EoI No. ICMR/EoI/Nipah-Virus/2025 dated 11/02/2025

Invitation for Expression of Interest (EoI)

For
Transfer of Technology
for

commercialization of Diagnostic assay/Kit

"A colorimetric RT-LAMP assay (isothermal) for rapid detection of *Nipah virus*"

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

CONTENTS

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 RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"* useful in Detection of Nipah.

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	**ICMR/EoI/Nipah-Virus/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 through registered post or by hand, 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/Nipah-Virus/2025** along with the title of the EOI as **"EoI for Transfer of Technology for commercialization of A colorimetric RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"*** 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 is the premier institute for virology and has demonstrated dedication in times of crisis and emergency, like COVID-19. It has shown remarkable responses to outbreak investigations and the diagnosis of newly emerging and existing viral diseases. National Institute of Virology has developed a technology entitled "A colorimetric RT-LAMP assay (isothermal) for rapid detection of Nipah 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 RT-LAMP assay (isothermal) for rapid detection of *Nipah 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 RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"* effective/useful in Detection of *Nipah virus*, 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 or further Joint development and commercialization of "A colorimetric RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"*

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product "A colorimetric RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"* (Details of technology/Product) or undertake further R&D and commercialize the end product(s) /technology.

iii. An Agreement (in case of joint development or 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 RT-LAMP assay (isothermal) for rapid detection of

Nipah 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 RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"*

Role of ICMR:

i. ICMR- National Institute of Virology will provide expert guidance & technical support for the production of "A colorimetric RT-LAMP assay (isothermal) for rapid detection of *Nipah 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 RT-LAMP assay (isothermal) for rapid detection of *Nipah 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 Technology Transfer

Interested companies/manufacturers are invited to join hands with ICMR for co-development/ 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 @ 2% on Net sales, as applicable, 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-Litigation (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)
General Criteria		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in 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 ten years, either in-house or through agreed collaboration and must have marketed same/similar products in the past with a good track record.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.
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 should not be involved in any major litigation that may have an impact of affecting or compromising the conditions required under this EoI and in the Agreement	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
Specific Criteria (Based on the nature of the Proposal)		
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
Mobile No.: 9082553865

Dr. Jitendra Narayan
Scientist-D, ICMR-HQ, New Delhi (*For Tech- transfer issues)*
Email: 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 RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"* (1) Diagnostic assay/ Kit against *Nipah virus* (2) disease.

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Ref: ICMR/EoI/Nipah-Virus/2025 dated / /2025

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.		

(1)- Name of the Technology or name of the product
(2)- Commercial use of the Technology/ Product

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:

(1)- Name of the Technology or name of the product
(2)- Commercial use of the Technology/ Product

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: EoI No. **ICMR/EoI/Nipah-Virus/2025** dated / /2025

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technology "A colorimetric RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"* (1) Diagnostic assay/ Kit against *Nipah Virus* (2) disease.

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:……..

(1)- Name of the Technology or name of the product
(2)- Commercial use of the Technology/ Product

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/Nipah-Virus/2025 dated / /2025

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 Non-conviction.
Ref: ICMR/EoI/Nipah-Virus/2025 dated / /2025

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/Nipah-Virus/2025 dated / /2025

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 RT-LAMP assay (isothermal) for rapid detection of *Nipah virus"* (Product details).

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

*The Laboratory/ facility requirement will depend on the technology/ product

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/Nipah-Virus/2025 dated / /2025
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 RT-LAMP assay (isothermal) for rapid detection of *Nipah 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:

RT-LAMP is a relatively new amplification and detection protocol. Unlike RT-PCR which requires denaturation, annealing and extension at different temperatures the RT-LAMP reactions are incubated at a single temperature (isothermal reaction) usually at 65^{o}C for 30-40 minutes. Therefore, LAMP assays are easy to perform, rapid and may become cost-effective. In this invention, a novel colorimetric RT-LAMP assay has been developed for the detection of Nipah virus. The invention involves designing six novel sets of RT-LAMP primers, especially specific to the nucleocapsid (N) and matrix (M) gene of the Nipah virus. The conserved genomic segments amongst the isolates of Nipah virus from India and abroad by performing multiple sequence alignment. The RT-LAMP primers were designed on the basis of four key factors such as the melting temperature (Tm), stability at the 3' and 5' end of each primer (Delta G), GC content and ability to form secondary structures. The primers were synthesized and dissolved in specific proportions which is to be used in the RT-LAMP reaction. RT-LAMP results are read by naked eye as change of the color (pink to yellow) of the reaction mixture at the end of the incubation without the aid of any equipment. Unique points about the assay:

- One temperature amplification reaction, hence does not require a thermal cycler as in case of PCR or real-time PCR.
- The assay specifically detects two genes of Nipah virus (N and M gene).
- The results are interpreted visually by observing the color change. Sophisticated reading instrument not needed.
- As sensitive as the currently available commercial real time RT-PCR assays approved by ICMR.

