

EoI No. ICMR / EoI / qRT-PCR / 2023

Dated 15th May 2023

Expression of Interest (EoI)

Transfer of Technology for Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2



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भारतीय आयुर्विज्ञान
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1. Letter of Invitation

INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research (ICMR), New Delhi, invites Expression of Interest (EoI) through email from experienced Indian agencies for undertaking *Transfer of Technology for commercialisation and marketing of Multiplex single tube Real time RT PCR assay for detection of Influenza A , B and SARS CoV2.*

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 / qRT-PCR / 2023 dated 15.05.2023 |
| Date of Publication | 15.05.2023 |
| Last date/Time of submission | 14.06.2023 |

Note: Due to the current COVID-19 situation, the EoI may be submitted through email to sadhana_s@ymail.com and wasona.hq@icmr.gov.in. Shortlisted firms/ organisation shall only be contacted for the further process of Technology Transfer. ICMR reserves the right to cancel this request for EoI and/ or invite afresh with or without amendments, without liability or any obligation for such request for EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add further details in the EoI as may be desired by the competent authority at ICMR and duly modified 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 itself to the growing demands of scientific advances in biomedical research on the one hand and to the need of finding practical solutions to the health problems of the country, on the other..

ICMR-National Institute of Virology (ICMR-NIV), one of the constituent institutes of the Indian Council of Medical Research (ICMR), New has developed a technology entitled “Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2” (hereinafter) referred to as “**Technology**”.

ICMR is lawfully entitled to enter into any form of **non-exclusive agreements** with experienced manufacturing companies hereinafter referred to as the “**Company**”/ “**licensee**” through a defined agreement for Licensing/Commercialization of Combo RT-PCR Kit , hereinafter referred to as the ‘**Product**’.

3. Objective

To license the ‘Technology’ for Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2 effective/useful in prevention of SARS CoV-2 and influenza A & B, for commercialization and marketing activities.

4. Broad Scope of Work

- i. ICMR is willing to transfer the said Technology to the Company on an Upfront license fee and Royalty basis on a fixed term contract for manufacturing and marketing of the Technology.

- ii. The Upfront /Licensing fees for the Technology shall be determined by a Committee constituted by ICMR having Technical experts from the Institute developing the technology and representative from ICMR Hqrs, Sr.FA or Nominee, Sr. Administration and External subject specific experts on the basis of Technology Readiness Level (TRL), Technology valuation etc.
- iii. The Company would be granted rights to undertake manufacture, sell, and commercialize the Product viz Combo RT-PCR Kit. under defined Agreement.
- iv. An Agreement following EoI is proposed to be executed on a “Non-Exclusive” basis with single/multiple companies to enable wider outreach of the Combo RT-PCR Kit for societal benefit.
- v. ICMR-National Institute of Virology (ICMR-NIV) has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of Combo RT-PCR Kit
- vi. ICMR-NIV Institute will provide expert guidance & technical support for the production of Combo RT-PCR Kit, in all phases. Such technical oversight by ICMR-NIV Institute would accelerate the development of the Product and its commercialization.
- vii. The technology developed is owned by ICMR and holds the IP, which 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; and shall include without limitation, the Technology, Licensed Patents and Licensed Trademarks developed/ created pursuant to this EoI through ICMR support.

5. Role of ICMR

ICMR-NIV Institute, shall hand over or provide ‘Technology’ for Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2 including detailed technical know-how to the licensee or manufacturers selected through the EoI to enable them to commercialise the technology for societal benefit

6. Role of company

- a. The Company shall undertake the scale-up as required, manufacturing and commercialization of the ‘Technology’ for Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2
- b. The company will share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

- c. The company agrees to allow authorized personnel/scientist/team of ICMR to visit the production facility as and when required, as envisaged under this EoI and subsequent Agreement.
- d. 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.

7. Intellectual Property Rights

ICMR is the 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) 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).

