



**EoI No. ICMR/EoI/MPox/2025 dated 11/02/2025**

**Invitation for Expression of Interest (EoI)**

**For**

**Transfer of Technology**

**A colorimetric isothermal (LAMP) assay for rapid detection of  
Monkeypox virus (Diagnostic assay/Kit)**

By ICMR-Hqrs

**Indian Council of Medical Research**  
(Department of Health Research, GoI)  
V. Ramalingaswami Bhawan,  
P.O. Box No. 4911, Ansari Nagar,  
New Delhi - 110029, India

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## Letter of Invitation

### 1. Invitation for Expression of Interest

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from the eligible organizations, companies, manufacturers for undertaking ‘**Transfer of Technology**’ for commercialization of “A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*” useful in Detection of Monkeypox

The EoI document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. can be downloaded from the ICMR website (<https://www.icmr.gov.in>).

Schedule for the Proponents is as under:

EoI Document Number	<b>ICMR/EoI/MPox/2025</b> dated 10/02/2025
Date of Publication	Date: 11/02/2025
Last date of submission	Date: 12/03/2025

**Note:**

Interested applicants may please send their proposals in a sealed envelope to the following address:

**Dr. Jitendra Narayan  
Scientist D  
Communicable Disease Division  
Indian Council of Medical Research,  
V. Ramalingaswami Bhawan,  
P.O. Box No. 4911,  
Ansari Nagar, New Delhi - 110029, India.**

EoI Document No. **ICMR/EoI/MPox/2025** along with the title of the EOI as “**EoI for Technology Transfer**” in **Bold** and complete address as above must be clearly mentioned on the sealed envelope.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EoI, as may be desired by the Competent Authority ICMR and duly notified on its website.

## 2. Background

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and the need of finding practical solutions to the health problems of the country, on the other.

ICMR- National Institute of Virology, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi. National Institute of Virology (Details of Institute) has developed a technology entitled “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***” (hereinafter) referred to as “**Technology**”.

ICMR is lawfully entitled to enter into any form of **exclusive/non-exclusive agreements** with eligible manufacturing companies hereinafter referred to as the “**Company**” through a defined agreement for Licensing/Commercialization of “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***”, hereinafter referred to as the ‘**Product**’, which shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

## 3. Objective

To license the ‘Technology’ for “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***” effective/useful in Detection of Monkeypox, for commercialization and marketing activities

## 4. Scope of Work

- i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking Transfer of technology and commercialization of “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***”
- ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***” or undertake further R&D and commercialize the end product(s) /technology.
- iii. An Agreement (in case of licensing) following EoI is proposed to be executed on a “**Exclusive/Non-Exclusive**” basis with single/multiple companies to enable wider outreach of the “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***” (Technology/Product) for societal benefit and public health use. All the related issues shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.
- iv. ICMR-National Institute of Virology has expertise in various techniques, methods and

information relating to aforesaid technology which could be used for the production of “**A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus***”

**Role of ICMR:**

- i. ICMR- National Institute of Virology will provide expert guidance & technical support for the production of “A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*” (1), in all phases. Such technical oversight by ICMR- National Institute of Virology would accelerate the development of the Product and its commercialization.
- ii. ICMR would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.
- iii. ICMR through its Institutes would provide support and facilitation to conduct the R&D/clinical study of new technology/ product in India through its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.
- iv. ICMR would provide technical support in development of technology/ product and will also facilitate the validation, if required, as per the terms & conditions of the Agreement.
- v. ICMR shall have no financial implications unless otherwise specified.

**Role of Company**

- i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development/ validation/ scale-up either directly or otherwise.
- ii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the “A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*”, in a set milestone.
- iii. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.
- iv. The Company agrees to allow authorized personnel/scientist/team of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.
- v. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for product development to its commercialization

## **5. Intellectual Property Rights**

It is submitted that in case of transfer of Technology, ICMR is the sole owner of the said Technology, including any underlying Intellectual Property(ies) and commercialization rights.

Intellectual Property (IP) shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents.

ICMR legally possess the rights and authority to retain full or part of the 'Technology' by itself or to assign at its discretion full or part of the Technology including any patent(s) or intellectual property rights(s) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive License Agreements with selected companies including transfer of the Technology through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of the Technology/ Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be jointly owned by ICMR and the Company. All such provisions related to intellectual property rights shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

## **6. Process involved in Partnership/Collaboration/Technology Transfer**

Interested companies/manufacturers are invited to join hands with ICMR for further development & commercialization of the Technology/ Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration/technology transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty @ 1 2% on Net sales, according to the ICMR Guidelines for Technology Development Collaboration.

