EoI No. ICMR/EoI/01-Aspergillosis/2025 dated 08.04.2025

Invitation for Expression of Interest (EOI)

For

Test Manufacturing of AfuPEPELISA Kits for the project titled "Evaluation of AfuPEPELISA kits and comparison of cure rate among presumptive TB patients and ATT non-responders with additional testing of Aspergillosis against standard care of TB testing - Diagnostic intervention trial"

By ICMR-Hqrs

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan,
P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

Letter of Invitation

1. Invitation for Expression of Interest

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from the eligible manufacturers for undertaking the Test Manufacturing of AfuPEPELISA Kits for the project titled "Evaluation of AfuPEPELISA kits and comparison of cure rate among presumptive TB patients and ATT non-responders with additional testing of Aspergillosis against standard care of TB testing - Diagnostic intervention trial"

a) **AfuPEPELISA for Detection of IgE – 40 Kits, with one kit accommodating 30 samples.**
b) **AfuPEPELISA for Detection of IgG – 40 Kits, with one kit accommodating 30 samples**.

Schedule

EoI Document No	**ICMR/EoI/01-Aspergillosis/2025 dated 08.04.2025**
Date of Publication	08.04.2025
Last Date of Submission	09.06.2025

Interested applicants may please send their proposals in a sealed envelope to the following address:

Director
ICMR-National Institute for Research in Tuberculosis
No 1, Mayor Sathyamoorthy Road
Chetpet, Chennai -31

EOI document **No. ICMR/EoI/01-Aspergillosis/2025 dated 08.04.2025,** along with the title of the EOI as **Test Manufacturing' of Enzyme-Linked Immunosorbent Assay (ELISA) kits for the project titled"Evaluation of AfuPEPELISA kits and comparison of cure rate among presumptive TB patients and ATT non-responders with additional testing of Aspergillosis against standard care of TB testing - Diagnostic intervention trial"** in **Bold** and complete address as above must be mentioned on the sealed envelope.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or obligation for such EoI, and without assigning any reason. Information provided at this stage is indicative. ICMR reserves the right to amend/add any further details in the EoI as may be desired by the Competent Authority ICMR and duly notified on its website.

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 the need to find practical solutions to the health problems of the country on the other hand.

ICMR- NIRT, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has developed a technology entitled "**AFUPEPELISA for the diagnosis of Aspergillosis"** (referred to hereafter as "the Technology"). ICMR-NIRT is lawfully entitled to enter into any form of **exclusive/non-exclusive agreements** with eligible manufacturing companies, hereinafter referred to as the **"Company,"** through a defined agreement for manufacturing of AfuPEPELISA kits, hereinafter referred to as the **'Product,'** which shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

2. Objective

To undertake the Test manufacturing of AfuPEPELISA Kits as per the technology and in quantities specified by the ICMR.

a) AfuPEPELISA for Detection of IgE – 40 Kits, with one kit accommodating 30 samples.
b) AfuPEPELISA for Detection of IgG – 40 Kits, with one kit accommodating 30 samples.

Scope of Work

i. ICMR shall provide manufacturing methodology to eligible manufacturers to undertake the test manufacturing of **AfuPEPELISA Kits** for aspergillosis diagnosis.
ii. The company would be granted the right to undertake the test manufacturing of the Product.

Role of ICMR:

i. ICMR-NIRT Institute will provide expert guidance & technical support for the test production of AfuPEPELISA kits.
ii. ICMR shall provide critical reagents and a QC sample panel for QC testing of the kits.
iii. ICMR shall also provide the artwork requirements for labeling for these kits
iv. ICMR shall pay the mutually agreed cost of the test batches

Role of Company

i. The Company shall have the infrastructure to manufacture ELISA Kits demonstrated through their product list
ii. The Company shall provide the cost of production of these kits including the shipment charges to ICMR-NIRT, Chetpet, Chennai -600031.
iii. The company shall be able to obtain a Test License from CDSCO to manufacture the required number of AfuPEPELISA Kits. ICMR MedTech Mitra shall extend the support if needed.
iv. The company shall be able to provide manufacturing records of the kits to ICMR along with the kits.
v. The company shall be able to provide the QC records of the manufactured kits
vi. The company shall be able to ship the kits to the destination provided by the ICMR in cold conditions (2-8^{o}C) along with the data logger.
vii. The Company agrees to allow authorized personnel/scientists/teams of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.

3. Intellectual Property 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), 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.

