RFP NO. ASLM/ACDC/MPOX/DIAG/09/30/25

REQUEST FOR PROPOSAL (RFP) FOR SUBMISSION OF MPOX DIAGNOSTIC TESTS KITS FOR EVALUATION

CLOSING DATE: 31 OCTOBER 2025

When responding to this RFP mention the RFP number in the subject line

1.0 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. For more information, please visit our website at https://aslm.org.

The Africa Centres for Disease Control and Prevention (Africa CDC) is the autonomous Health Agency of the African Union (AU) that supports Member States in their efforts to strengthen their health systems. Africa CDC was officially launched in Addis Ababa, Ethiopia, on January 31, 2017, and is guided by the principles of leadership, credibility, and ownership, and delegated authority, timely dissemination of information, transparency, accountability, and value addition. The Africa CDC is Africa's first continent-wide public health agency and envisions a safer, healthier, integrated, and stronger Africa, where Member States are capable of effectively responding to outbreaks of infectious diseases and other public health threats. For more information, please visit: https://africacdc.org/

2.0 OBJECTIVE OF THE ASSIGNMENT | SCOPE OF WORK | EXPECTED DELIVERABLES

2.1. Background:

The Africa Centres for Disease Control and Prevention (Africa CDC) through the Center for Laboratory Diagnostics and Systems (CLDS) has established the Diagnostic Advisory Committee (DAC) and one of the missions of the DAC is to improve access to In Vitro Diagnostics (IVDs) in Africa by supporting evaluation and recommendation of diagnostic tests

for priority diseases. It is in that regard that Africa CDC, in collaboration with the ASLM, invites manufacturers to submit Mpox Rapid Diagnostic Tests (RDTs) and RT-PCR kits for independent evaluation. The goal is to identify high-performing diagnostic tests suitable for use in African contexts and to generate evidence through structured performance studies.

Objectives

- To select local manufacturers with diagnostic tests for mpox to be validated.
- To assist local manufacturers will clinical performance evaluation for consideration in the continental listings by the African Medicines Agency (AMA).

Scope of Products for Submission

Local manufacturers in Africa can submit information about molecular tests and rapid antigen tests for mpox.

Local manufacturers that submit their tests for consideration should meet the following key requirements:

I. Must have a test for mpox that has completed at least the analytical phase of the validation.
II. The mpox test fulfils key minimum criteria in the WHO TPP (see below).
III. The manufacturer must have the ISO 13485 certification or in the process of obtaining ISO 13485 certification.
IV. The manufacturer should agree to sign non-disclosure agreements with Africa CDC.
V. Manufacturers will provide the kits needed for the validation and any other documentation that will be essential for screening and selection.

In addition to key TPP requirements, molecular tests submitted for consideration should meet the following criteria:

I. Sample type: Dry lesion material (swabs of surface or exudate, or crusts) and those placed in transport media.
II. Inclusivity: Able to detect clades I, IIa and IIb.
III. Limit of detection (LOD): determined using control material of defined quantity, equivalent to at least 1,000 genomic copies per ml of specimen.
IV. Analytical specificity: - assay performance should not be impacted by common interfering substances- assay should not cross-react with other common human pathogens, especially those causing similar signs and symptoms as MPXV (e.g., VZV, HSV).- MPXV specific target(s), at least one per assay, should not cross-react with other closely-related human OPXV, e.g., Vaccinia virus (VACV), Cowpox virus (CPXV).

In addition to key TPP requirements, rapid antigen tests submitted for consideration should meet the following criteria:

I. Sample type: Lesion material swabs (surface or exudate).
Inclusivity: Able to detect MPXV clades I, IIa and IIb.
II. LOD: determined using control material of defined quantity, equivalent to at least 10^6 PFU per ml of specimen.
III. Analytical specificity: - assay performance should not be impacted by common interfering substances- assay should not cross-react with other human non-OPXV, especially those causing similar signs and symptoms as MPXV (e.g., VZV, HSV). Cross reactivity with other OPXV is acceptable and should be clearly documented in IFU.

NB: African Local manufacturers of DNA extraction kits are also eligible to apply.

Composition of the submitted file

I. Information about the manufacturer (location, staffing, site of manufacturing, production capacity, leadership)
II. Information about the test (IFU, reports of analytical validation other evaluations)
III. Other documentation: ISO 13485 certificate

PERIOD OF PERFORMANCE AND OPTIONAL PERIODS:

The initial term (or period of performance) of the contract shall be from 5th December 2025 to 31st December 2026.

ASLM may exercise its right to extend the contract/scope subject to the performance of the consultant and availability of funding.

3.0 MANDATORY REQUIREMENTS

- Company profile with Certificate of Incorporation, Tax Clearance and all other applicable licenses, permit, authorizations, affiliations and certifications required per applicable laws and regulations. The company profile should provide additional information such as Registration name and trading name if applicable, physical address, telephone, contact person, period in business, key personnel/management and line of business.

4.0 EVALUATION CRITERIA AND SUBMISSION REQUIREMENTS

ASLM will accept proposals from bidders that provide Best Value and satisfy the requirements stipulated in the solicitation. All submissions/proposals will be evaluated against the set Evaluation Criteria provided below. Each proposal should contain the items listed in the Submission Requirements column in the following table.