8. Revenue upon technology rights/Royalty payouts

Manufacturers may quote Royalty not less than 5 % (five percentage) on net Sales of the PRODUCT on half yearly basis as entered in the books of account maintained by COMPANY, up to 31st March and up to 30th September respectively every year regularly and punctually and in any event not later than the first day of May and first day of November immediately following in every such year provided that the liability of the COMPANY to pay royalty under and in terms of this sub-clause (A) shall accrue upon the commencement of the commercial sale of the Product ("**Royalty**") manufactured at the plant and shall continue till the Term as per the terms of "**ICMR-Technology Transfer and Revenue Sharing Guidelines 2021**" and as per the amendments approved by the Competent Authority from time -to- time.

In the event of default in payment of royalty as above, interest @ 12% per annum on the Royalty due shall be charged for the first six months. If default persists for more than six months interest at similar rate will be charged on the accrued interest also from the due dates of payments till realisation/recovery of such amounts by the ICMR. Taxes and levies, as made applicable by the Government, shall be charged at the time of payments made to ICMR over and above the payments that shall be applicable as per the terms of specified License Agreement to be executed with selected companies.

9. Validity of Contract

- i. A License Agreement shall be executed with the selected Company to decide conditions for execution of this collaborative activity or Licensing activity.
- ii. This Agreement shall be valid from the EFFECTIVE DATE and subject to covenants and conditions herein contained and shall remain in force for a period of twenty (20) years commencing from the accrual of COMPANY's obligation to pay Royalty to ICMR, after the commercialization of the Product (the "Term"). After the period of 20 years the LICENSE will be royalty free.

“NET SALES” shall mean Revenue from sales of goods or services by all ICMR grantees/Licensees/Sub-licensee(s) based on the net sales realization from operations, net of discounts and indirect taxes as defined by Cost Accounting Standards-24 and certified by the Chartered Accountant

10. Instructions to Proponents

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements w.r.t technical / financial capabilities for acceptance and submission of documents for verification by ICMR.

Documents to be furnished are:

Technical Bid

- a. Authorization Letter (Format – 1)
- b. Declaration - Expression of Interest (Format – 2)
- c. Undertaking with regard to Blacklisting (Format-3)
- d. Undertaking with regard to Non-Litigation (Format – 4)
- e. Production Capacity Undertaking (Format-5)
- f. Royalty Offer (Format-6)
- g. EoI document with each page duly stamped and signed by the Authorized signatory.
- h. Supporting documents, as mentioned in Format-2
- i. MSME Certificate (if applicable)
- j. Any other information which proponent may like to provide.

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

Financial Bid

Upfront/License fee and Royalty Offer (Format-6)

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

11. Rejection Criteria

The application is liable to be rejected if:

- a. The proposal is not submitted as per the requirements indicated in the EoI.
- b. Not in the prescribed format.
- c. Not properly stamped and signed as per requirements.
- d. Received after the expiry of due date and time.
- e. All relevant supporting documents are not furnished with the PQC.
- f. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

12. Disclaimer

- a. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
- b. ICMR reserves the right to reject all applications without assigning any reasons thereof.
- c. 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.
- d. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

13. 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. Only shortlisted proponents shall be contacted for discussion, finalization & execution of the License Agreement/Agreement.

The evaluation of the EoI shall be carried out in two distinct stages-

Stage 1: Technical stage where technical aspects will be evaluated.

Stage II: Financial Stage where eligible Stage I applicants will be evaluated on the basis of their quoted upfront fee and proposed royalty percentage.

The interested applicants are requested to apply in two separate envelopes **Technical Bid (Annexure A)** and **Financial Bid (Annexure B)** as per the Format given in the EoI Document. The envelope shall also bear the EoI reference number.

Mention on the top of the envelope, the following details:

1. CONFIDENTIAL – **Technical Bid** for Licensing of Technology
2. CONFIDENTIAL – **Financial Bid** for Licensing of Technology

Note : The Financial Bids of only those applicants shall be opened who qualify the Technical Bid.

