Annex. 4

PRODUCT SPECIFICATIONS

AND

TECHNICAL REQUIREMENTS

THIS DOCUMENT IS TO PROVIDE THE OFFERORS WITH THE PRODUCT(S) SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR THE PROCUREMENT OF COMMODITIES LISTED IN THE EOI.

Rapid Diagnostic Test Kits

|  |  |
| --- | --- |
| **Description** | **Destination** |
| Malaria Rapid Diagnostics Test P.f. (HRP2) | All PMI-supported countries[[1]](#footnote-1) |
| Malaria Rapid Diagnostics Test P.f. (HRP2) POCT | All PMI-supported countries |
| Malaria Rapid Diagnostics Test P.f. (HRP2/pLDH) | All PMI-supported countries |
| Malaria Rapid Diagnostics Test P.f. (HRP2/pLDH) POCT | All PMI-supported countries |
| Malaria Rapid Diagnostics Test Pf/PAN | All PMI-supported countries |
| Malaria Rapid Diagnostics Test Pf/PAN POCT | All PMI-supported countries |
| Malaria Rapid Diagnostics Test Pf/PV | All PMI-supported countries |
| Malaria Rapid Diagnostics Test Pf/PV POCT | All PMI-supported countries |
| Malaria Rapid Diagnostics Test Pan (pLDH) | All PMI-supported countries |

# Quantity

Any awards resulting from this EOI will be in the form of an indefinite delivery, indefinite quantity subcontract with fixed-price orders to be issued on a competitive basis thereunder for selected products within the corresponding ceiling fixed unit rates established in the IDIQ subcontract.

# Conformity with Quality and Products Standards

Offerors and the products presented and delivered must fully comply with the following eligibility requirements:

* 1. The *P.falciparum* HRP2 must obtain WHO pre-qualification
  2. For products that detect *P.vivax*, the panel detection score in the WHO Malaria RDT Product Testing Program should be at least 75% at 200 parasites μl.
  3. The false-positive rate should be less than 10%.
  4. The invalid rate should be less than 5%.
  5. Evidence of real time data to support storage temperature shall be available.
  6. Evidence of third party field data testing including stability data shall be available. Evidence of real time stability testing data for a minimum period of 18 months shall be available. Testing conditions for stability of temperature and humidity should be comparable to those found in typical malaria endemic countries.
  7. Specificity testing results of at least 90% and sensitivity greater than 90% shall be available. Only test reports issued by Research Institute for Tropical Medicine – Philippines acceptable.
  8. The kits shall be complete, containing all necessary accessories to successfully perform the test.
  9. The kits shall include an “Instruction Booklet” in the appropriate language. Also, any major limitations of the test which may lead to misdiagnosis shall be acknowledged.
  10. The manufacturer of the RDTs supplied must be ISO 13485 or USFDA 21 CFR 820 certified.

# Quality Assurance Provision

# According to Annex 1 - General Terms and Conditions and Annex 7 – Additional Technical Requirements.

The vendor shall coordinate with GHSC-PSM’s Quality Assurance (QA) contractor, SGS, who will implement sampling, QA testing and acceptance within the terms and conditions outlined below.

# Pre-Acceptance Sampling and Testing requirements

Not applicable for this procurement.

# Sampling requirements

Unless otherwise specified in the Subcontract, each RDT batch delivered to GHSC-PSM shall be inspected and sampled by SGS and tested by a designated independent testing laboratory. The vendor shall advise SGS when the complete consignment is ready for sampling and supply SGS with the packing list and manufacturer’s Certificates of Analysis for each batch. SGS will submit the samples to the designated testing laboratory or may request the vendor to do this. The vendor is required to replace the sampled quantity by equal quantity of the same batch, so that the full quantity of RDTs ordered will be shipped.

In general, the consignment may not be shipped before independent test results show the products to be in compliance. In some cases, GHSC-PSM may determine that products may be shipped prior to receipt of the quality assurance testing results, in reliance on the vendor’s certification that the commodities procured under the subcontract are in compliance with the required technical specifications and will inform the vendor of such in writing. If after such written confirmation the consignment is shipped, the vendor accepts all responsibility for shipping costs and the costs of returning the goods if independent test results show non-compliance of goods and goods are deemed out of specification.

# Test method

Unless otherwise specified in the Subcontract, each RDT batch delivered to GHSC-PSM shall comply with all product specifications and test procedures in effect at the time of subcontract award. Testing will be conducted at a laboratory assigned by the WHO-FIND Malaria RDT Lot Testing Programme.

