EOI No. ICMR / EOI / Rapid Antibody/ 2020 Dated 03/11/2020

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

**Invites**

**Expression of Interest (EOI)**

**For**

# Transfer of Technology on "ICMR COVID-19 Rapid Antibody detection kit"

**CONTENTS**

## 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 "***Transfer of Technology on ICMR COVID-19 Rapid Antibody detection kit"***

The EOI Document containing the details of qualification criteria, submission details, briefobjective & 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 /Rapid Antibody / 2020 |
| Date of Publication | 03/11/ 2020 |
| Last date/Time of submission | 13/11/.2020 : 1300 hrs |

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 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 andwithout 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 Immunohematology is one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has 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 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 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 LICENSE 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 workfor execution & requirements w.r.t technical / financial capabilities for acceptance andsubmission 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. ICMRmay 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 theminimum 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 authorised 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 manufactured ELISA products for | Pamphlet / brochure of the product |

| | | |
|---|---|---|
| | any other disease, atleastin three (3) immediate preceding years (2017-18 to 2019-20). | |
| 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 three (3) immediate preceding years (2017-18 to 2019-20). | Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3). |
| 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 parallely | Licence copy |
| 10 | Capacity to produce atleast one lakh ELISA test kits per week | Undertaking (As per format – 5) |
| 11 | Royalty offer | (As per format – 6) |

In case of any clarification required, please contact:

**Dr Manisha Madkaikar,**

Director, ICMR-National Institute of Immunohaematology,

Mumbai, Phone: 022-24132928 (***For scientific issues***)

**Dr. Sadhana Srivastava**

Scientist F, IPR Unit,

Indian Council of Medical Research (ICMR), New Delhi;

Phone: 011-26589959; 011- 26589745/Ext. 372 (***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 / ..... / 2020 dated ..... 2020

Sir,

This has reference to your above mentioned Expression of Interest (EOI) for development of .....

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 technology on.....

Ref: EOI No. ICMR / EOI / ..... / 2020 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 | As per format – 3 | |

| | | | |
|---|---|---|---|
| | & 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 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:

**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 / RAPID ANTIBODY / 2020 dated ……. 2020

Sir,

It is hereby confirmed and declared that M/s _____ is notblacklisted/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:

**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 / RAPID ANTIBODY / 2020 dated ……2020

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 / RAPID ANTIBODY/2020 dated …….2020

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 Rapid Antibody against SARS CoV-2.

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 / RAPID ANTIBODY / 2020 dated ……., 2020

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 Rapid Antibody against SARS CoV-2.

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

## SCHEDULE – A

## TECHNOLOGY

**Title: ICMR COVID-19 Rapid Antibody detection kit**

**ICMR's invention/Collaborated Inventions:** It is developed by **ICMR- National Institute of Immunohematology** a premiere institute of ICMR.

**Need of Technology:**

The corona virus disease 2019 (COVID-19) has been rapidly spreading nationwide and abroad. The "gold - standard" test for the diagnosis of COVID-19 is real time (RT) PCR, not all patients or cases with mild symptoms or asymptomatic cases are subjected to RT- PCR analysis. It is also not practically feasible in a country like India, considering the cost, number of subjects to be screened and the required technical expertise. The sero-conversion in case of COVID-19 generally occurs from $4^{th}$ or $5^{th}$ day after the onset of symptoms. The antibody response, which is critical for clearance of these viruses from the body can not only be used for diagnosis but also can provide an estimate of the actual rate of infection. IgM are the first antibodies that appear in response to the initial exposure to an antigen, while IgG appear later to the antigen. The antibody tests are useful for

(a) they can act as complementary tests to RT-PCR

(b) they are cheap, quick, and accessible as point of care (POC) tests(c) plasma/ serum or whole blood samples can be used and there is no need of buccal swabs.

**Technology details:**

Please consider not disclosing technical detail. Standardization of the LFIA antibody test involved many different experiments and combinations. Different size of gold nanoparticles were prepared and used. These GNPs were then adjusted to different pH for optimal binding using different buffers. The pore size of membranes play an important role and temperature & RT were checked for maximum sensitivity. With commercially available recombinant COVID antigen, the antibody test was standardized for giving specific and sensitive results. The results should be recorded between 15-20 minutes only. Beyond 30 minutes false positive results may be observed. The kit detects the COVID-19 IgG and IgM antibodies present in the given sample.

**Application areas/Applicability:**

The antibody diagnosis approach is important in COVID-19 epidemic to diagnose the asymptomatic cases, to assess the magnitude of infection as well as to assess the number of people who are protected from infection.

**Unique points:**

- The sensitivity of IgM is 90.67% and for IgG is 96%, being highly sensitive.
- The specificity is 98.8% for IgM and 95.2% for IgG, this having good specificity.

- The kit is cost effective.

**Up scaling Status**

In the laboratory scale, in each batch, 50 to 500 kits were prepared without any loss of sensitivity and specificity.

**Validation (3rd Party):** 3rd party validation done at Rajiv Gandhi Centre for Biotechnology (RGCB)-DBT

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