^{4,5}.

Molecular testing for COVID-19 has played a key role in containing the spread of infections by detecting cases earlier and reducing onward transmission^{6,7}; however, with the current molecular diagnostic platforms on the market, several needs remain unmet. First, most platforms are large, complex instruments that cannot be used in decentralized, point-of-care (POC) settings, such as Level 1 (primary) and Level 2 (secondary) health facilities⁸. Despite the development of more than 176 molecular technologies for COVID-19⁹ worldwide and the 2.2 billion tests performed (March 2020-June 2021)¹⁰, testing in low- and middle-income countries (LMICs¹¹) remains infrequent or non-existent outside of urban areas, where most testing takes place in highly centralized facilities^{12,13} that have the infrastructure to conduct molecular tests. High-income countries (16% of the world’s population) account for 60% of the total tests performed, while middle-income countries (76% of the world population) and low-income countries (8% of the world’s population) account for 40% and 0.5% of tests performed, respectively^{14,15,16}. Decentralized molecular testing would not only enable testing at more accessible healthcare levels, but also improve patient management by enabling more rapid clinical decision-making and referrals of severe cases to a tertiary level. Secondly, because patients often present with non-specific symptoms such as cough, fever, headache, muscle ache, runny nose, and sore throat^{17,18,19,20}, there is a need for a molecular platform that can simultaneously detect multiple respiratory pathogens for differential diagnosis of acute respiratory illness. Distinguishing between COVID-19 and other respiratory pathogens can facilitate rapid, accurate diagnosis, treatment, and isolation in the case of COVID-19 patients and will become increasingly important as SARS-CoV-2 becomes endemic in many settings. Moreover, such a diagnostic could substantially guide the rational use of available antibiotics at Level 1 and 2 facilities, and result in appropriate referral of patients to higher levels of care. Importantly, decentralized molecular diagnostic platforms may serve as a vehicle to expand access to additional critical molecular tests needed in LMICs, including, but not limited to:

- (1) Detection of *M. tuberculosis* (along with genes associated with resistance): Annually, about half a million people fall ill with drug-resistant TB globally. Patients face significant economic and social costs and have limited access to quality care. Reaching the missing patients remains a significant public health challenge.
- (2) Detection and quantitation of bloodborne viruses such as HIV/HCV/HBV: Although molecular tests for these viruses exist, they are often performed on large, complex instruments that are not suitable for POC settings. The introduction of innovative technologies to diagnose and quantitate disease in primary healthcare settings is a key component of integrated care, enabling rapid diagnosis and treatment.
- (3) Detection of other bacterial infections: Current tools for diagnosis of bacterial infections rely on multiple clinical parameters and time-consuming lab-based culture methods. Development of POC tools has the potential to enable appropriate use of antibiotics, thereby reducing the potential for antimicrobial resistance.

The ongoing COVID-19 pandemic has presented an immense challenge to LMICs^{21,22}, which have struggled not only to obtain diagnostic tests, but also to deliver them equitably across the population. **This RFP seeks to broaden the reach of molecular diagnostics globally, and to leverage the momentum gained from significant private and public funding that has accelerated the development of molecular platforms and technologies for COVID-19.**

OBJECTIVE AND SCOPE

FIND aims to **accelerate the development, manufacturing, and launch of point-of-care, multi-pathogen, molecular diagnostic platforms** (“POC MDx”) for use in LMICs. The main areas of focus for this RFP are:

- ✓ Differential diagnosis of respiratory pathogens, including COVID-19
- ✓ Suitability of the platform for use in decentralized healthcare facilities in LMICs, specifically at Level 1 and Level 2 facilities
- ✓ Sample-to-answer systems that can be operated with minimal user training
- ✓ Affordability by LMICs, with a target production COGS for the assay of \$5 (single-plex pathogen detection) or \$10 (multiplex detection)

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). These product requirements and specifications are largely informed by the WHO’s “COVID-19 Target product profiles (TPP) for priority diagnostics to support response to the COVID-19 pandemic v.0.1.” We encourage all applicants to review these TPPs, particularly that for “Point of care test for suspected COVID-19 cases” and for “Test for diagnosis or confirmation of acute or subacute SARS-CoV-2 infection, suitable for low or high-volume needs” for reference.