The Manufacturer’s data demonstrating compliance with the product performance characteristics (i.e. sensitivity, sensibility, reproducibility), adequacy of RDTs for clinical use, and stability over the product shelf life shall be on record for each batch shipped to GHSC-PSM and shall be available to GHSC-PSM upon request for a length of time equal to five (5) years from the time of acceptance.

# Compilation of laboratory testing data

Not applicable for this procurement

# Lot disposition

Not applicable for this procurement

# Frequency monitoring

Unless otherwise specified in the Subcontract, each RDT batch delivered to GHSC-PSM shall be subject to sampling and testing requirements as specified above.

# Manufacturer Furnished inspection data

Not applicable for this procurement

# Post-Acceptance inspection/ Non-compliance

If inspection, Sampling or Testing, including interval testing to monitor stability over RDT shelf life (long term storage), reveal that goods are not in compliance and goods are deemed out of specification (OOS), the vendor must perform an OOS investigation and if required, submit to GHSC-PSM a robust corrective and preventive action (CAPA) plan addressing root cause(s) of the noncompliance issues. Each non-compliance issue shall be reviewed individually and GHSC – PSM may work together with the vendor to resolve the matter. GHSC – PSM reserves the right to review and/or approve the investigation report and the corresponding CAPA plan. The related costs to remediate each non-conformance shall be the responsibility of the vendor, including but not limited to order cancelation, replacement of goods, additional sampling and testing, product recalls and other remedial actions.

# Product documentation

# Evidence of compliance with standards indicated in Section II above

# Complete Quality Assurance Diagnostic Product Questionnaire in Annex 6 with supporting documentation[[2]](#footnote-2)

# Material Safety data sheet (MSDS) for the offered RDTs.

# Shelf life

Offered product must be freshly manufactured and have a minimum shelf-life of 85% on receipt unless otherwise stated in the firm order. For products offered from stock offerors must clearly indicate the manufacturing date and expiry date.

# Shipping specifications

Offered prices will be governed by the rules prescribed in the 2010 edition of INCOTERMS published by the International Chamber of Commerce. Offerors must include details of the estimated shipping specification with each quotation as follows:

Please quote prices on the following basis: **FCA-2010** (*indicate pick-up address*)

* Number of boxes, per pallet, per destination and total number of boxes
* Number of pallet, per destination and total number of pallet
* Gross Weight (kgs) and dimensions (cms) of each carton and destination
* Gross Weight (kgs) and dimensions (cms) of each pallet and destination
* Total gross weight (kgs) and total volume (m3) of each pallet and destination
* Total Number of Tests and Total Number of Kits
* Total # of Cartons and Total # of Pallets
* Number of Cartons per pallet
* Storage Conditions

Individual kit box (box of 25 tests) and shipping cartons (tertiary packaging) must be shrink wrapped and tied in order to protect the RDTs during transit time.

# Packaging and Packing

# The RDT to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage. The box will be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and ensure the products is safe, adequate for its intended use and of good quality.

# Shipping cartons (tertiary packaging) must be palletized with European standard pallets. The maximum pallet height does not exceed 157 cm\*\*\*"

# USAID Marking requirements

The manufacturer(s) will be responsible for ensuring that all export shipping packages, whether shipped from the United States or from any other source country, carry the official PMI logo below.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping package and the nature of the surface to be marked. The emblem on each export-shipping package will be affixed in a manner which assures that the emblem will remain legible until the package reaches the consignee.

The size of an emblem will vary depending upon the size of the commodity and the size of the export-shipping package. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Packaging, packing and marking shall be similar or equal of the Offeror’s normal and standard commercial packing. The PMI logo shown below must be included in the tertiary packaging on the three adjacent sides of the tertiary packaging (outer shipping unit).

PMI Logo:



# Innovation

# Bar coding

Not applicable for this procurement

# EDI (Electronic Data Interchange)

Not applicable for this procurement

# Vendor Management Inventory

Not applicable for this procurement

1. *PMI works in 24 focus countries in Africa and the Greater Mekong Sub region in Asia:* <https://www.pmi.gov/where-we-work>. *Additionally, non-PMI focus countries may procure malaria RDTs during the period of performance of this IDIQ* [↑](#footnote-ref-1)
2. For each diagnostic product submitted in the offer, please fill out one separate questionnaire. However, the same questionnaire can relate to different commercial presentations if their contents, in nature, are essentially similar. If this is relevant please indicate explicitly in the corresponding sections. [↑](#footnote-ref-2)