



**EoI No.ICMR/EoI/PM/04/AFuPEPLISA Immunodiagnostic  
Kit/2025**

**Invitation for Expression of Interest (EoI)**

**For**

**Transfer of Technology  
of**

**AFuPEPLISA Immunodiagnostic Kits for Detection  
of *Aspergillus Fumigatus* in Patients with Bronchial Asthma  
and Pulmonary Tuberculosis  
(Diagnostic Kit)**

By ICMR-Hqrs

**Indian Council of Medical Research**  
(Department of Health Research, GoI)  
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New Delhi - 110029, India

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## **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 organizations, companies, manufacturers for undertaking ‘**Transfer of Technology**’ for commercialization of “**AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis**” useful in **Diagnosis of Bronchial Asthma and Pulmonary Tuberculosis**.

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/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025
Date of Publication	Date: 27/06/2025
Last date of submission	Date: 27/07/2025

#### **Note:**

Interested applicants are invited to submit their Expression of Interest (EoI) through the Medical Innovation Patent Mitra portal (<https://patentmitra.icmr.org.in/company-eoi-registration/>). Applicants must first register by providing requisite company information, including details of the authorized representative. Upon successful registration, applicants are required to complete and submit the e-EoI form available on the portal.

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 any further details in the EoI, as may be desired by the Competent Authority ICMR and duly notified on its website.

### **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 the growing demands of scientific advances in biomedical research on the one hand and the need of finding practical solutions to the health problems of the country, on the other.

ICMR-National Institute for Research in Reproductive and Child Health (ICMR-NIRRH) is one of the Institutes of the Indian Council of Medical Research (ICMR), New Delhi has developed a technology entitled “AFuPEPLISA Immunodiagnostic Kits for

Detection of *Aspergillus Fumigatus* in Sera of Patients” (hereinafter) referred to as **“Technology”**.Funding has been received from Department of Biotechnology for this project.

ICMR 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 Licensing/Commercialization of **“AFuPEPLISA Immunodiagnostic Kits for Detection of *Aspergillus Fumigatus* in Sera of Patients with Bronchial Asthma and PulmonaryTuberculosis”**, hereinafter referred to as the **‘Product’**, which shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

### 3. Objective

To license the ‘Technology’ for **“AFuPEPLISA Immunodiagnostic Kits for Detection of *Aspergillus Fumigatus* in Sera of Patients with Bronchial Asthma and PulmonaryTuberculosis”**, for commercialization& marketing activities.

### 4. Scope of Work

- i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking Transfer of technology and commercialization of the Technology/product entitled **“AFuPEPLISA Immunodiagnostic Kits for Detection of *Aspergillus Fumigatus* in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis”**.
- ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product entitled **“AFuPEPLISA Immunodiagnostic Kits for Detection of *Aspergillus Fumigatus* in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis”**.
- iii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on an “Exclusive/Non-Exclusive” basis with single/multiple companies to enable wider outreach of the Technology/product entitled **“AFuPEPLISA ImmunodiagnosticKits for Detection of *Aspergillus Fumigatus* in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis”**for societal benefit and public health use. All the related issues shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.
- iv. ICMR- NIRRH Institute has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of the Technology/product entitled**“AFuPEPLISA Immunodiagnostic Kits for Detection of *Aspergillus Fumigatus* in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis”**.

### Role of ICMR:

- i. **ICMR-National Institute for Research in Reproductive and Child Health** will provide expert guidance & technical support for the production ofthe Technology/product

entitled “**AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis**”, in all phases. Such technical oversight by **ICMR- National Institute for Research in Reproductive and Child Health** would accelerate the development of the Product and its commercialization.

- ii. ICMR would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.
- iii. ICMR through its Institutes would provide support and facilitation to conduct the R&D/clinical study of new technology/ product in India through its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.
- iv. ICMR would provide technical support in development of technology/ product and will also facilitate the validation, if required, as per the terms & conditions of the Agreement.
- v. ICMR shall have no financial implications unless otherwise specified.

#### **Role of Company**

- i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development/ validation/ scale-up either directly or otherwise.
- ii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the “**AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis**” in a set milestone.
- iii. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.
- iv. The Company agrees to allow authorized personnel/scientist/team of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.
- v. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for product development to its commercialization.

