Request for Quotes (RFQ) to Support Africa CDC’s Effort to strengthen Monkeypox Virus (MPXV) testing in African Union Member States

August 2022
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Introduction:

The African Society for Laboratory Medicine (ASLM) is a Pan-African professional body, working to advocate for the critical role and needs of laboratory medicine and networks throughout Africa. Since the beginning of 2022, cases of Monkeypox Virus (MPXV) have been reported in eleven African Union (AU) Member countries – eight are endemic countries and three are non-endemic countries. Most are suspected cases (85%), which means that only 15% of cases were confirmed by laboratory tests. The recent emergence of MXPV in non-endemic Member countries and the continent’s limited capacity to test for MPXV are diagnostic concerns. Recognizing this, Africa CDC has been supporting AU Member States with the ultimate goal of improving the capacity and quality of MPXV RT-PCR testing. To this end, Africa CDC has been involved in coordinating the continued provision of supplies and consumables, including test kits and instruments, based on accurate forecasting of needs, ensuring in-country availability of quality-assured MPXV testing, building human resource capacity, and developing policy guidance documents for the response to MPXV outbreak in Africa.

RFP Objective:

In this BMGF-funded project, the introduction of MPXV RT-PCR test as one of the testing services provided by already established national or subnational molecular laboratories for the detection of SARS-CoV-2 is required. MPXV RT-PCR test kits should be delivered efficiently to ensure uninterrupted in-country availability of quality-assured MPXV testing. This project activity will focus on the effective use of existing SARS-CoV-2 laboratory infrastructure and human resources for the purpose of MPXV testing to better inform public health action for the control and prevention of MPXV in Africa.

The goals of the project are:

1. To provide a financial proposal (quotes) for MPXV RT-PCR test kit (Targeting 20,000 tests) in a bundle (sample collection materials, virus transport medium (VTM), extraction kit, and detection kit) for the purpose of In Vitro Diagnostics, including delivery to final consignee; which will be Ethiopia
2. To provide a plan to support the continuous supply of MPXV RT-PCR test kits in a bundle to Ethiopia.

Scope of Work: For this Requests for Quotes (RFQ), the requirements for the supplier(s) are to cover a wide range of multifunctional activities to provide all procurement and resources necessary including but not limited to:

- Provide quotes for the requested items and supplies including delivery dates, methods of shipment (air and/or ocean), freight and handling fees; to Ethiopia
- Provide Certificate from the Manufacturer Warranty and the original Country of Origin Certificate;
• All items should be supplied with at least one year of full warranty and expiry date of more than one year.

5  Application comments

Final selection of the supplier(s) will be based on technical, cost and other considerations as deemed necessary by the scope of work and the product list in Appendix II. ASLM shall enter into a contract with the selected supplier(s). The review shall include checking the quotation in relation to the requirements in Appendix II. Where the supplier(s) fails to meet the contract requirements, ASLM shall communicate formally of its decision.

6. Instructions for submitting proposals

The format of the submission, in response to this RFQ, must include, but not limited, to the following:

A. Provide quotes for the requested items and supplies including delivery dates, methods of shipment (air and/or ocean), freight and handling fees; to Ethiopia
B. Provide Certificate from the Manufacturer Warranty and the original Country of Origin Certificate;
C. All items should be supplied with at least one year of full warranty and expiry date of more than one year.
D. Include a certificate from FDA and/WHO for the approval or endorsement of the items to be used in a diagnostic laboratory.

Send your completed quotes by email to rfpsubmission@aslm.org, and Copy, EShumba@aslm.org, by September 5th, 2022. (11:59 pm EAT).

Point of contact
Direct any written questions or request for information about this RFP by August 23, 2022 to:

Rajab Banda
Contracts and Procurement Manager
Tel: +265 999 402 471
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Skype: rajab.banda
African Society for Laboratory Medicine-ASLM
www.ASLM.org

7. Evaluation and Award Process

A team of ASLM staff and outside experts will evaluate the quotations received based on the lowest price that meets the specifications in Appendix II as well as including all the countries where the kits are to be delivered.
ASLM reserves the right (but is not under obligation to do so) to enter into discussions with one or more Respondents in order to obtain clarifications or additional details, to suggest service delivery refinements in the proposal or other aspects of the proposal, or to negotiate the cost proposal. Formal notification to award the contract and the actual execution of the contract are subject to receipt of funds from the US Centers for Disease Control and Prevention.

