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भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH
वी. रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029
V. RAMALINGASWAMI BHAWAN. ANSARI NAGAR. POST BOX 4911. NEW DELHI - 110 029

EOI NO: 56/01/2024-SickleCell/Misc/NCD **DATE:** 20/09/2024

Request for Expression of Interest (EOI)

for Diagnostics Laboratories for conducting independent performance evaluation of Sickle Cell Disease in vitro diagnostic tests including Rapid Test Cards

Date of Issue of EOI	: 20/09/2024 (17:00 Hrs)
Last date of submission of EOI	: 11/10/2024 (17:00 Hrs)
Opening of EOI	: 14/10/2024 (14:00 Hrs)

For any queries related to the call, please contact

Dr. Heena Tabassum,
Scientist & Program Officer, Division of Non-Communicable Diseases (NCD)
Indian Council of Medical Research
Ministry of Health and Family Welfare, Government of India
V. Ramalingaswami Bhawan
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CONTENTS

EXPRESSION OF INTEREST

Subject: Expression of Interest for for Diagnostics Laboratories for conducting independent performance evaluation of Sickle Cell Disease in vitro diagnostic tests including Rapid Test Cards

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from Laboratories with experience in conducting independent performance evaluations of in vitro diagnostics (IVDs) to submit an Expression of Interest (EOI) to become a Performance Evaluation Laboratory. Currently, applications are open for the following types of tests:

Ser.	Name of Services
1	Diagnostic laboratories for validation and batch/LoT testing of Sickle Cell in vitro diagnostic tests including Rapid Test Cards

Interested Laboratories should submit their Application / Expression of Interest in the prescribed format on or before 11/10/2024 by 05:00 pm at ICMR Headquarters, New Delhi

Address for Submission of hard copies:
Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India

1. Background

Indian Council of Medical Research (ICMR) is the apex body for the formulation, coordination, and promotion of biomedical research in India. It is committed to promote, support and conduct research to improve health of all our citizens, and to make India a global leader in Health. ICMR recognizes that India is becoming a global power in health research. A number of research institutions of public and private sectors including medical colleges and nongovernmental organizations have contributed towards this achievement. ICMR aims to foster an enabling and sustainable ecosystem for collaborative, multidisciplinary biomedical research in the country. In this backdrop, ICMR is inviting Expression of Interest for recognition of ICMR

2. Purpose:

ICMR has been actively involved in supporting the government's mission to lower the prevalence of SCD through prevention using universal screening and early detection promoting appropriate interventions. Manufacturers have developed indigenous techniques for sickle cell screening/ diagnosis which are being validated by ICMR for inclusion in the National Sickle Cell Anaemia Elimination Mission, 2047. ICMR has been enlisted with CDCSO for Performance Evaluation of In-Vitro Diagnostics. In view of the increasing requirement for validation and quality testing for batches, ICMR wants to identify validation centres that will undertake validation and random sample testing of batches of SCD diagnostic kits for quality assurance.

3. Scope

Creation/Identification of the performance Laboratory of In - Vitro Diagnostic Medical Devices for sickle cell anemia would - (a) enhance the reliability of results & continuous adherence to national and international laboratory practices, (b) result in greater availability of competent laboratories and proficient personnel, (c) allows uniformity in protocols and procedures across the laboratory network; and, finally (d) allows effective utilization of existing laboratory infrastructures in support of national health development.

4. Role

The identified performance evaluation laboratory would conduct laboratory testing of the SCD in vitro diagnostic kits as follows:

a) Validation that the device performs according to the claims of the manufacturer (and according to the common specifications when available and used by the manufacturer), and has an In - Vitro Diagnostic Medical Device license as per the Medical Devices Rules, 2017, Ministry of Health and Family Welfare.
b) Batch/Lot testing of licensed in vitro SCD diagnostic kits
c) Shall coordinate the exchange of information amongst notified laboratories.
d) Shall collaborate and collate data generation for purposes of data banking related to their specific domain.
e) Shall carry out such other functions, as may be specified by the ICMR fromtime to time in the related areas.

5. Process involved in Partnership/Collaboration

Interested laboratories/facilities are invited to join hands with ICMR for conducting independent performance evaluation of in vitro diagnostics (IVDs). Under this EoI, the laboratories/facilities who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified laboratories/facilities will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration.

6. Who can apply/ Eligibility criteria

Tentatively, it is proposed to identify non ICMR performance evaluation laboratories for sickle cell diagnostic tests including rapid test cards. An assessment will ascertain the potential for a laboratory to undertake a performance evaluation according to the relevant regulatory protocol, as well as the laboratory's compliance with the principles of ISO/IEC 17025:2005 and ISO 15189:2012. Additional references relating to good practices for laboratories performing IVD evaluations, including other ISO standards, will be referred to during the audit. Applications are open to laboratories with experience in conducting independent performance evaluations of IVDs, including:

a) ICMR Collaborating Centers
b) National laboratories or laboratories that provide testing services to the government in their respective regions
c) Laboratories located in geographical areas corresponding to the intended setting of use of the IVDs submitted for assessment.