Lastly, preference will be given to applicants with interest in expanding manufacturing capacity in LMICs and those platforms amenable to operate in an “open” configuration, where third parties may be able to develop assays for use on the instrument.

FIND will support pre-market activities for platforms that are in mid- to late-stage development with the goal of submission to World Health Organization Prequalification Programme²³ (WHO PQ) by the end of Q4 2022.

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, verification of performance, and validation of a multi-pathogen respiratory panel on an existing instrument (e.g. development of a multiplex assay).
- 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).
- Increase or optimization of manufacturing capacity to serve markets in LMICs, with a preference for expansion of production in facilities located in LMICs.
- Financial, logistic, and operational support for in-country registration, and/or clinical studies/trials that meet the regulations of WHO PQ.
- Go-to-market planning and launch strategy to address a supplier’s gaps in marketing a product in LMICs, which may include assistance in commercialization and marketing plans, financial forecasting, identification of distribution partners, and outlining of in-country registration requirements.

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

Priority will be given to those platforms that can perform multiplex assays (detect multiple pathogens within the same test). In parallel to the activities in this RFP, **FIND will engage in market assessment activities to estimate the demand in the relevant market segments for specific multiplex assay configurations**, and to understand the clinical use of such a platform. This information will guide further refinement of final product design specifications. Specifically, FIND’s market research should enable the definition of a specific multiplexed respiratory panel that is relevant to as many high-priority LMICs as possible. The panel should consist of a pathogen menu that, across several LMICs, takes into account the level of disease burden, the political willingness to authorize a test, the level of funding to combat COVID-19 and other respiratory illnesses, and/or the willingness to innovate on similar products.

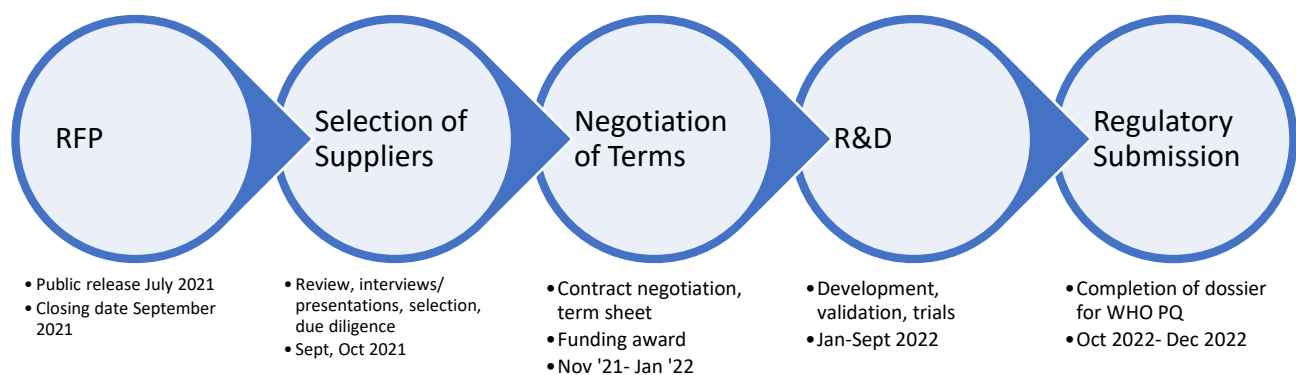
Importantly, the market assessment information generated by FIND in parallel to this RFP may also be used at a later date to secure volume commitments and negotiate pricing in preparation for market introduction of assays and platforms developed through this RFP.