Each Respondent submitting a proposal will be notified in writing or via e-mail of ASLM’s decision concerning their proposal. Should your organization be recommended for acceptance, the contract shall be effective on the contract execution date and shall run until October 15th, 2022. All work must be scheduled and completed within the contract period timeframe. Any modifications or extensions must be negotiated in advance, and submitted to ASLM for review and approval. The selected Respondent's proposal, and any subsequent material submitted in response to requests for additional information, will become the basis of contractual agreements with said Respondent.

8. **Contractual Terms and Conditions**

Responses must be in accordance with the guidelines as specified in this RFP. This RFP does not commit ASLM to accept any proposals submitted, nor is ASLM responsible for any costs incurred in the preparation of responses to this RFP. All materials submitted in response to this RFP or developed during the life of the contract will become the property of ASLM. The detailed itemized budget must be submitted in US dollars and will be evaluated in terms of best value to ASLM.

ASLM reserves the right to delay, amend, reissue or cancel all or part of this RFP at any time without prior notice. ASLM discourages ex parte communication with any Board Member, the public and/or staff member after the deadline for the receipt of proposals. ASLM will be under no obligation to reveal, or discuss with any Respondent on how a proposal was assessed, or to provide any other information relative to the selection process. Respondents whose proposals are not selected will be notified in writing and shall have no claim whatsoever for any kind of compensation.
Appendix I

General conditions

WARRANTY

• The supplier warrants that the items provided by the supplier will be free from defects.
• If not mentioned elsewhere in the PURCHASE ORDER or the SALES AGREEMENT, the warranty for any delivered items will not be less than one year from the date of accepting the delivered items. Supplier has to submit a warranty certificate with the invoice and a copy of it to the HAAD’s procurement section.

PAYMENT

• The Purchase Order number must be quoted on all the documents and copy of the Purchase Order and Original Delivery Note should be attached with the invoice.
• The authority will make payment no later than 30 days from the date of receiving invoice.
• All original invoices must be submitted to the Manager of the Finance Department at ASLM.
Appendix II

Product list and Technical Specifications

The following specification is developed if AU/Africa CDC and its partners procure Monkeypox Virus Real-Time PCR (MPXV RT-PCR) Kit for AU Member States (Table 1). This detailed description prioritizes the MPXV RT-PCR Kits in the WHO Prequalification (PQ) list and Emergency Use Listing (EUL) if any in the market.

Table 1: Monkeypox Virus Real-Time PCR Kit Specification

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkeypox Virus Real-Time PCR Kit in a bundle (Sample collection materials, transport medium, extraction kit, and detection kit)</td>
<td>Intended Use and Design of the Assay</td>
<td>The MPXV RT-PCR Kit should be based on real-time PCR technology. It should have highly specific primers and probes designed to detect Monkeypox virus of Central and West African clades. The kit should contain an internal control (IC) for specimen sampling and nucleic acid extraction. Also, it should be applicable to the primary RT-PCR systems or PCR instruments.</td>
</tr>
<tr>
<td>Packaging and Pack size</td>
<td></td>
<td>The pack size should be 25 Tests/Kit or as per manufacturer packaging size.</td>
</tr>
<tr>
<td>Storage and Stability</td>
<td></td>
<td>The kit should be stable with a storage temperature -20 ± 5°C.</td>
</tr>
<tr>
<td>Contents</td>
<td>Minimum: Disposable sampling swab kit, Viral transport medium (VTM), DNA extraction kit, and MPXV RT-PCR detection kit – in bundle. And Instructions for Use (IFU) – adequate document describing the principle, components, MPXV RT-PCR kit, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided within each kit.</td>
<td></td>
</tr>
<tr>
<td>Testing Time</td>
<td>Less than 90 minutes</td>
<td></td>
</tr>
<tr>
<td>Shelf-life</td>
<td>The kit should have a minimum of 12 months of shelf-life</td>
<td></td>
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<tr>
<td>Diagnostic Performance</td>
<td>At a minimum, the assay should have a sensitivity of ≥97% and specificity of 100%; preferably the assay sensitivity and specificity results obtained from independent evaluation studies.</td>
<td></td>
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<tr>
<td>Regulatory Body Approval</td>
<td>Approved by regulatory bodies for <em>In Vitro</em> Diagnostics (IVD), preferably World Health Organization (WHO) Prequalification (PQ) and Emergency Use Listing (EUL) <em>if any in the market</em></td>
<td></td>
</tr>
<tr>
<td>Delivery Point</td>
<td>Ethiopia, but specific point to be included in the PO</td>
<td></td>
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