7. Categories of Organizations:

Public, academic, and research institutions, including medical colleges, universities, etc.

8. Financial Support:

Need based financial support may be provided to the selected non-ICMR Performance evaluation laboratory(s).

9. Assessment process

Assessment of a candidate laboratory consists of:

a) Submission by the laboratory/facility of an EOI.
b) Stage 1 audit: assessment by ICMR of the EOI and the specific quality management system (QMS) documentation submitted by the manufacturer.
c) Stage 2 audit: on-site audit by ICMR of the laboratory to assess compliance with regulatory requirements.
d) If the laboratory meets all requirements, listing of the laboratory as an ICMR Performance Evaluation Laboratory.

10. Eligibility criteria

ICMR would consider the following categories of diagnostic laboratories to become a Performance Evaluation Laboratory:

a. **NABL / NABH accredited Diagnostic Laboratories**
b. **Non- NABL / Non- NABH accredited Diagnostic Lab**

The *eligibility criteria** - for an applicant to be a Performance Evaluation Laboratory is as follows-

a. The agency service provider should have a general experience of a minimum of 1 year to run the required type of services.
b. Should have technically qualified and well-experienced in-house manpower.
c. Should have sufficient in-house infrastructure and laboratory equipment to carry out the test method development and research activities in the area specified.
d. The Diagnostic laboratory center must have been in operation for at least one year. Copy of audited balance sheet, profit, and loss account for the last financial year (Main documents only- summary sheet-) are to be submitted.
e. Diagnostic Laboratories must have the capacity to submit all claims/bills in electronic format to the Bill Clearing Agency and must also have dedicated equipment, software, and connectivity for such electronic submission.
f. Copy of NABL / NABH Accreditation in case of NABL / NABH Accredited Diagnostic Laboratory, if applicable.
g. Copy of QCI recommendation in case of Non-NABH/Non-NABL accredited laboratories.
h. Lists of investigation facilities available with diagnostic lab/imaging centre are to be submitted.
i. Diagnostic lab must have been registered with State Government / Local bodies, wherever applicable.
j. Compliance with all statutory requirements including that of Waste Management.
k. Desirable to have experience in conducting hands-on training facilities either in-house or at third party premises

Note:
Notification/recognition by other regulatory agencies will attract additional weightage during evaluation*.

**Documentary evidence should be provided for fulfilling each condition as part of the application.*

11. Authorized Signatory

The 'Applicant' mentioned in the EOI document shall mean the one who has signed the EOI document forms. The applicant should be the Head of the laboratory/institution/organization or a duly Authorized Representative, for which a Certificate of Authority shall be submitted. All certificates and documents (including any clarifications sought and any subsequent correspondence) submitted thereby, as far as possible, shall be furnished and signed by the Authorized Representative. Whosoever signs the application, he/she shall be the contact nodal point for future communications in reference to ICMR-Performance Evaluation Laboratory, if selected.

12. Documents to accompany EOI

a) The application shall accompany the Expression of Interest and related forms in Annexures I, II, III, IV, and V along with the necessary supporting documents below:
   i. PAN card
   ii. Laboratory/Facility Registration Certificate.
   iii. GST Certificate, if any.
   iv. Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for the last three financial years, Income Tax return.
   v. Proof of a registered office and a manufacturing Unit in India. Including DSIR certificate, if applicable
   vi. Other Statutory Registrations/Licenses, if any.
   vii. Experience details, along with supporting contract copies (format attached)
   viii. Any other document as required under other provisions of this EOI document and not mentioned herein above.

b) Every sheet and all forms shall be complete in all respects and duly numbered. The Power (s) of Attorney supporting/authorizing the signatory shall be enclosed with the offer. Any / all corrections made in the proposal shall be duly authenticated by the signature of the Authorized Signatory.

c) All documents are to be sent to the Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India on or before **11.10.2024** by **5.00 P.M.**

13. Amendment to EOI

At any time prior to the last date for receipt of proposals, the ICMR, may for any reason, whether at its own initiative or in response to a clarification requested by a prospective applicant, modify the EOI document by an amendment. In order to provide prospective applicants with reasonable time in which to take the amendment into account in preparing their proposals, the ICMR may, at its discretion, extend the last date for the receipt of proposals and/or make other changes in the requirements set out in the EOI.

14. Evaluation

ICMR will constitute a high level evaluation committee comprising renowned scientists/ administrators both from National bodies. The committee will be notified in due course. The committee will devise criteria for evaluation purposes.

15. Technical Evaluation

The Evaluation committee along with ICMR officials may visit the facilities to evaluate and/or ask the applicant to make a presentation at the ICMR HQ, New Delhi.