TIMELINE

The expectation is that this RFP will enable suppliers to submit a dossier for the instrument and assay panel to WHO PQ by the end of Q4 2022. **Priority will be given to applicants who demonstrate a high likelihood to achieve validation by Q4 2022.** The anticipated timeline for this initiative is as follows (may vary depending on applicant):

1. Selection of suppliers (2 months)
2. Negotiation of terms and financing (3 months)
3. R&D activities and/or clinical validations (9 months)

Development of dossier for submission to WHO PQ (3 months)



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 November 2021.

FUNDING AWARDS

Funding for the RFP is provided through FIND from several donor grants under ACT-A; a **budget envelope of US\$25 million will be available to support 2-3 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, as part of the overall ACT-A initiative, this programme 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) (See **Appendix 1**).
- 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 3 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, reagent-only products (no instrument platform), serology-based technologies, 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)²⁴). 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 of approximately 15 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 scores from the Technical Assessment (cell J45), Business Assessment (cell F35), and Alignment Criteria (cell C14):

$$\begin{aligned} \text{Applicant's Total Score} = & \\ & (\text{Technical Assessment}) * 0.25 + \\ & (\text{Business Assessment}) * 0.25 + \\ & (\text{Alignment Criteria}) * 0.50 \end{aligned}$$

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 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 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 15)</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 25 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.
 - 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 respiratory pathogens, 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 F), and provide supporting evidence and/or data (column G) to support the claims in column F.
 - 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 ‘ACT-A Dx: POC MDx’ as the ‘Disease Area’ 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**.

QUESTIONS & FURTHER INFORMATION

Please email questions to: Rfp_acta_POC_MDx@finddx.org. Questions will be accepted and responded to expediently until 26 August 2021. Submitted questions (and corresponding answers) will be publicly available at: <https://www.finddx.org/poc-mdx-qa/>. All applicants are invited to attend a webinar on 6 August 2021. The webinar will present the RFP scope, content, and process, and will address questions submitted (to date) to the email address listed above. Attendance is encouraged to obtain clarification and further information. A webinar recording will be posted for those unable to attend.

CONFIDENTIALITY

All information supplied to the applicant by FIND, including the RFP and all other documents relating to the RFP process, must be treated as confidential, and not disclosed to any third party unless the information is already in the public domain or is required to be disclosed and vice versa. FIND considers any application and supporting documents received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement with interested applicants prior to proposal submission. FIND shall not disclose the proposal to third parties without the prior written agreement of the proposal submitter. All members of the review panel shall also be under confidentiality and shall be recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team.

CONTRACTUAL TERMS AND CONDITIONS

FIND will use a commercial level contractual mechanism where the standard Terms and Conditions address the requirements of supplying a product for public health particularly in LMICs, as set forth under **Appendix 5**.

COMPLAINTS

Applicants who 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 Rfp_acta_POC_MDx@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 POC 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.

Negotiated pricing for the public sector

Through the work of many ACT-A partners, pricing has been secured for the public sector in eligible countries to purchase certain molecular tests. For example, assays for TB, SARS-CoV-2, HCV, HBV, HIV, Ebola virus, human papillomavirus (HPV), *Chlamydia trachomatis* (CT)/*Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) manufactured by Cepheid are available at prices ranging from US\$9.98–19.80, ex-works and prepaid²⁵. Following Cepheid Xpert System approval by WHO PQ in late 2010, more than 45 million Xpert MTB/RIF cartridges have been delivered under the negotiated pricing, along with over 12,000 instruments²⁶. Commitments by international organizations such as USAID, OGAC, Unitaid/WHO and the Bill and Melinda Gates Foundation brought pricing down from the initial price of US\$16.86/test in 2010 to US\$9.98/test by 2013 (plus US\$17,000/instrument). This price was locked for 10 years (expected to expire in 2022) and was available for 145 countries – more specifically for the public sector, including governments and government-funded institutions, non-governmental organizations, United Nations organizations, and donors and funding mechanisms that support eligible countries (e.g. The Global Fund). The price was broken down to include²⁷:

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

With the pandemic, negotiated pricing for molecular COVID-19 tests was also obtained at US\$19.80/test. Suppliers participating in the negotiated pricing included Roche²⁸ and Hologic²⁹, amongst many others. It should be noted that since the publication of negotiated pricing of certain molecular tests in LMICs, calls for additional buy-downs and pricing concessions have been made³⁰, including the recent statement from the “Time for \$5 Coalition”³¹. These public announcements have highlighted the need for pricing that is affordable for the LMIC public sector³².