Evaluation Criteria	**Submission Requirements**	**Weight**
Technical	○ Provide detailed information on molecular tests and rapid antigen tests for Mpox. Further, provide the stage of the diagnostic test. A near market ready diagnostic test kit that passed the analytical phase will be preferred.	35%
Production Capacity	○ Provide production capacity of the test kits	35%
2.Price	○ Provide indicative cost of the diagnostic test kits and accompanying supplies	30%
Total		**100%**

5.0 CONTRACT TYPE

For this procurement, ASLM will issue out a Firm Fixed Price Contract on its terms and conditions indicating the consultant's quoted firm fixed price, scope of work, deliverables, timelines duration of contract and other instructions.

6.0 SUBMISSION REQUIREMENTS

Completed proposals must be addressed to the Procurement Committee and send electronically on or before the closing date and time to rfpsubmission@aslm.org **ONLY**.

7.0 PROPOSED TIMELINES

Date	Activity
1 October 2025	Release of RFP and publicly posted on ASLM website:
15 October 2025	Deadline for submission of inquiries related to this RFP directed to Email to: JShonhe@aslm.org, SMate@aslm.org; EShumba@aslm.org and all questions must clearly identified with the solicitation #
	Indicate the RFP number indicated at the top of this RFP (i.e. RFQ #) in your proposals.
17 October 2025	Response to all inquiries released and posted publicly on ASLM website
31 October 2025	Deadline for Proposal submission.
28 November 2025	Final decision announced and Bidders receive feedback
5 December 2025	Contract confirmed & issued out.

While ASLM is desirous of maintaining the proposed timelines, delays necessitated by unforeseen circumstances may be inevitable.

8.0 ASLM TERMS AND CONDITIONS

The following are the terms and conditions of ASLM and any exceptions to these should be noted in writing at submission**:**

8.1. This RFP is not an offer to enter into agreement with any party, but rather a request to receive proposals from companies interested in providing the goods or services outlined in this RFP.

8.2. The specifications prescribed are not in any way limited to any specific tenderer as they are based on generally achievable requirements and thus, participation in this solicitation is open to all legal vendors that are registered and comply with the laws of doing business in the applicable country(ies) where services will be rendered. The necessary legal, commercial, technical and financial requirements should be satisfied.

8.3. ASLM does not bind itself to accept the lowest tender price and reserves the right to reject all submissions, in whole or in part, enter negotiations with any party, and/or award multiple contracts.

8.4. ASLM reserves the right (but is not under obligation to do so) to enter 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 quotation.

8.5. All quotations/proposals MUST be typed, on company official letterhead with full contact details including physical address, contact phone, email. Submissions **MUST** be received on or before the **closing date** and **time** and all bids received after the closing date and time may not be considered.

8.6. ASLM shall NOT be responsible for any costs involved in the preparation and submission of bids or proposals. All costs to be borne by the bidder and this is irrespective of the outcome.

8.7. Bid validity of quotation/proposals shall be 90 days.

8.8. Unless otherwise specified in the final contract, full payment will be made by ASLM to the Vendor within 30 days of receipt of invoice from the Vendor and either delivery of goods or completion of required deliverable.

8.9 ASLM provides an equal opportunity for any vendor/supplier to participate irrespective of race, colour, religion, sex, or national origin and will receive equal treatment.

8.10. By participating, preparation and submitting this quotation or proposal, you represent that none from your organization has any conflict of interests.

8.11. To the maximum extent practical and possible, ASLM will strive to ensure that the finances provided in this procurement do not support organisations, companies and individuals associated with acts of terrorism, prostitution and drug trafficking.

8.12. ASLM reserves the right to delay, amend, reissue, or cancel all or part of this RFP at any time but feedback will be provided to the vendors who participated. Additionally, ASLM will be under no obligation to reveal, or discuss with any bidder how a quotation/proposal was assessed, or to provide any other information relative to the selection process. Respondents whose quotations are not selected will be notified in writing and shall have no claim whatsoever for any kind of compensation.

8.13. ASLM reserves the right to waive or permit cure of non-material variances in the bid proposal if, in the judgment of ASLM, it is in ASLM's best interest to do so. Non-material variances include minor informalities that do not affect responsiveness; that are merely a matter of form or format; that do not change the relative standing or otherwise prejudice other vendors; that do not change the meaning or scope of the RFP; or that do not reflect a material change in the services. In the event ASLM waives or permits cure of nonmaterial variances, such waiver or cure will not modify the RFP requirements or excuse the vendor from full compliance with RFP specifications or other contract requirements if the vendor is awarded the contract. The determination of materiality is in the sole discretion of ASLM.

8.14. Failure to provide any of the above specifications and requirements may be considered non-responsive and disqualify the bidder from final selection**.**

8.15. As part of its commitment to engrain a culture of honesty and integrity in all its business processes, unethical conduct such as undisclosed conflict of interests, bribes and kickbacks and other corrupt activities are strictly prohibited and denounced. No employees at ASLM are allowed to use their position to pursue personal and unethical gain. In the same vein, bidders or potential suppliers and contractors are proscribed from offering bribes aimed at influencing the process and the outcome(s). ASLM implore vendors to embrace this culture in their interactions with us. Violation of this ethical principle and requirement will result in the supplier or service provider disqualified and ASLM will not solicit or accept bids in the future from the same. Should you experience or suspect unethical behaviour by an ASLM employee, please reach out to via email: ASLM@tips-offs.com or through the website: http://www.tip-offs.com/.