## **7. Publication**

- i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).
- ii. Support of ICMR must be duly acknowledged in all publications by the Company.
- iii. ICMR Scientists can be given due to advantage of authorships in the publications arising out of Licensing/co-development.

## **8. Data Rights**

- i. Data Rights will be exclusively with ICMR, if ICMR provide 100% funding.
- ii. Data rights shall be jointly owned by ICMR and Licensee/Co-developer, in case of joint funding.
- iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.
- iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 while dealing with such data

## **9. Details of documents to be furnished**

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.

Documents to be furnished are as follows:

- i. Declaration - Expression of Interest (Format – 1)
- ii. Authorization Letter (Format – 2)
- iii. Undertaking with regard to Blacklisting (Format-3)
- iv. Undertaking with regard to Non-Conviction (Format – 4)
- v. EoI document with each page duly stamped and signed by the Authorized signatory.
- vi. Undertaking with regard to laboratory facility (Format – 5)
- vii. Production Capacity Undertaking (Format-6)
- viii. Supporting documents, as mentioned in Format-1
- ix. MSME Certificate (if applicable)
- x. Concept note on business plan- A brief concept note on R&D, clinical studies, planning & execution, production, marketing etc. with timeline (not more than 5 pages)
- xi. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgement in evaluation.

## 10. Rejection Criteria

The application is liable to be rejected if:

- i. The proposal is not submitted as per the requirements indicated in the EoI.
- ii. Not in the prescribed format.
- iii. Not properly stamped and signed.
- iv. Received after the expiry of due date and time.
- v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).
- vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.
- vii. Applications not fulfilling the terms of the document will be summarily rejected.
- viii. Any other non-compliance.

## 11. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted.

## 12. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	Pre-Qualification Criteria (General)	Supporting copy of documents required (All documents must be self-attested by the authorized person of the proponent)
<b>General Criteria</b>		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from India..	Registration of firm/ organization/Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable
2	The proponent must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The proponent should have proven prior experience of manufacturing and/or R&D with manufacturing during the last three years, either in-house or through agreed collaboration and must have	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.



	marketed same/similar products in the past with a good track record.	
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track record and currently not black-listed/ barred by any Central / State Government / Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only).	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
7	The proponent and its promoters should not have been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
<b>Specific Criteria (Based on the nature of the Proposal)</b>		
9.	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
10.	Capacity to produce at least .....(quantity) per week	Undertaking (As per format – 6)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

### 13. Disclaimer

- i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
- ii. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
- iii. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.
- iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.
- v. For International Clients, please note that EoI and other necessary correspondences shall be

submitted in English only.

#### **14. Arbitration**

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as per the Arbitration & Conciliation Act, 1996 and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi and the courts at New Delhi will have exclusive jurisdiction.

#### **15. Contacts**

In case of any clarification required, please contact:

**Dr. Shyam Sundar Nandi**

**Scientist E, ICMR-NIV Mumbai unit (*For scientific issues*)**

Email- [nandi.shyamsundar@icmr.gov.in](mailto:nandi.shyamsundar@icmr.gov.in)

Mobile No.: 9082553865

**Dr. Jitendra Narayan**

**Scientist-D, ICMR-HQ, New Delhi (*For Tech- transfer issues*)**

Email: [jitendra.narayan@gov.in](mailto:jitendra.narayan@gov.in)

## Format-1

### Expression of Interest

(To be submitted on Company's Letter Head)

To,

**The Director General,**  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi.

**Subject:** Submission of Expression of Interest (EoI) for Transfer of Technology "A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*" (1) against Monkeypox (2) disease.

**Ref:** ICMR/EoI/MPox/2025 dated .....

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to your transfer of technology, and do hereby express the interest to undertake the research & development/manufacture/ sale /commercialization of the product as mentioned in the EoI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	Documents required	Type of document attached	Page No.
1	Company Incorporation Certificate from ROC/Partnership deed etc.		