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 Molecular Diagnostic Platforms for Decentralized Diagnosis of Acute Respiratory Illness (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 and related Terms and Conditions for the public sector in 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 (“XYZ” and FIND) to each agreement denoted by [●].

1. SOME KEY DEFINITIONS

Manufacturing Cost of Goods Sold (COGS)	All direct costs such as labour, material, and allocated overhead costs in Product production;
COVID-19	Coronavirus disease caused by SARS-CoV-2, declared as a Public Health Emergency of International Concern by WHO on 30 January 2020;
Ex Works (EXW)	Defined under INCOTERMS 2020 and based on COGS;
Eligible purchasers	All Public Health Sectors (PHS) in LMICs and other private (i.e. non-governmental) healthcare 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	Meaning set forth under the Article [●].
Intellectual property (IP)	Patents, rights to inventions, copyright and related rights, moral rights, trademarks, trade names and domain names, rights in get-up, rights in goodwill or to sue for passing off, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which may now or in the future subsist in any part of the world. Such IPR may be encompassed in part or in whole under the deliverables and/or Product;
Know-how	All technical and other information which is not in the public domain (other than a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, relating to but not including Foreground Intellectual Property or Intellectual Property, as previously defined in this Agreement;
Licence Agreement (Licence)	The licence, as further set forth under the Article [●];
LMICs (Territory)	Those 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;

Manufacturer of Record	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	Meaning set forth under the Article [●];
Product	The POC MDx System 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	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 (PHS)	(i) Any government in the LMICs, including any government ministry of health, department or agency, or any local or regional governmental body, authority or entity, and (ii) any officially recognized, not-for-profit organization including private not-for-profit organizations, or funds, that pursue activities to relieve suffering, promote the interests of the poor, provide basic social services, or undertake community development, including, but not limited to, the World Health Organization, UNICEF, Save the Children Fund, and Médecins Sans Frontières;
Stringent Regulatory Authority (SRA)	Defined by WHO here: https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs , and may be updated from time to time;
Technology transfer	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 (Licence)	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 (TPP)	The 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	The specific assay and all required ancillary reagents and other consumables to run a single test on a single human specimen.

2. QUALITY REQUIREMENTS

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 providing access to the Product on an affordable basis, including the required in-country registrations as agreed with FIND, and to 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 and 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, which may include consumables used for sample preparation or instrument (if required);
- b. Affordable Price to be available to Eligible Purchasers looking to supply Product to LMICs
- 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 and Volume Commitments. 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.

