Seeking manufacturers of multiplex rapid diagnostic tests for HIV/HCV/HBV and HIV/HCV self-testing who are willing to undergo usability and performance evaluation

Frequently Asked Questions (version 05 March 2024)

this FAQ will be updated until the 11th of March, 5pm CET

1. Does HIV/HCV/HBV and HIV/HCV require any certificate like CE or FDA?

[FIND RESPONSE]: Products that are either commercially available or in development are eligible. However, products in development must be near design-locked and the developer/manufacturer must provide evidence that it can produce pilot lots in time for the planned assessment and evaluation. Regarding commercial products, it is preferable if they are covered by a certificate like CE or US FDA but this is not an eligibility criterion as we will review the analytical and clinical data supporting the performance claims of the product. Therefore, it is important that the applicants provide supporting performance data and explain how their products have been validated.

2. Should the test be approved for self-test used

[FIND RESPONSE]: This is not an eligibility criterion. However, we will review the assay ease-of-use and compatibility with self-testing requirements. We encourage applicants to describe which components of their assay might be missing or must be upgraded to be compliant with the requirements of self-test use and what would be the plan to meet these requirements.
3. Where would these products export to, Switzerland or other African countries?

[FIND RESPONSE]: Countries for product delivery are not finalized yet, but the preliminary list is as follows: India, Kyrgyzstan, Indonesia, South Africa, Kenya. This list can be shortened or extended at the final stage of country selection.

4. What is the order quantity?

[FIND RESPONSE]: As per the eligibility criteria, we anticipate that the applicants can deliver the following quantities (tentative numbers. Could be amended as part of the study design):

- Commit to supply 600 assay kits1 for HIV/HCV/HBV and 400 assay kits for HIV/HCV by May 31, 2024 for manufacturer-independent usability and acceptability assessments upon FIND procurement. The provided assay kits should include samples/examples of positive and negative test results.
- Commit to supply 400 assay kits2 by July 31, 2024 for manufacturer-independent performance laboratory evaluation upon FIND procurement.