Frequently Asked Questions

Seeking a manufacturing and commercialization partner for an antigen-based rapid diagnostic test for schistosomiasis infection with a focus in low- and middle-income countries

1. **How complete is the development program at FIND’s product development partner?**
   *Nearing the end of development, pre-design freeze. Optimization and robustness testing have been completed. One large lot of 5000 devices has been produced for field evaluations and for stability studies.*

2. **Could we get access to the best-mode summary and/or the design history file prior to submission?**
   *Development has been based on ISO standards with the relevant documentation, including a Design History File. This will only be made available to the selected manufacturer, once the contract has been signed.*

3. **Did FIND’s product development partner find problems reproducing its own processes and data?**
   *No*

4. **Why is FIND’s product development partner not manufacturing the test?**
   *The developer is a CRO and does not have manufacturing or commercialization capacity.*

5. **Was the FIND’s product development partner process card-to-card or reel-to-reel?**
   *The process is card-to-card*

6. **What is the largest number of tests that FIND’s product development partner has produced as a single lot?**
   *5000 devices*

7. **What is the largest scale on which conjugation has been done?**
   *Enough to support 5000 devices.*
8. How many lots of critical materials have been checked by FIND’s product development partner?
   Three lots of each critical reagent or material.

9. Which nanoparticles have been used? Upconverting phosphorus, gold, latex?
   Cellulose Nanobead

10. Would FIND’s product development partner provide notebook-style procedures or ISO-like batch records?
    FIND’s product development partner will provide electronic notebook entries, not batch records.

11. Who would provide the CAA to be used as positive control?
    Our partner would provide CAA enriched Adult Worm Antigen to be used as a positive control.

12. Can FIND’s product development partner provide a bill of materials and a Cost of Goods analysis?
    A preliminary Cost of Goods would be available to short-listed applicants only.

13. Has FIND’s product development partner performed stability studies?
    Limited studies have been undertaken to date. However, data on 10 weeks at 55°C shows no decrease in performance.

14. One eligibility criteria is: “Have gained WHO Prequalification or other stringent regulatory body (e.g. FDA or CE mark) approval for at least one IVD product”. At this moment we do not have CE mark or FDA or pre-qualification at WHO. However, we had CE mark for many of our products in the past (up to 2022). We understand the expression. “Have gained” means the company does not necessarily need to have it at the moment of application for the call of partnership. It means is eligible for those companies that had it at some moment in the past. We would like to confirm this understanding to be sure if we are eligible?!!
    A company that has WHO PQ, MDSAP certification or has undergone pre-market assessment from a Stringent Regulatory Authority (EU, USA, Japan, Australia and Canada) for at least one product in the past is eligible. If this is no longer available please explain why in your proposal.

15. Market: We understand that low- and middle-income countries are spread across all continents of the world, mainly Africa. Our question is, if in this project we focus on Latin America only (due to the limitations we have in operationalizing sales to Africa/Asia), would we be automatically disqualified?
    It is important that this device is made available to all SCH-endemic countries.

16. WHO ERPD: Are there any costs associated with the test evaluation by the Expert Review Panel for Diagnostics? If so, what would be the costs and how would be this process? In our understanding, we perceived as a different process than WHO PQ or WHO EUL (which WAMA developed for the COVID-19 Ag RDT), is that correct? Therefore, we shall understand it as not being a certification, but a test evaluation?
    The NTD ERPD process is still very new, and expressions of interest for two NTDs are currently open. More information on what is required can be found here and here for LF and VL, respectively.
17. **CE Mark:** We would need to study the particularities of each country in more detail, but we believe that in order to implement the product in Africa/Asia, we would also need a CE mark for this test. Is that correct?
   
   *To have an expedited review in most Asian and African countries, the test will need to have approval by a Stringent Regulatory Authority. For WHO this usually means approval from the following jurisdictions: EU, USA, Australia, Japan and Canada.*

18. **Conduct clinical trials:** We were wondering what role the selected company would play in this action? Who would build the prototypes and who would carry out the tests? Would be 6000 people in Kenya and Philippines?
   
   *The selected manufacturer would provide the tests once the transfer to manufacturing and verification and validation have been successfully completed. FIND has the funds to support this. The testing will then be done by our in-country partners in both Kenya and the Philippines.*

19. **SCH rapid diagnostic test:** What is the test methodology?
   
   *It is a lateral flow test, that doesn’t require a reader for detection. Please refer to Appendix 1 – TPP in the RFP for more information.*

20. **Would it be possible for us to receive more information about the product/partner?**
   
   *Information about FIND’s product development partner will be made available to short-listed applicants.*

21. **Costs:** What is the criterion for the product being affordable in low- and middle-income countries (required less than USD3.00 and ideal less than USD1.00) if we have no idea of the costs involved in manufacturing the test and the market prices?
   
   *The TPP was developed through the WHO DTAG schistosomiasis subgroup. The SCH CAA is a lateral flow, which uses antibodies to detect CAA. We don’t anticipate costs to be different from other lateral flow tests. Companies are therefore requested to provide a quote based on the information available in the RFP. Those meeting the TPP requirements would score better than those whose costs are higher.*

22. **Manufacturing:** What are the production process requirements for this test? Is any specific equipment required (e.g. Reel to Reel Dispensing System)?
   
   *It doesn’t require reel-to-reel but does require the typical lateral flow equipment.*

23. **Taxes:** Taxation in Brazil is very heavy and assuming that the Brazilian company would be selected, we would be taxed on 46% of the value of the project. Would it be possible to include this cost as something extra in the project?
   
   *FIND would not be able to cover these costs.*