16. Rejection of EOI

The application is liable to be rejected if:

a) Not in the prescribed form and not containing all the required details
b) Not signed by the signing authority
c) Received after the last date of submission
d) Offer is received by fax, telegram, or e-mail & not followed/supported by theprescribed documents within the stipulated date.
e) Any other non-compliance.

17. Disclaimer

a. ICMR shall not be responsible for any late receipt for any reason whatsoever. The applications received late will not be considered and returned unopened to the applicant.
b. ICMR reserves the right
    a. To 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
    b. To include any other item in the Scope of work at any time after consultation with applicants or otherwise
    c. To cancel EOI in part or in full without assigning any reasons thereof

18. Why participate?

Laboratories that successfully apply to become a performance evaluation laboratory would:

a. Contribute to National Health: Support ICMR's mission to improve access to accurate diagnostics for priority diseases
b. Strengthen Diagnostic Capacity: Help build national infrastructure for independent IVD evaluation, especially in resource-limited settings.
c. Recognition and Collaboration: Gain visibility and collaborate with leading health institutions.
d. Access to New Technologies: Early exposure to innovative diagnostic tools.
e. Capacity Building: Enhance skills through advanced training and evaluation processes.

Annexure I
(on the letterhead of the firm)
PERFORMA FOR APPLICATION

To,

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

Subject: Submission of Expression of Interest (EoI) for Diagnostics Laboratories for conducting independent performance evaluation of in vitro diagnostics (IVDs)

.

Ref: ICMR/EoI/…… /202X dated …….

Sir,

The undersigned having read and examined in detail all the EoI documents for Diagnostics Laboratories for conducting independent performance evaluation of in vitro diagnostics (IVDs), and do hereby express the interest to undertake the performance evaluation as mentioned in the EoI document. The details of the laboratory/Diagnostic Facility and contact person are given below:

1.	Name of the Laboratory/Diagnostic Facility	
2.	Address	
3.	Name, designation & address of the person (to whom all communications shall be made)	
4.	Telephone No. (with STD code)	
5.	Mobile No. of the contact person	
6.	Email ID of the contact person	
7.	Whether NABL/NABH Accredited	Yes/No
8.	Whether NABL/NABH applied for	Yes/No
9.	Details of Accreditation and validity period (if applicable):	
10.	Availabilities of Personnel (whatever is applicable)	
	a. No. Clinicians	
	b. No. Basic Scientists	
	c. No. of Technical staff	
11.	Waste disposal system as per statutory requirements	Yes/No
12.	Super Specialty/ Investigations applied: Specialized Hematological, bio-chemical and immunological investigations	Yes/No
13.	Any other investigation for Hemoglobinopathies, if applicable	

Signature of the applicant

Details of work experience: - (contract copy to be enclosed), if any

Sl. No.	Worked With (Name of Organizations)	\Period	
		From	To

I/We hereby submit the proposal for Performance evaluation center for Sickle cell anemia diagnostic tests at (name of the facility). I/We undertake to agree to all terms and conditions ofthe document. It is certified that we fulfill the eligibility criteria mentioned by the Institute in EOI. Supporting documents of all the above information are also attached

Date:

Signature with stamp/seal

Annexure II

Authorization Letter

(To be submitted on Facility'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/……. /202X dated …….

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Diagnostics Laboratories for conducting independent performance evaluation of in vitro diagnostics (IVDs)

Mr./Ms./Mrs./Dr…….is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s…… (Laboratory/Facility Name), whose signature is below.

(Specimen Signature of Representative)

Date:
Place:

Yours faithfully,

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

Annexure-III

Undertaking with regard to blacklisting

(To be submitted on Facility'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/…… dated……..

Sir,

It is hereby confirmed and declared that…… (Laboratory/Facility 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:

Annexure-IV

Undertaking with regard to Non-Litigation

(To be submitted on Facility's Letter Head)

To,

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

Subject: Undertaking regarding Non-Litigation.
Ref: ICMR/EoI/……dated ……..

Sir,

It is hereby confirmed and declared that M/s…..(Laboratory/Facility Name) and owner of the firm / board of directors, have not been convicted for any offense 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:

Annexure-V

Undertaking with regard to laboratory facility

(To be submitted on facility's Letter Head)

To,

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

Subject: Undertaking regarding laboratory infrastructure.
Ref: ICMR/EoI/……dated……..

Sir,

It is hereby confirmed and declared that M/s…..... (Laboratory/Facility Name) do have

i. Adequate laboratory infrastructure (equipped laboratory facility). Please tick NABL/NABH/BSL-2/BSL-3/BSL-3/GMP/GLP/ Other* (if other please specify) and

ii. Adequate no. of experienced staff/skilled manpower to undertake the IVD validation/batch testing of …….

Yours faithfully,

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