Request for Quote (RFQ)

# Developing a launch strategy for an HCV core antigen RDT in low- and middle-income countries

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## 1. ABOUT FIND

FIND, established in 2003 as a global non-profit, is dedicated to accelerating the development, evaluation and use of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, febrile illnesses and infectious diseases with outbreak potential, such as Ebola. Over the last decade, FIND has partnered in the delivery of 14 new diagnostic tools, including eight for tuberculosis, and has created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility.

FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has over 200 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, clinical trial sites, and bilateral and multilateral organizations (especially WHO). To learn more, visit www.finddx.org.

## 2. BACKGROUND

Viral hepatitis is a growing global health problem. It is estimated that 71 million people globally have chronic hepatitis C virus (HCV) infections and about 399,000 people die each year from HCV. Despite the considerable morbidity and mortality associated with HCV, only 20% of HCV-infected people have been diagnosed with the disease and only 7% of those diagnosed have received treatment.

In its 2017 guidelines on Hepatitis B and C testing, the WHO recommended the use of HCV rapid diagnostic tests (RDTs) to screen for HCV antibodies in settings where there is limited access to laboratory testing and/or for hard-to-reach populations for whom rapid testing would improve linkage to care. The 2017 FIND HCV Diagnostics Market Intelligence (DXMI) Report found that many countries facing underdeveloped lab networks, high sample transport costs, and/or a shortage of skilled laboratory staff are gravitating towards RDTs as a way to increase access to HCV testing.

FIND is currently supporting feasibility studies for the development of a core antigen (cAg) RDT for HCV screening and diagnosis (see https://www.finddx.org/newsroom/pr-28jul18-2/).

In parallel, FIND has commissioned a high-level market sizing analysis on the potential for a dual antibody/core antigen RDT for HCV screening and diagnosis. The analysis report provides an initial estimate of what market uptake could look like for a dual antibody/core antigen RDT for HCV diagnosis in 28 countries that account for ~80% of the global HCV burden. It is estimated the uptake and subsequent market potential for such a test could represent between 9 million and 158 million tests between 2021 and 2025 under different pricing and performance scenarios. Across countries and scenarios, the primary use case for the dual RDT is likely to be diagnosis of high-risk populations, such as people who inject drugs. However, substantially greater uptake could be anticipated under a more aggressive scenario in which select countries also opt to use the dual RDT for some limited general population screening given the relative affordability of the dual RDT versus the current diagnostic algorithm.

## 3. OBJECTIVE

Following the initial market analysis conducted on the dual antibody/core antigen RDT, there is a need to refine the initial market assessment analysis, perform a similar analysis for a single cAg RDT and develop a full launch strategy for one of both tests:

Phase 1: Market assessments for two different cAg RDTs

- Refinement of the market assessment for the dual Ab/cAg RDT: building on the initial analysis, refine some of the estimates and hypotheses underlying the model in order to narrow the demand volume estimates
- Development of a market assessment for a single cAg RDT: prepare a similar analysis as for the high-level market assessment of the dual Ab/cAg RDT

  Based in part on the results of the feasibility studies and the insights gathered from the Phase 1 market analysis, the decision to move forward with either the dual Ab/cAg or single cAg RDT will be taken.

Phase 2: Launch strategy plan for one cAg RDT

- Develop a launch strategy plan for one of both tests, detailing all activities required to get those products to the market in 5 high-priority countries.

  The launch strategy plan should contain the following sections:
  - Description of the current national context for each of the 5 high-priority countries:
    - Healthcare profile: gain knowledge about the public and private healthcare infrastructure, access to care, main providers and workforce
    - HCV landscape: understand the public health burden, epidemiology and national strategy in place for HCV
    - HCV diagnostic practices: understand access to care, patient flow, diagnostic algorithms and testing practices
    - HCV diagnostic regulatory, procurement financing & distribution mechanisms: understand the national mechanisms from procurement to distribution
  - Product description and use case: know more about use cases and patient populations targeted by the test
  - Country prioritization: understand the methodology and criteria used to identify early-adopter countries
  - Roll-out plan: provide a detailed roll-out plan to support market access actions. The roll-out plan should be structured around the following access topics: market landscape, product, regulatory strategy, policy & advocacy, financing strategy and distribution, logistics and quality management
  - Key market access challenges: evaluate market accessibility and key barriers for a successful product adoption: testing practices, funding, RDT selection, procurement & distribution, policy & advocacy, regulatory, training & communication
  - Key interventions: identify key FIND interventions needed to mitigate key market access challenges

- Demand forecast and willingness to pay: quantify market potential and demand for different use cases at difference price points

## 4. DELIVERABLES

Phase 1:

- Written MS Word report (one for dual Ab/cAg RDT and one for single cAg RDT), following the structure from the high-level dual Ab/cAg RDT market assessment (that will be made available)
- Synthesized version of the MS Word report in PPT format
- Excel file detailing high level market sizing calculations and outputs

Phase 2:

- Written MS Word report for the Launch Strategy Plan
- Synthesized version of the MS Word report in PPT format
- Multiyear year excel model demand forecasts of the market volume needed to serve the 5 high priority countries
- Source data/information provided in a readable format (preferably MS Word or excel)

## 5. TIMELINE

Phase 1: completion by September 30, 2019

Phase 2: completion by November 30, 2019

## 6. BUDGET

To be determined

## 7. QUOTE GUIDELINES

If you are interested in providing a quote, please send your quote (in English and formatted in Microsoft Word or PDF) to mael.redard@finddx.org by **6pm CEST on July 31, 2019**.

Applicants can apply to the entire RFQ (Phases 1 and 2) or can also choose to opt for either Phase 1 or Phase 2 of the RFQ.

Selection of the applications will be based on separate assessments of the offers. FIND reserves the right to request further information throughout the RFQ process. All email subject lines and document naming must be in the following format:

Your organization name–Offer–FIND–cAg Plan-2019

Any questions or clarifications regarding this RFQ should be submitted in writing via e-mail to mael.redard@finddx.org prior to the closing date.

## 8. EVALUATION CRITERIA

To ensure being considered for this RFQ, your offer should be complete and include all of the following information:

- **Organizational profile:** Bidders will be evaluated on their organizational strategy, experience and capability as it pertains to access to diagnostics, therapeutics and treatment in the global health domain.

- **Experience, capability & capacity:** Bidders will be evaluated on their capability and capacity, including history of their work pertaining to the development of access programs for infectious diseases, including roll-out plans, within the global health domain, as well as client testimonials and references.

- **Understanding of key access challenges:** Bidders will be evaluated on their understanding of key diagnostic challenges when commercializing and distributing diagnostic products for infectious diseases in low-and middle-income countries. Bidders should briefly discuss what they consider key access challenges in the diagnostics space and provide possible solutions to those issues by linking with the bidder's own experience on the matter (case studies if possible).

- **Financial proposal:** Bidders will be evaluated on the quality of the financial proposal for this RFQ as well as the transparency and breakdown of all financial elements comprising the final bid. Bidders should provide as much information as possible to explain the proposed budget.

- **Proposed team:** Bidders will be evaluated on the quality of the team that will work on the RFQ. Bidders are asked to submit complete CVs of the proposed team and present the working team, detailing how their background and experience will be of benefit for this work.

Where FIND judges more than one application to be complementary, FIND reserves the right to suggest partnership within the RFQ process.