14. 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 | Supporting copy of documents required <i>(All documents must be self-attested by the authorised person of the proponent).</i> |
|---------|--|--|
| 1 | The proponent shall be a legal entity, registered as a Company/LLP/Society/ partnership firm/ proprietorship firm under respective acts in India. | Company Incorporation Certificate from ROC/Partnership deed etc. |
| 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 manufactured qRT PCR products for any other disease, at least in three (3) immediate preceding years (2017-18 to 2019-20). | Pamphlet / brochure of the product |
| 4 | The proponent has to be profitable and should not have incurred loss at least in three (3) immediate preceding years (2017-18 to 2019-20). | Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return. |
| 5 | The proponent should not have been black-listed by any Central /State Government / Public Sector Undertaking, Govt. of India, at least in | Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3). |

| | | |
|----|--|---|
| | three (3) immediate preceding years (2017-18 to 2019-20). | |
| 6 | The proponent should have a registered office and a manufacturing Unit in India | Registration copies of both |
| 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 MoU. | Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4) |
| 8 | GMP and ISO Certification | Registration copies of both |
| 9 | DCGI License, can be obtained parallelly | Licence copy |
| 10 | Capacity to produce at least one lakh qRT-PCR test kits per week | Undertaking (As per format – 5) |
| 11 | Royalty offer | (As per format – 6) |

In case of any clarification required, please contact:

For scientific issues

Dr. Varsha Potdar, Scientist-E, ICMR-NIV, Pune - 9890307757

For Administrative issues

Dr. R. Lakshminarayanan, ADG (A), ICMR, New Delhi - 9422517998

Format-1

Authorization Letter

(To be submitted on Agency's Letter Head)

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

Subject: Letter for Authorized Signatory
Ref. No. Ref: EoI No. ICMR / EoI / qRT-PCR /2023 dated -----
Sir,

This has reference to your above mentioned Expression of Interest (EoI) for Transfer of Technology for Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2 for screening human respiratory samples.

Mr./Miss/Mrs/Dr _____ is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s _____ (Agency Name).

The specimen signature is attested below:

Name: _____

(Specimen Signature of Representative)

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

Format-2
Expression of Interest
(To be submitted on Agency'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 Multiplex single tube Real time RT PCR assay for detection of Influenza A , B and SARS CoV2 for screening human respiratory samples.

Ref: EoI No. ICMR / EoI / qRT-PCR /2023 dated -----

Sir,

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

| | | |
|---|--|--|
| 1 | Name of the Proponent | |
| 2 | Address | |
| 3 | Name, designation & address of the person to whom all references shall be made | |
| 4 | Telephone No. (with STD code) | |
| 5 | Mobile No. of the contact person | |
| 6 | 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 | Pamphlet or Brochure | | |
| 4 | Certificate from the Chartered Accountant of the Organization/Audited Balance sheets for last three financial years, Income Tax return. | | |
| 5 | Proof of a registered office and a manufacturing Unit in India. | | |

| | | | |
|----|--|-------------------|--|
| 6 | GMP and ISO Certification. Registration copies of both | | |
| 7 | DCGI License | | |
| 8 | Authorization Letter | As per format – 1 | |
| 9 | Expression of Interest | As per format – 2 | |
| 10 | Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory. | As per format – 3 | |
| 11 | Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory | As per format – 4 | |
| 12 | Undertaking to produce atleast one lakh test kit per week | As per format – 5 | |
| 13 | Royalty Offer | As per format – 6 | |
| 14 | MSME Certificate (if applicable) | | |

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 Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

Format-3
Undertaking with regard to blacklisting
(To be submitted on Agency's Letter Head)

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

Subject: Undertaking regarding Blacklisting / Non-Debarment

Ref. No. Ref: EoI No. ICMR / EoI / qRT-PCR /2023 dated ---

Sir,

It is hereby confirmed and declared that M/s _____ is not blacklisted/debarred by any Government Department/Public Sector Undertaking/ Private Sector/or any other agency for which works/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

Format-4
Undertaking with regard to Non-Litigation
(To be submitted on Agency's Letter Head)

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

Subject: Undertaking regarding Litigation

Ref. No. Ref: EoI No. ICMR / EoI / qRT-PCR /2023 dated 15.05.2023

Sir,

It is hereby confirmed and declared that M/s -----, does not have any litigation / arbitration history with any Government department/ Public Sector Undertaking/ / or any other public authority with which any MoU was / has been executed / undertaken.