#### **5. Intellectual Property Rights**

It is submitted that in case of transfer of Technology, ICMR is the sole owner of the said Technology, including any underlying Intellectual Property(ies) and commercialization 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 legally possesses 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) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive License Agreements with selected companies including transfer of the Technology through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of Technology/ Product, Background Intellectual Property (“BGIP”) shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be jointly owned by ICMR and the Company. All such provisions related to intellectual property rights shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

## **6. Process involved in Technology Transfer**

Interested companies/manufacturers are invited to join hands with ICMR for commercialization of the Technology/Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities, and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for technology transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty @2% on Net sales, as applicable, according to the ICMR Guidelines for Technology Development Collaboration.

## **7. Publication**

- i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).
- ii. Support of ICMR must be duly acknowledged in all publications by the Company.
- iii. ICMR Scientists can be given due advantage of authorships in the publications arising out of Licensing/co-development.

## **8. Data Rights**

- i. Data Rights will be exclusively with ICMR, if ICMR provide 100% funding.
- ii. Data rights shall be jointly owned by ICMR and Licensee/Co-developer, in case of joint funding.
- iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.
- iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 while dealing with such data

## **9. 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 for verification by ICMR.

Documents to be furnished are as follows:

- i. Declaration - Expression of Interest (Format – 1)
- ii. Authorization Letter (Format – 2)
- iii. Undertaking with regard to Blacklisting (Format-3)
- iv. Undertaking with regard to Non-Conviction (Format – 4)
- v. EoI document with each page duly stamped and signed by the Authorized signatory.
- vi. Undertaking with regard to laboratory facility (Format – 5)
- vii. Production Capacity Undertaking (Format-6)
- viii. Supporting documents, as mentioned in Format-1
- ix. MSME Certificate (if applicable)
- x. Concept note on business plan- A brief concept note on R&D, clinical studies, planning & execution, production, marketing etc. with timeline (not more than 5 pages)
- xi. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgement in evaluation.

## **10. Rejection Criteria**

The application is liable to be rejected if:

- i. The proposal is not submitted as 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 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.

## 11. 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.

## 12. 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)
<b>General Criteria</b>		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from 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 proven prior experience of manufacturing and/or R&D with manufacturing during the last three years, either in-house or through agreed collaboration and must have marketed same/similar products in the past with a good track record.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track	Undertaking on the Letter Head of the

	record and currently not black-listed/ barred by any Central / State Government / Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only).	Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
7	The proponent and its promoters should not have been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
<b>Specific Criteria (Based on the nature of the Proposal)</b>		
9.	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
10.	Capacity to produce at least.....(quantity) per week	Undertaking (As per format – 6)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

### 13. Disclaimer

- i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
- ii. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
- 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 thereof.
- iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.
- v. For International Clients, please note that EoI and other necessary correspondences shall be submitted in English only.

### 14. Arbitration

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as 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 at New Delhi will have

exclusive jurisdiction.

## **15. Contacts**

In case of any clarification required, please contact:

### **For scientific issues-**

#### **Dr. Taruna Madan Gupta**

Scientist G and Head, Development Research,  
Indian Council of Medical Research,  
V. Ramalingaswami Bhawan, P.O. Box No. 4911  
Ansari Nagar, New Delhi - 110029, India  
Email: [guptat@nirrch.res.in](mailto:guptat@nirrch.res.in)

### **For Technical issues –**

Medical Innovations Patent Mitra Team,  
Email: [patentmitra.hq@icmr.gov.in](mailto:patentmitra.hq@icmr.gov.in)

## 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 Transfer of Technology and commercialization of **"AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis"** and commercialization of the Technology/product useful in Diagnosis of **Bronchial Asthma and Pulmonary Tuberculosis**.

**Ref:**ICMR/EoI/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025dated .....

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 research & development/manufacture/ sale /commercialization 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	DCGI/CDSCO license for the existing products available in the market		
4	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for las three financial years, Income Tax return.		
5	Proof of a registered office and a manufacturing Unit in India. Including DSIR certificate		
6	GMP/ GLC and ISO Certification. Registration copies of both		
7	Authorization Letter	As per format – 2	
8	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory	As per format – 3	
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
10	MSME Certificate (if have any)		
11	Business Plan	A brief concept note on planning & execution, production, marketing etc. (not more than 5 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: ICMR/EoI/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025dated .....

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technologyentitled **“AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis”** commercialization of the Technology/product useful in Diagnosis of **Bronchial Asthma and Pulmonary Tuberculosis.**

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

(Specimen Signature of Representative)

Date:

Place:

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

### Format-3

**Undertaking with regard to blacklisting**  
(To be submitted on Company'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/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025dated.....