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

- ¹ <https://covid19.who.int/table>
- ² <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---1-june-2021>
- ³ Sempowski GD, et al. Pandemic preparedness: developing vaccines and therapeutic antibodies for COVID-19. *Cell* 181, 1458–1463 (2020).
- ⁴ Domingo, E. & Holland, J. J. RNA virus mutations and fitness for survival. *Annu Rev. Microbiol.* 51, 151–178 (1997).
- ⁵ <https://www.nature.com/articles/d41586-021-00121-z>
- ⁶ Burke RM (2020). Symptom profiles of a convenience sample of patients with COVID-19 – United States, January–April 2020. *MMWR Morbidity and Mortality Weekly Report* 69, 904–908.
- ⁷ Wu Z and McGoogan JM (2020). Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases from the Chinese Center for Disease Control and Prevention. *JAMA* 323, 1239–1242.
- ⁸ World Health Organization, 2012. Guide to Infrastructure and Supplies at Various Levels of Health Care Facilities.
- ⁹ https://www.rockefellerfoundation.org/wp-content/uploads/2020/12/LMIC-Covid-19-Landscape-Analysis_20-Nov-2020.pdf
- ¹⁰ Hasell J, Mathieu E, Beltekian D, et al. A cross-country database of COVID-19 testing. *Sci Data* 7, 345 (2020)
<https://www.nature.com/articles/s41597-020-00688-8>
- ¹¹ <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>
- ¹² Shadmi E, Chen Y, Dourado I, et al. Health equity and COVID-19: global perspectives. *Int J Equity Health* 19, 104 (2020).
- ¹³ Carter C, et al. “COVID-19 disease: perspectives in low- and middle-income countries.” *Clinics in Integrated Care* vol. 1 (2020): 100005.
- ¹⁴ <https://covid19.who.int/table>
- ¹⁵ FIND COVID-19 test tracker: <https://www.finddx.org/covid-19/test-tracker/>
- ¹⁶ <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---1-june-2021>
- ¹⁷ Park M, et al. (2020) A systematic review of COVID-19 epidemiology based on current evidence. *Journal of Clinical Medicine* 9, 967.
- ¹⁸ Sun Y, Koh V, Marimuthu K, Ng OT, Young B, Vasoo S, Chan M, Lee VJM, De PP, Barkham T, Lin RTP, Cook AR, Leo YS, National Centre for Infectious Diseases COVID-19 Outbreak Research Team, Epidemiological and Clinical Predictors of COVID-19, *Clinical Infectious Diseases*, Volume 71, Issue 15, 1 August 2020, Pages 786–792.
- ¹⁹ Mao Y, Tan YR, Thein TL, Chai YAL, Cook AR, Dickens BL, Lew YJ, Lim FS, Lim JT, Sun Y, Sundaram M, Soh A, Tan GSE, Wong FPG, Young B, Zeng K, Chen M, Ong DLS. Identifying COVID-19 cases in outpatient settings. *Epidemiol Infect.* 2021 Apr 5;149:e92.
- ²⁰ Zhao D, Yao F, Wang L, Zheng L, Gao Y, Ye J, Guo F, Zhao H, Gao R. A Comparative Study on the Clinical Features of Coronavirus 2019 (COVID-19) Pneumonia With Other Pneumonias. *Clin Infect Dis.* 2020 Jul 28;71(15):756-761.
- ²¹ O'Donnell O, *Cad. Saúde Pública* 23 (12) • Dec 2007
- ²² Walker P, et al. *Science*, 24 July 2020: 413-422
- ²³ World Health Organization Prequalification Programme: <https://extranet.who.int/pqweb/>
- ²⁴ <https://tier7.us/biomedical-dod-trls-medical-devices/>
- ²⁵ <https://www.finddx.org/pricing/genexpert/>
- ²⁶ https://www.usaid.gov/sites/default/files/documents/The_Cepheid_buy-down_agreement-Evaluation_and_implications_for_the_future_Nov_2019.pdf
- ²⁷ Cepheid Xpert MTB/RIF Communication September 2011
- ²⁸ https://diagnostics.roche.com/nl/en/article-listing/global-access-program_copy.html
- ²⁹ <https://www.hologic.com/globalaccessinitiative>
- ³⁰ <https://www.msf.org/diagnostic-company-cepheid-charging-more-it-should-covid-19-tests>,
<https://www.treatmentactiongroup.org/statement/treatment-action-group-statement-on-the-high-price-of-cepheids-xpert-test-for-covid-19/>
- ³¹ <https://www.treatmentactiongroup.org/statement/time-for-5-coalition-statement-cepheids-updated-genexpert-pricing-does-not-address-country-needs/>
- ³² Fonjongo PN, Boeras DI, Zeh C, Alexander H, Parekh BS, Nkengasong JN. Access and Quality of HIV-Related Point-of-Care Diagnostic Testing in Global Health Programs. *Clin Infect Dis.* 2016 Feb 1; 62(3):369-374.