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

Format-5
Undertaking with regard to production capacity
(To be submitted on Agency's Letter Head)

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

Subject: Undertaking regarding Production Capacity

Ref. No. Ref: EoI No. ICMR / EoI / qRT-PCR /2023 dated 15.05.2023

Sir,

It is hereby confirmed and declared that M/s -----, does have the capacity (including fund, material, staff etc) to produce and market at least 01 (one) lakh test kits per week of Multiplex single tube Real time RT PCR assay for detection of Influenza A , B and SARS CoV2 for screening human respiratory samples.

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

Format-6
Undertaking for Royalty
(To be submitted on Agency's Letter Head)

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

Subject: Undertaking for Royalty

Ref. No. Ref: EoI No. ICMR / EoI / qRT-PCR / 2023 dated 15.05.2023

Sir,

It is hereby confirmed that M/s -----, agrees to pay a Royalty of ---- % (in words----) on Net Sales to the ICMR, as per the terms for the Transfer of Technology of Multiplex single tube Real time RT PCR assay for detection of Influenza A, B and SARS CoV2 for screening human respiratory samples

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

SCHEDULE – A

TECHNOLOGY

Multiplex single tube Real time RT PCR assay for detection of Influenza A , B and SARS CoV2 for screening human respiratory samples.

ICMR's invention/Collaborated Inventions: It is developed by ICMR- National Institute of Virology (ICMR-NIV), Pune, India a premiere institute of ICMR.

Inventors: Dr. V A Potdar

Co-Inventors: Mrs Sheetal Jadhav, Mrs Veena Vipat

Coordinators: Director, ICMR-NIV, Pune

Need of Technology:

Increased testing capacity is key for control of SARS CoV-2 pandemic. ICMR National Institute of Virology Pune as apex laboratory developed robust RT PCR diagnostic method to detect SARS CoV-2 and technology was successfully transferred. In addition, the test is widely used in public health laboratories, validation of make in India kits and Covaxin phase II and III clinical trials for rule out infection.

Influenza surveillance in the community is an important tool for monitoring circulating strains, detection of emerging / remerging viruses, and epidemiological trends and to define seasonality in different geographical areas. It is also relevant for the evaluation of antigenic and genetic characteristics of circulating strains in comparison with recommended vaccine strains. The influenza virus surveillance system has been well established in India and has greatly contributed to vaccine selection and control of influenza virus infections.

India, though physically located in northern hemisphere, has distinct seasonality related to latitude and environmental factors. Given the diverse topography and climatic conditions in various parts of India, a systematic laboratory-based surveillance of influenza viruses revealed major peaks of influenza coinciding with the rainy season though some level of circulation was observed throughout the year.

In the year 2021 globally and in India influenza activity was noticed along with SARS COV-2. The vigilance is required to understand the co circulation of influenza viruses. It is necessary to have a combined test to detect SARS CoV 2 and influenza in one go to avoid delay in reporting

Technology details:

Selection of target genes:

The composition of the kit was adapted from existing influenza CDC and the WHO SARS CoV2 protocols. The protocol was validated using control material i.e. influenza isolates and the in hose prepared synthetic RNA for SARS CoV2.

The target genes includes ORF 1b gene specific to SARS CoV 2, M gene for universal detection of all influenza A, HA types and NS gene for Type B along with *Beta Actin* housekeeping gene

Preparation of positive control (In vitro Transcribed RNA)

in vitro transcribed (IVT) RNA was synthesized using T7 Riboprobe (Promega). Ten-fold serial dilutions of each transcribed RNA product were tested with respective gene primer probes sets for specific detection and limit of detection.

Validation of the kit

The kit was validated by 6 VRDL laboratories.

Panel Prepared by ICMR NIV Pune and distributed to six VRDL

To have a consistent panel for all validation exercises by VRDLs, a standard panel from in-vitro grown viruses were prepared. This ensured the uniformity of titre and viral load of samples between subsequent panels. Lab grown influenza viruses (A and B) tested using NIV's duplex real time RTPCR (qRT PCR) assay as a gold standard assay. Similarly, SARS-CoV2 positive tested using NIV's single tube multiplex assay as a gold standard assay.

