



Request for quote (RFQ)

**Diagnostic accuracy of rapid screening tests
for the detection of anti-hepatitis C virus
antibodies in oral fluids: a systematic review
and meta-analysis**

Issue date: 21 October 2020
Closing date: 30 October 2020

1. ABOUT FIND

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs).

Since 2003, we have been instrumental in the development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control, and prevention.

2. BACKGROUND

The introduction of direct-acting antiviral drugs has transformed the treatment landscape for chronic hepatitis C infection. These medicines are now increasingly available at low cost in LMICs. However, a major barrier to treatment access is that the majority of infected persons remain undiagnosed and unaware of their status. This stands as an obstacle to reach the World Health Organization (WHO) ambitious targets to eliminate viral hepatitis by 2030. There is therefore an urgent need to increase access to testing.

The use of low-cost and accurate rapid diagnostic tests (RDTs) has improved access to testing for HIV and other infectious diseases. Previous studies have shown that HCV RDTs have a high diagnostic performance and there are currently four WHO prequalified HCV RDTs for professional use. These tests can be conducted with blood or oral fluids.

Tests that can be used with non-invasive samples, such as oral fluids, allow testing to be decentralized further and can be used in outreach settings or adapted for HCV self-testing. Oral-based HCV testing may be particularly useful in populations where venepuncture may be difficult, such as people who inject drugs. A previous meta-analysis conducted in 2017 showed that HCV oral-based testing conducted by professional staff have high sensitivity and specificity. A substantial number of new studies have been published since 2017 including also HCV self-testing and thus a more up to date meta-analysis is warranted.

FIND in collaboration with WHO is conducting a series of studies in LMICs to assess the usability and acceptability of oral-based tests for HCV self-testing among different populations in LMICs with the aim to inform future WHO recommendations on HCV self-testing.

3. OBJECTIVE AND AIM

FIND would like to complement the usability and acceptability HCV self-testing pilot studies with an updated systematic review and meta-analysis focusing on the diagnostic performance of oral-based HCV screening tests. FIND is looking for a consultant or consultant company with experience in conducting systematic reviews and meta-analysis to be carried out within a short timeframe.

The objectives of this systematic review and meta-analysis are to:

1. Assess the diagnostic accuracy of commercially available oral-based HCV screening tests compared to a reference standard.
2. Evaluate diagnostic accuracy according to type of setting where testing was undertaken and type of users conducting the test e.g. professional versus lay people.
3. Assess diagnostic accuracy among different population groups e.g. general population and key populations such as people who inject drugs, MSM, prisoners, sexual workers, etc.

4. SCOPE OF WORK AND METHODOLOGY

- Develop a systematic review and meta-analysis study protocol for registration in PROSPERO in accordance with PRIMA-P standards.
- Conduct search in at least 3 databases to identify published studies in peer-reviewed journals since 2017 as well as search grey literature such as conference abstracts.
- Abstract data from primary studies using a pre-pilot data extraction form and perform critical appraisal of selected studies using the QADAS-2 checklist for quality assessment of diagnostic accuracy studies.
- Conduct meta-analysis of sensitivity and specificity [true positive, false negative, false positive, true negative] using either the hierarchical bivariate random-effects model or the hierarchical summary receiver operating characteristic (HSROC) model.
- Assess heterogeneity across studies through the visual inspection of forest plots and SROC plots to examine the width of the prediction region as well as subgroup analysis.
- Assess publication bias through funnel plot asymmetry for diagnostic test accuracy studies e.g. Deek's funnel plot asymmetry test.

5. DELIVERABLES

- Study protocol registered in PROSPERO.
- Study report summarizing findings and recommendations.

6. BUDGET AND TIMELINES

The total budget is up to US\$ 15,000.00.

The work should be conducted in November/December 2020

7. QUOTE GUIDELINES

If you are interested, please send your quote (in English and formatted in Microsoft Word or PDF) to RFP_HCV@finddx.org by 6 pm CET on Monday 2 November 2020.

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.

Any questions or clarifications regarding this Request for Quote (RFQ) should be submitted in writing via e-mail to RFP_HCV@finddx.org prior to the closing date.

8. EVALUATION CRITERIA

To ensure consideration for this RFQ, your offer should include all of the following criteria:

- Individual CV or organizational profile: Bidders will be evaluated on their organizational strategy (where appropriate), experience and capability as it pertains to conducting systematic reviews and meta-analysis either as led researcher or part of a team conducting the review (include client testimonials and references).
- Experience conducting diagnostic test accuracy meta-analysis: Bidders will be evaluated on their experience in conducting this type of meta-analysis. Unlike other traditional meta-analysis for intervention studies, diagnostic meta-analysis requires specific statistical approaches to simultaneously evaluate pairs of sensitivity and specificity rather than a single measure of effect. Moreover, in diagnostic accuracy studies heterogeneity is the rule rather than the exemption, and random effects are more appropriate to handle the binomial nature of the data.
- 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 their proposed budget.
- Proposed team: If applicable, bidders will be evaluated on the quality of the team that will work on the project. Bidders are asked to submit CVs or biographies of the proposed 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 project.