EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) rRT-PCR/2021, dated 17.12.2021

Expression of Interest (EOI)

Indian Council of Medical Research, New Delhi

invites EoI for

Transfer of technology for development and commercialization of SARS-CoV-2 Omicron (B.1.1.529) Real time rRT-PCR assay

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

INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research, New Delhi, invites Expression of Interest (EOI) through email from experienced IVD kit manufacturers for undertaking Transfer of technology for development and commercialization of SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay (rRT-PCR) through a novel diagnostic kit, developed by ICMR.

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/ToT/SARS-CoV-2 (OMICRON) rRT-PCR/2021dated 17.12.2021
Date of Publication	Date: 17.12.2021
Last date/Time of submission	Date: 22.12.2021, Time 17:30 IST

Note: Due to the current COVID-19 pandemic situation, the EOI may be submitted through email to jitendra.narayan@gov.in. Shortlisted manufacturing companies shall only be contacted for the further process of Technology Transfer.

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 further details in the EOI.

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 to the need of finding practical solutions to the health problems of the country, on the other.

Objective

ICMR-Regional Medical Research Centre, NE (ICMR-RMRC-NE) one of the Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has developed a novel TECHNOLOGY i.e. **Real time RT-PCR assay for detection of the Omicron (B.1.1.529) variant of SARS-CoV-2 and a kit for the same.** ICMR is the owner of said TECHNOLOGY including any underlying Intellectual Property(ies) and Commercialization rights. ICMR is lawfully entitled to enter into any form of non-exclusive license agreements with selected manufacturer / manufacturers including transfer of the TECHNOLOGY through suitable agreement to any other interested manufacturers.

Broad Scope of Work

Subject to the terms and conditions of an Agreement, more particularly a license agreement, ICMR shall grant a non-exclusive License to the manufacturer (s), a royalty bearing right and license to use and practice the Technology and PROCESSES ("Licensed Technology") to manufacture, sell and commercialize the Product **(Technologies as indicated in Schedule-A)**, including a non-exclusive right to manufacture, sell and market Products worldwide and the right to use Licensed Technology for manufacturing Products worldwide; during the Term of a specific license Agreement ("License"). The Agreement, following EoI is proposed to be executed on "Non-Exclusive" basis with multiple manufacturers, due to the extensive demand of SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay that is being envisaged.

Product Validation

a. ICMR is currently undertaking external validation of this technology and 'Technology Transfer' will be executed only after its successful completion.
b. The product manufactured/developed by the manufacturer (s) shall be validated to ensure the quality and performance as per the validation norms, prior to seeking test license from DCGI. Subsequent, validation shall be undertaken as and when decided by ICMR. Failing in developing/manufacturing product with Standard Quality, may lead to cancellation of this contract.

Revenue upon Technology Rights

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 LICENSEE, up to 31st March and up to 30th September respectively every year regularly and punctually and in any event not later than the last day of April and last day of October immediately following in every such year provided that the liability of the LICENSEE 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, as per the terms of ICMR-Technology Transfer and Revenue Sharing Conditions.

In the event of default in payment of royalty as above, interest @ 12% (twelve percentage) 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 realization/recovery of such amounts by the LICENSOR. Taxes and levies, as made applicable by the Government, shall be charged at the time of payments made to LICENSOR over and above the payments that shall be applicable as per terms of specified license Agreement to be executed with selected companies.

"NET SALES" shall mean the gross sales made by the company/ its license/ its sub-licenses based on the MRP of the product excluding excise duty. GST or any other levies, as defined by the Indian Accounting Standard and certified by the Charted Accountant.

Validity of contract

This LICENCE 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 LICENSEE's obligation to pay Royalty to LICENSOR, after the commercialization of the Product (the "Term"). After the period of 20 years the LICENSE will be royalty free.

Instructions to Proponents

Documents to furnish

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

Documents to be furnished are:

i. Authorization Letter (Format – 1)
ii. Declaration - Expression of Interest (Format – 2)
iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to Non-Litigation (Format – 4)
v. Production Capacity Undertaking (Format-5)
vi. Royalty Offer (Format-6)
vii. EOI document with each page duly stamped and signed by the Authorized signatory.
viii. Supporting documents, as mentioned in Format-2
ix. MSME Certificate (if applicable)
x. 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.

Rejection Criteria

The application is liable to be rejected if:

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

Disclaimer

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

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. Shortlisted proponent shall be sent the License agreement, approved by the competent authority, ICMR for execution.

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** (All documents must be self-attested by the authorized person of the proponent)
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 prior experience in manufacturing of Real-Time rRT-PCR diagnostic assays for any infectious disease and must have marketed such products in three (3) immediate preceding years.	Pamphlet / brochure of the product/DCGI License for existing rRT-PCR product
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years.	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 on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).

	Undertaking, Govt. of India, at least in three (3) immediate preceding years.	
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		
10	Capacity to produce at least one lakh rRT-PCR test kits per day	Undertaking (As per format – 5)
11	Royalty offer	(As per format – 6)

In case of any clarification required, please contact:

For scientific issues-
Dr. Biswajeet Borkakoty, Scientist-E, ICMR-RMRC, Dibrugarh, Mobile: -9435131316, email: - biswaborkakoty@gmail.com

For Administrative issues
Dr. R. Lakshminarayanan, DDG (Admin), ICMR HQ, New Delhi
Mobile: 9422517998, Email: - lakshminarayanan.r@icmr.gov.in

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: EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) rRT-PCR/2021dated 17.12.2021

Sir,

This has reference to your above-mentioned Expression of Interest (EOI) for technology transfer for development of SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay.