Sir,

It is hereby confirmed and declared that M/s.....(Company 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:

**Format-4**

**Undertaking with regard to Non-Conviction**

(To be submitted on Company's Letter Head)

To,

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

**Subject:** Undertaking regarding Non-Conviction.

**Ref:**ICMR/EoI/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025dated .....

Sir,

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

**Format-5**

**Undertaking with regard to laboratory facility**

(To be submitted on Company's Letter Head)

To,

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

**Subject:** Undertaking regarding laboratory infrastructure.

**Ref:**ICMR/EoI/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025dated.....

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) and
- ii. Adequate no. of experienced staff/skilled manpower to undertake manufacture/ research/ commercialization of **“AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis”**.

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

**Format-6**

**Undertaking with regard to production capacity**

(To be submitted on Company's Letter Head)

To,

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

**Subject:** Undertaking with regard to production capacity.

**Ref:**ICMR/EoI/PM/04/AFuPEPLISA Immunodiagnostic Kit/2025dated .....

Sir,

It is hereby confirmed and declared that M/s..... does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for manufacturing of “**AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients with Bronchial Asthma and Pulmonary Tuberculosis**”, minimum.....(mention the quantity per week/per month).

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

## **SCHEDULE-A**

### **TECHNOLOGY DETAILS**

#### **i. About the Technology/Product/Process:**

The technology “**AFuPEPLISA Immunodiagnostic Kits for Detection of Aspergillus Fumigatus in Sera of Patients**” useful for patients of **Bronchial Asthma and Pulmonary Tuberculosis** has been solely developed by ICMR-NIRRH, Mumbai, India which is a premier institute of Indian Council of Medical Research, under Department of Health Research, Ministry of Health and Family Welfare, Government of India.

Globally Tuberculosis infected patients were estimated at 10 million and a total of 1.5 million people died from TB in 2020. TB stands at 13th position for leading cause of death and it is the second infectious killer disease after Covid-19. With such growing numbers, the global Tuberculosis Testing Market is expected to grow at a high CAGR of 5.2% during the forecasting period (2020-2027).

In addition to TB, 300 million people worldwide have asthma with 37.9 million in India, which equals 55% of the total UK population. A global respiratory pathogen testing kits will witness a substantial CAGR of 6.5% between 2020 and 2027.

With high potential in both TB detection and asthma screening domain, the present technology offers an excellent opportunity for tapping the growing immunodiagnostic kits for detection of specific IgG and IgE antibodies.

#### **Unique points of Technology:**

- Synthetic-peptide based
- Low intra-assay and inter-assay variations
- High sensitivity and specificity
- Cost effective
- Shelf life
- Amenable to use in labs of Sub-district/ District hospitals

#### **ii. Need and utility of the Technology from Public health perspective:**

The fungi, *Aspergillus fumigatus* complicates cases of the patients of bronchial asthma and pulmonary tuberculosis. Elevated levels of specific IgE and IgG antibodies found in the sera of patients are relevant for serodiagnosis. The early diagnosis and treatment can halt the development of bronchiectasis and end-stage fibrosis in bronchial asthma and pulmonary tuberculosis patients.

Currently used tests for serodiagnosis comprise of ImmunoCAP, Immulite 2000, Platellia Aspergillus IgG ELISA, and Aspergillus IgG-IgM ICT for detection of Asp antibodies. All these tests show diverse sensitivities depending on the quality of antigens used. Comparative evaluation of ImmunoCAP and Immulite showed a considerable scatter in a comparison of individual sera. Diversity of the *A. fumigatus* extracts (Esch, 2004), the solid-phase matrix, and the method of immobilization involved in the preparation of the *A. fumigatus*-containing reagent used in each of the assays (Hamilton et al., 2008) can be an explanation for the inter-assay differences.

iii. **Technology Readiness level (TRL)**

- Technology has been successfully validated, independently at three sites.
- Technology Readiness level- 6
- GMP finalized
- The technology is ready to transfer for commercialization.

iv. **Validation Status and outcome:**

The kits were independently validated for bronchial asthma samples n=1307, wherein at PGIMER, Delhi n=1131 and at VPCI, Delhi it was n=176. Additionally, for suspected pulmonary TB samples, RBIPMT, Delhi tested it for n=254. The assays showed an agreement of 68.65% with ImmunoCAP demonstrating a good concordance. A total of 82 (32.3%) cases were positive for *A. fumigatus* specific antibodies.

v. **IP Filing Status/Publications**

Patent application number: 202411008706

Date of filing: February 08, 2024.

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