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

Nipah virus (Nipah Virus, NiV) is a new paramyxovirus in recent years, can cause acute central nervous system disease in humans and animals. The Nipah virus infection is a Zoonotic disease transmitted to humans via Bats. The virus can also be transmitted through contaminated food or direct contact with infected individuals. There is no vaccine or other medical antiviral treatment available and the mortality rate is around 60 to 90%. Therefore, Nipah virus is classified under Biosafety Level 4 (BSL4) virus.

The development of a rapid molecular is of prime importance here because there are no effective field tests available currently for the detection of Nipah virus. This invention discloses a reverse transcription loop-mediated isothermal amplification (RT-LAMP) for the detection of Nipah virus. The laboratory diagnosis of Nipah virus infection includes the following: virus isolation and identification, serum neutralization test (Serum neutralization test, SNT), enzyme-linked immunosorbent assay (Enzyme-linked immunosorbent assays, ELISA), RT-PCR detection, etc. All these detection techniques even though well-established they requires expertise and can be performed only in high-end laboratories. Therefore, the currently available diagnostic tests cannot be applied for surveillance and detection at the point of care. The present invention can be applied to the suspected clinical samples that can be used in the field as a rapid detection assay. This invention is easy to perform, rapid and the results can be interpreted visually and does not require any instruments.

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

The NIV Mumbai Unit designed the LAMP Asssay. In the developer's lab, testing was completed, as the initial pilot study. In BSL-4, NIV, Pune (which is the only laboratory doing *Nipah 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 *Nipah 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, 150 samples (Nipah Isolate, Spiked Human Nasal Swab/Throat Swab samples) were used in the BSL-4, NIV, and Pune (which is the only laboratory doing *Nipah virus* detection.) for performance evaluation of the RT-LAMP. Comparing the RT-LAMP assay to the Real Time PCR, the overall diagnostic sensitivity and specificity was 100% and 100%, respectively.

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: RT-LAMP Assay for the detection of Nipah virus.
Application of the assay: Nipah virus molecular diagnosis.
Details of assay components: Primers (M gene & N gene), Warm Start Colorimetric LAMP Master Mix with UDG, Enhancer, Nuclease free water (NFW)

Objective: To determine the sensitivity and specificity of RT-LAMP Assay developed for detecting Nipah virus in comparison with TaqMan based Real time PCR assay.

Result of the panel tested

ICMR NIV, Pune	Nipah RT-LAMP assay		
Test	**Positive**	**Negative**	**Total number of samples tested**
Nipah Positive	75	0	75
Nipah Negative	0	75	75
Total	75	75	150

Sensitivity = 100%
Specificity = 100%
Comments on performance of the assay: Satisfactory
Conclusion: Satisfactory
(*Sensitivity and Specificity have been assessed in controlled lab settings*)
Remarks:

- The bench marking criteria of validation was as below:
  Sensitivity: ≥95%
  Specificity: ≥ 95%

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

This report is exclusively for Nipah virus RT-LAMP assay provided by ICMR NIV Mumbai unit.

Kit evaluation by
Dr. Anita Shete-Aich, Scientist E

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

20-ए, डा. आंबेडकर मार्ग, पोस्ट बॉक्स संख्या 11, पुणे – 411 001, भारत.
20-A, Dr. Ambedkar Road, Post Box No. 11, Pune 411 001, India
Tel.: NIV Camp +91-020-26127301, 26006290, Fax : 26122669
NIV Pashan +91-020-26006390 Fax : 25871895
E-mail : director.niv@icmr.gov.in Website : www.niv.co.in

IP Filing Status/Publications

Patent: Development of a colorimetric isothermal (RT-LAMP) assay for rapid detection of *Nipah virus*

Indian Patent ApplicationNo: 202211057074, Dated 04/10/2023.

Inventors: Shyam Sundar Nandi (PI), Sonali Sawant, Upendra Lambe, Yadav Pragya, Shete-Aich Anita, Jagadish Deshpande.

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