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

(Specimen Signature of Representative)

Date:

Place:

Yours faithfully,

(Signature of the Authorized signatory)

Name:……..

Designation:……..

Seal:……..

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 Technology for development of SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay.
Ref: EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) rRT-PCR/2021 dated 17.12.2021

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 development/ commercialization /manufacture/ sell 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	Pamphlet or Brochure of kits		

	manufactured earlier		
4	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for las three financial years, Income Tax return.		
6	Proof of a registered office and a manufacturing Unit in India.		
8	GMP and ISO Certification. Registration copies of both		
9	DCGI License for existing rRT-PCR diagnostics		
10	Authorization Letter	As per format – 1	
11	Expression of Interest	As per format – 2	
12	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory	As per format – 3	
13	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
14	Undertaking to produce at least one lakh test kit per day	As per format – 5	
15	Royalty Offer	As per format – 6	
16	MSME Certificate (if have any)		

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-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: EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) RT-PCR/2021 dated 17.12.2021.

Sir,

It is hereby confirmed and declared that M/s……has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other agency 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-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: EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) RT-PCR/2021 dated 17.12.2021.

Sir,

It is hereby confirmed and declared that M/s…..... and owner of the firm / board of directors, do not have any litigation / arbitration pending/under trial in court.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
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 with regard to production capacity.
Ref: EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) RT-PCR/2021 dated 17.12.2021.

Sir,

It is hereby confirmed and declared that M/s…… does have the capacity in all mean (including infrastructure, fund, material, staff etc.) to produce and market at least 01 (one) lakh SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay per day.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
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: EOI No. ICMR/EOI/ToT/SARS-CoV-2 (OMICRON) RT-PCR/2021 dated 17.12.2021.

Sir,

It is hereby confirmed that M/s ……, agrees to pay a Royalty of **5 % (Five Percent)** to the ICMR to be calculated against the Net Sales done with respect to the ICMR technology of SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay. (As per the terms of ICMR-Technology Transfer and Revenue Sharing Conditions, the 'Net sales' shall means the gross sales made by the company/ its license/ its sub-licenses based on the MRP of the product excluding excise duty. GST or any other levies, as defined by the Indian Accounting Standard and certified by the Charted Accountant.)

Yours faithfully,

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

SCHEDULE – (A)

About the Technology

Detection of the SARS-CoV-2 Omicron (B.1.1.529) variant by Real time RT-PCR assay

ICMR's invention/Collaborated Inventions: The technology for detection of the SARS-CoV-2 Omicron (B.1.1.529) variant by Real time RT-PCR is solely developed by ICMR-Regional Medical Research Centre, North East (ICMR-RMRC-NE), Dibrugarh, India which is a premiere institute of Indian Council of Medical Research governed by Department of Health Research, Ministry of Health and Family Welfare, Government of India.

Running title of technology: Development of SARS-CoV-2 Omicron (B.1.1.529) Real time RT-PCR assay and diagnostic kit thereof.

Need of Technology:

A new variant was first detected in specimens collected on November 11, 2021 in Botswana and on November 14, 2021 in South Africa, which was identified as SARS-CoV-2 lineage B.1.1.529. On November 26, 2021, WHO named the lineage B.1.1.529 as Omicron and classified it as a Variant of Concern (VOC).This has now spread to over 58 countries within one-month. The Omicron variant of SARS-CoV-2 is reported to have up to 40% mutation majorly in S gene. Over 50 mutations have been reported so far, including 32 in the important surface glycoprotein or Spike protein compared to the reference Wuhan strain NC 045512.2. These mutations may have consequences in increased transmission in public and infected people may have moderate to severe symptoms. There is a risk over its high transmission rate that it could infect larger population. Therefore, for early diagnosis for Omicron variant, there is a substantive need to have dedicated rRT-PCR assay that can detect the Omicron variant.

Methodology:

The technical details including methodology are main part of the technology transfer, which is duly covered under the intellectual property rights solely owned by ICMR, the same shall be shared only after finalization and execution of License Agreement.

Application areas/Applicability:

The test is a real time RT-PCR assay to detect the presence of SARS-CoV-2 and specifically distinguish it separately the Omicron variant (B.1.1.529) of SARS-CoV-2 based on use of multiple fluorescent reporter and quencher dyes.

Unique points:

This is first kind of kit developed in India that has the ability to detect SARS-CoV-2 and distinguish Omicron variant (B.1.1.529).

Up scaling Status

The technology for rRT-PCR assays for detection of SARS-CoV-2 (Omicron variant) has been developed and standardized at ICMR-RMRC, Dibrugarh. The technology is ready to transfer for commercialization.

Expected Product:

A rRT-PCR Assay and a diagnostic kit for detection of SARS-CoV-2 and specifically for identification of Omicron variant (B.1.1.529) from the human samples.

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