ICMR is the sole owner of said Technology, including any underlying Intellectual Property(ies) and commercialization rights. The company shall not use the given ICMR technology for any commercial manufacturing or share it with any other party for any other purpose.

4. Process involved

a) Interested manufacturers are invited to show their interest in test manufacturing of this kit.
b) The manufacturers who fulfill requirements under the “role of the manufacturer” as mentioned in Section 2 above shall be short-listed.
c) Qualified manufacturer quoting the lowest cost will only be contacted for the execution of MoA/MoU/Agreement for the test manufacturing of this kit.

5. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject to verification by ICMR.

Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)
ii. Authorization Letter (Format – 2)
iii. The EoI document with each page is duly stamped and signed by the authorized signatory.
iv. Undertaking about manufacturing facility
v. Supporting documents, as mentioned in Format-1
vi. MSME Certificate (if applicable)
vii. Brief production plan including cost.
viii. Any other information that proponents may wish to provide to support the EoI.

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

6. Rejection Criteria

The application is liable to be rejected if:

i. The proposal has not been submitted per the requirements indicated in the EoI.
ii. Not in the prescribed format.
iii. Not properly stamped and signed.
iv. Received after the expiry of the due date and time.
v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).
vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.
vii. Applications not fulfilling the terms of the document will be summarily rejected.
viii. Any other non-compliance.

7. 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. Qualified manufacturer quoting the lowest cost will only be contacted for the execution of MoA/MoU/Agreement for the test manufacturing of this kit.

8. 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 (General)**	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)
General Criteria		
1	The proponent shall be a legal entity registered as an Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India.	Registration of firm/ organization/Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed, etc., whichever is applicable
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 a manufacturing unit in India as demonstrable with their product list.	Registration copies/ factory license/ DSIR certificate, if any.
4	The cost of production of the kits.	Submit the cost of production, including the cost of obtaining a test license and shipping to the destination, i.e ICMR-NIRT, Chetpet, Chennai-600031

Note- for MSMEs and Start-ups, Start-Up-India, Make-in-India, and other relevant guidelines of the Government of India shall be applicable.

9. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reason whatsoever.
ii. ICMR reserves the right to cancel the call for EoI without assigning any reasons.
iii. 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.

10. Arbitration

Any dispute and/ or part of the dispute that couldn't be resolved through mutual consultation shall be referred to the sole arbitrator per the Arbitration & Conciliation Act, 1996, and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi, and the courts in New Delhi will have exclusive jurisdiction.

11. Contacts

In case of any clarification is required, please contact:

For scientific clarifications-

Dr. Priya Rajendran, Scientist D, ICMR NIRT, Chennai 31 (044 - 28369660**)**

For Administrative clarifications

Ms. Chithra Sivakumar, Administrative Officer, ICMR NIRT, Chennai 31 (044 -28369652)

Format-1

Expression of Interest

(To be submitted on Company's Letter Head)

To,

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

Subject: Submission of Expression of Interest (EOI) for Test Manufacturing of AFUPEPELISA Kits for Aspergillosis Diagnosis.

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Ref: ICMR/EoI/…… /202X dated …….

Sir,

Having read and examined all the EoI documents in detail, the undersigned hereby express an interest in undertaking the manufacture 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	Proof of a registered office and a manufacturing Unit in India. Including DSIR certificate		
4	Authorization Letter	As per format – 2	
5	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory.	As per format – 3	
6	MSME Certificate (if you have any)		
7	Production Plan including the cost.	A brief concept note on planning , execution, and production (not more than five pages)	

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-2

Authorization Letter

(To be submitted on Company'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 is in reference to your above-mentioned Expression of Interest (EoI) to undertake the manufacture of the product against Aspergillosis disease as mentioned in the EoI document.

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

(Specimen Signature of Representative)

Date:
Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:……..
Designation:……..
Seal:……..

Format-3

Undertaking laboratory facility

(To be submitted on Company's Letter Head)

This is not needed

To,

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

Subject: Undertaking regarding laboratory infrastructure.
Ref: ICMR/EoI/…… /202X dated……..

Sir,

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

i. Adequate laboratory infrastructure (equipped laboratory facility). Please tick BSL-2/BSL-3/ABSL-3/GMP/GLP/ Other* (if other, please specify),
ii. Adequate no. of experienced staff/skilled human resources to undertake manufacture/ research/ commercialization of ……. (Product details).

Yours faithfully,

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