2	GST Registration or GST exemption certificate/ PAN Card.		
3	DCGI/CDSCO license for the existing products available in the market		
4	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for las three financial years, Income Tax return.		
5	Proof of a registered office and a manufacturing Unit in India. Including DSIR certificate		
6	GMP / GLC and ISO Certification. Registration copies of both		
7	Authorization Letter	As per format – 2	
8	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory	As per format – 3	
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
10	MSME Certificate (if have any)		
11	Business Plan	A brief concept note on planning & execution, production, marketing etc. (not more than 5 pages)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

**Format-2**

**Authorization Letter**

(To be submitted on Company's Letter Head)

To,

**The Director General,**  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi.

**Subject:** Letter for Authorized Signatory

**Ref:** ICMR/EoI/MPox/2025 dated .....

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technology "A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*"

Mr./Ms./Mrs./Dr.....is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s..... (Company Name) ....., who's signature is below.

(Specimen Signature of Representative)

Date:

Place:

Yours faithfully,

(Signature of the Authorized signatory)

Name:.....

Designation:.....

Seal:.....

**Format-3**

**Undertaking with regard to blacklisting**  
(To be submitted on Company's Letter Head)

To,

**The Director General,**  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi.

**Subject:** Undertaking regarding Blacklisting / Non-Debarment.

**Ref:** ICMR/EoI/MPox/2025 dated .....

Sir,

It is hereby confirmed and declared that M/s..... (Company Name) currently has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other company for which works/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

**Format-4**

**Undertaking with regard to Non-Conviction**

(To be submitted on Company's Letter Head)

To,

**The Director General,**  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi.

**Subject:** Undertaking regarding Conviction.

**Ref:** ICMR/EoI/MPox/2025 dated .....

Sir,

It is hereby confirmed and declared that M/s.....(Company Name) and owner of the firm / board of directors, have not been convicted for any offence in India by any competent court or judicial body during the past 3 years

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

**Format-5**

**Undertaking with regard to laboratory facility**

(To be submitted on Company's Letter Head)

To,

**The Director General,**  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi.

**Subject:** Undertaking regarding laboratory infrastructure.

**Ref:** ICMR/EoI/MPox/2025 dated .....

Sir,

It is hereby confirmed and declared that M/s .....(Company Name) do have

- i. Adequate laboratory infrastructure (equipped laboratory facility). Please tick BSL-2/BSL-3/ABSL-3/GMP/GLP/ Other\* (if other please specify) and
- ii. Adequate no. of experienced staff/skilled manpower to undertake manufacture/ research/ commercialization of "A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*" (Product details).

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:



**Format-6**

**Undertaking with regard to production capacity**

(To be submitted on Company's Letter Head)

To,

**The Director General,**  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi.

**Subject:** Undertaking with regard to production capacity.

**Ref:** ICMR/EoI/MPox/2025 dated ...

Sir,

It is hereby confirmed and declared that M/s.....does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for manufacturing of "A colorimetric isothermal (LAMP) assay for rapid detection of *Monkeypox virus*" (Name of Technology/Product), minimum 01 (one) lakh test kits per month (mention the quantity per week/per month).

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

## SCHEDULE-A

### TECHNOLOGY DETAILS

i. **About the Technology/Product/Process:**

The diagnosis of the Mpox is based on detection of an *Orthopoxvirus* genus specific gene and confirmation based on *Monkeypox virus* specific gene. The oligonucleotide primers have been designed targeting the genus specific B6R (Envelope protein) and species specific F3L (F3 protein which an enzyme double-strand RNA-binding domain) genes for the development of this assay. LAMP amplification reactions were incubated. The results were interpreted in the form of color change from pink to yellow only in 40 minutes time. The LAMP assay for B6R and F3L genes along with internal control Beta-actin gene were carried out in separate tubes. Unlike real-time PCR, this isothermal amplification technique does not require a thermal cycler. It is possible to conduct the experiment using a single temperature heating apparatus ( $65 \pm 1^\circ \text{C}$ ). The assay only takes forty minutes to complete. No further complex tools are needed to interpret the results; they may be comprehended visually. This technology is affordable. Field testing outside of the diagnostic laboratory may be made possible by this assay.

