

EOI No. ICMR / EOI /CC16/ 2021

Dated 5<sup>th</sup> April, 2021

**Indian Council of Medical Research, New Delhi**

**Invites**

**Expression of Interest (EOI)**

**For**

**Transfer of Technology on “A point of care rapid detection kit for semi quantitative estimation of CC16 in human samples”**

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## 1. Letter of Invitation

### INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research, New Delhi, invites Expression of Interest (EOI) through email from experienced Indian agencies for undertaking “**A point of care rapid detection kit for semi quantitative estimation of CC16 in human samples**”

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.

Schedule for the Proponents is as under:

EOI Document Number	ICMR / EOI / CC16/2021
Date of Publication	6 <sup>th</sup> April, 2021
Last date/Time of submission	21 <sup>st</sup> April, 2021

Note: Due to the current COVID-19 situation, the EOI may be submitted through email to [sadhana\\_s@ymail.com](mailto:sadhana_s@ymail.com) and [wasona.hq@icmr.gov.in](mailto:wasona.hq@icmr.gov.in). Shortlisted manufacturing companies 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.

## 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. The ICMR has come a long way from the days when it was known as the IRFA, but the Council

is conscious of the fact that it still has miles to go in pursuit of scientific achievements as well as health targets.

### **3. Objective**

**ICMR- National Institute of Virology, Mumbai Unit and ICMR- National Institute of Occupational Health** both are the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, have developed a new and useful TECHNOLOGY, (Technology as indicated in **Schedule-A**) and is the owner of said TECHNOLOGY including any underlying Intellectual Property(ies) and Commercialization rights. By virtue of financial support and research endeavour provided by ICMR, they 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) on the invention(s) arising out of such endeavours, and/or 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.

### **4. Broad Scope of Work**

Subject to the terms and conditions of an 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 commercialise the Product (Technologies as indicated in Schedule-A) in the designated Territory, including without limitation the right to use, copy, modify, distribute, make derivative works of and otherwise exploit the Licensed Technology 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 this Agreement (“License”). The agreement is proposed to be executed on “Non-Exclusive” basis with multiple manufacturers.

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 31<sup>st</sup> March and up to 30<sup>th</sup> 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 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 and shall continue till the Term from such commencement and after the Term the Licensed Technology will be royalty free. In the event of default in payment of royalty as above, interest @ 2% (two 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 realisation/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 mentioned in this Agreement.

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 LICENCE will be royalty free.

“**NET SALES**”, means, with respect to a given calendar quarter, the gross amount invoiced, less the deductions calculated in accordance with the Indian Accounting Standards.

## **5. Instructions to Proponents**

### **5.1 Documents to furnish**

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:

- 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.

## **5.2 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.

## **5.3 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.

## **6. 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 proponents shall be sent the Memorandum of Understanding (MoU), Material Transfer Agreement (MTA) and other required documentations.

### 7. 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 ELISA products for any other disease, atleast 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 atleast 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, atleast 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 1 lakh Lateral flow test kits per week	Undertaking (As per format – 5)
11	Royalty offer	(As per format – 6)

In case of any scientific clarification required, please contact:

**Dr. Shyam Sundar Nandi (Scientist D/ Assistant Director)**

**ICMR-NIV Mumbai unit (*For scientific issues*)**

M-9082553865

***(For Tech-transfer issues)***

**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 /CC16 / 2021 dated ..... 2021

Sir,

This has reference to your above mentioned Expression of Interest (EOI) for development of "A point of care rapid detection kit for semi quantitative estimation of CC16 in human 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:

**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 on “A point of care rapid detection kit for semi quantitative estimation of CC16 in human samples”

Ref: EOI No. ICMR / EOI / ..... 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.		
6	Proof of a registered office and a manufacturing Unit in India.		
8	GMP and ISO Certification. Registration copies of both		
9	DCGI License		
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	As per format – 3	

	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 atleast one lakh test kit per week	As per format – 5	
15	Royalty Offer	As per format – 6	
16	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:

Place:

**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 / ..... Dated .....  
2021

Sir,

It is hereby confirmed and declared that M/s \_\_\_\_\_ is not blacklisted/debarred by any Government Department/Public Sector Undertaking/PrivateSector/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:

**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 / ..... dated .....2021

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:

**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 / .....dated .....2021

Sir,

It is hereby confirmed and declared that M/s -----, does have the capacity (including fund, material, staff etc) to produce and market atleast 01 (one) lakh test kits per week of point of care rapid detection kit for semi quantitative estimation of CC16 in human samples.

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

**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 / ..... dated ....., 2021

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 development of 'A point of care rapid detection kit for semi quantitative estimation of CC16 in human samples.'

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:



**SCHEDULE – A**  
**TECHNOLOGY DETAIL**

**Title: “A point of care rapid detection kit for semi quantitative estimation of CC16 in human samples”**

ICMR’s invention by ICMR-NIV Mumbai Unit and ICMR-NIOH

Inventors: Dr. Shyam Sundar Nandi, Dr. Upendra Lambe, Dr. Kamalesh Sarkar, Sonali Ankush Sawant, Trupti Gohil, Dr. Jagadish Mohan Deshpande

**Need of Technology:**

At present-day, the CC16 detection is performed with commercially available enzyme linked immunosorbent assays (ELISA) of clinical field application. The available commercial assays are very expensive and cannot be afforded by the daily wage workers. Thus, there is a need for economical, user friendly and rapid detection devices and methods which do not require expensive instrumentation or specialized skills for testing and analysis.

**Technology details:**

The present invention provides a point of care device and method based on sandwich enzyme linked immunosorbent assay for CC16 quantification in serum and plasma samples. A novel membrane based semi quantitative detection of physiological levels of CC16 in the serum and plasma has been provided. The device of the present invention is affordable and easy to use strip based diagnostic test for CC16 for early detection of silicosis through periodic screening among occupationally silica dust exposed workers.

**Application areas/Applicability:**

1. The test provides a point of care assay for screening of silicosis by semi-quantitative detection of CC16 protein in serum samples.
2. This immuno-assay is applicable for semi-quantitative detection of CC16 protein.
3. The assay will be most preferred for screening of patients for early detection of silicosis through periodic screening among occupationally silica dust exposed workers.

**Unique Selling Points:**

- The method of the present invention is quite robust and requires low amount of sample of about 10µl.
- The device of the present invention is a point of care device and thus can be used without high operational needs/equipment.
- The time for diagnosis is 10 minutes whereas the conventional tests take a minimum of 3 hours and 20 minutes depending on the techniques used.
- There is no need of any technical expertise or training to diagnose the patients with the present kit as the diagnosis is based only on visualization of bands i.e. presence or absence and number of bands on the strips.

**Patent:**

Indian Patent Application No: 202011014266 and International PCT application no. *PCT/IN2021/050328* (31<sup>st</sup> March, 2020) has been filed.