Each virus was serially and appropriately diluted (10 fold dilutions) to have samples with medium (Ct 24-27) and high (30-35) Ct values.

1. All the neat and diluted virus will be stored in aliquots at -80C with suitable protectant.
2. Influenza and SARS-CoV-2 cell culture samples (equal representation of individual Influenza A, Influenza B, SARS-CoV2 and combined samples with low, medium and high Ct values) formed positive panel. Limit of Detection (LoD) for each sample checked before making the panel.
3. Each individual sample taken in replicates of 5 for each Ct value which will count 45 and combined samples taken in replica of 3 for each Ct value (table A and B below) which will count 27 (total n=72).

Table

A: Neat sample distribution (n=45) in replica of 5

| Virus type | Ct range | | |
|----------------|--------------|----------------|---------|
| | High (30-35) | Medium (24-29) | Low <20 |
| Inf A (15) | 5 | 5 | 5 |
| Inf B (15) | 5 | 5 | 5 |
| SARS-CoV2 (15) | 5 | 5 | 5 |

B. Combination to be tested for co-infection (n=27) in triplicates

| Virus | | Ct range | | | | | | | | |
|-----------|-----------|----------|--------|-----|--------|------|--------|------|--------|------|
| Inf A+ | Inf A | High | Medium | Low | High | High | Medium | Low | Medium | Low |
| Inf B+ | Inf B | High | Medium | Low | Medium | Low | High | High | Medium | Low |
| SARS-CoV2 | SARS-CoV2 | High | Medium | Low | Medium | Low | Medium | Low | High | High |

4. Negative samples (n=85)
5. Clinical samples negative for Influenza A, Influenza B and SARS-CoV-2 but positive for other respiratory viruses (ORVs) such as Human corona virus, Parainfluenza virus, Rhino virus, Respiratory Syncytial virus as per availability (n =10). Cell culture supernatant without virus inoculation (n=75)

Five centre independently validated NIV Multiplex assay and submitted the results to ICMR. **The performance for the kit was satisfactory with sensitivity 98-99% and specificity 100%.**

• **Analytical sensitivity / limit of detection was determined using 10-fold serial dilutions of in-vitro transcripts (RNA) of ORF1ab of SARS-CoV-2 M gene of Influenza B and NS gene of Influenza B. Performance of each target was as follows ORF 1ab detects 22 copies, Influenza A detects 15 copies and Influenza B detects 15 copies**

Application areas/Applicability:

- Single tube multiplex RT PCR test developed for detection of SARS CoV-2 and Influenza A and B viral RNA in suspected ILI and SARI cases.
- To check the reinfection and co infections
- To check the SARS Cov-2 status before vaccination.
- In anti SARS CoV-2 and anti-influenza property of compound

Unique points:

- The NIV Single tube multiplex assay is robust detection system and allow simultaneous detection of SARS CoV2 and Influenza A and B
- This is a gold slandered assay which is used by Pan India surveillance of influenza and SARS CoV 2 mainly by 30 ICMR VRDL laboratories.
- This is the first SARS CoV-2 and Influenza combo assay developed and implemented in program.
- The test developed is rapid, cost-effective, user friendly and can detect SARSCoV-2 and Influenza A and B viral RNA in respiratory sample.
- The kit can detect co infections with SARS CoV 2 and Influenza A and B
- It can give high through put testing capacity 93 samples per run in short turnaround time (actual run time is 45 mints)
- The kit reagents are stable at -20⁰ C for long time i.e. 12 months from the date of preparation.
- **Up scaling Status**
- The technology can be scaled up for wide used.
- Individual kit lots will be tested for QA/Qc and only then dispatched as per need.
- Till date 1.5 Lakh reagents were distributed to Government laboratory all over India
- Validation (3rd party): We participated in two WHO External Quality assurance program and had 100% concordant results

Patent profile: Has been filed on September 16, 2022 and the patent application number is 202211052927.