ii. **Need and utility of the Technology from Public health perspective:**

*Monkeypox virus* (Mpox) causes a smallpox-like disease in non-human primates and humans. This infection is endemic to central and western Africa. Mpox is divided into two genetically different groups, Congo Basin and West African Mpox, with the former being the more virulent. The invention discloses a loop-mediated isothermal amplification (LAMP) for rapid and low cost detection of *Monkeypox virus*. The principle of this assay is by using pH sensitive dyes to exploit the change in the pH resulting from proton accumulation while incorporation of dNTPs. Change in the color of reaction can be detected by naked eyes. No sophisticated instruments are required for the performance and results interpretation. By application of the LAMP for detection as described in this invention, the demerits of real-time PCR such as long detection period, complex operation, and sophisticated instrument requirement have been overcome. This assay is suitable to be performed as a point of care diagnostic assay at the health care centres, surveillance laboratories and other areas and has important significance for preventing and controlling the spread of *Monkeypox virus*.

iii. **Technology Readiness level (TRL)**

The NIV Mumbai Unit designed the LAMP Assay. In the developer's lab, testing was completed, as the initial pilot study. In BSL-4, NIV, Pune (which is the only laboratory doing *Monkeypox virus* detection.), the assay's performance was compared to real-time PCR, yielding very positive outcomes. Real-time PCR assays approved by DCGI were used for the comparison. It was discovered that the developed LAMP assay for *Monkeypox virus* detection was just as sensitive and selective as the gold standard Real Time-PCR assay.

**TRL 04/05**

iv. **Validation Status and outcome:**

As a part of independent validation, 160 clinical samples (NPS OPS Swabs, Lesion fluids) were used in the BSL-4, NIV, Pune (which is the only laboratory doing *Monkeypox virus* detection.) for performance evaluation of the LAMP. Comparing the LAMP assay to the Real Time PCR, the overall diagnostic sensitivity and specificity was 100% and 100%, respectively.

v. **IP Filing Status/Publications**

Title of the patent “Development of a colorimetric isothermal assay for detection of *Monkeypox virus*.” Inventors: Dr. Shyam Sundar Nandi (PI), Sonali Sawant, Dr. Upendra Lambe, Dr. Pragya Yadav, Dr. Anita Aich Shete, Dr. Jagadish Deshpande. Patent application filed on 04/10/2023. Indian Patent ApplicationNo: 202211057074.

## Validation report with 100% Sensitivity and 100% Specificity



**icmr**  
INDIAN COUNCIL OF  
MEDICAL RESEARCH  
Serving the nation since 1911

**NIV**  
NATIONAL INSTITUTE  
OF VIROLOGY

आई सी एम आर - राष्ट्रीय विषाणु विज्ञान संस्थान

स्वास्थ्य अनुसंधान विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

**ICMR - NATIONAL INSTITUTE OF VIROLOGY**

Department of Health Research  
Ministry of Health & Family Welfare, Govt. of India

### Validation Report

**Name of the Assay:** LAMP Assay for the detection of Monkey pox virus (MPXV LAMP Assay)

**Application of the assay:** Monkey pox virus molecular diagnosis.

**Details of assay components:** Primers (B6R gene & F3L gene), Warm Start Colorimetric LAMP Master Mix with UDG, Enhancer, Nuclease free water (NFW)

**Objective:** To determine the sensitivity and specificity of LAMP based assay for detection of Monkey pox virus in comparison with TaqMan based Real time PCR assay

### Result of the panel tested

ICMR NIV, Pune	MPXV LAMP assay		
	Positive	Negative	Total number of samples tested
MPXV Positive	80	0	80
MPXV Negative	0	80	80
Total	80	80	160

Sensitivity = 100%

Specificity = 100%

**Comments on performance of the assay:** Satisfactory

**Conclusion:** Satisfactory

(Sensitivity and Specificity have been assessed in controlled lab)

### Remarks:

- The bench marking criteria of validation was as below:

Sensitivity:  $\geq 95\%$

Specificity:  $\geq 95\%$

**Assay performance was satisfactory.** Kit performance was found to be satisfactory using the validated panel of MPXV positive, negative samples.

This report is exclusively for Monkeypox LAMP assay provided by ICMR NIV Mumbai unit.

**Kit evaluation done by**

Dr. Anita Shete-Aich, Scientist E

*Ashete*

**Prepared by**

Dr. Pragya D Yadav,  
Scientist 'F' and Group Leader,  
Maximum Containment Facility,  
ICMR NIV Pune



**Approved by**

Director In-Charge, ICMR NIV Pune

**Director In-Charge**

ICMR-National Institute of Virology  
20-A, Dr. Ambedkar Road,  
Pune - 411001

*[Signature]*  
19/1/24