EoI No. ICMR/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

Invitation for Expression of Interest (EoI)

For

Transfer of Technology

of

A CRISPR Cas based TB detection system (Diagnostic kit and device)

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

CONTENTS

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 **A CRISPR Cas based TB detection system** for the detection of ***Mycobacterium 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/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024
Date of Publication	13.09.2024
Last date of submission	30.09.2024

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

Dr. Nivedita Gupta,
Scientist G & Head,
Division of Communicable Diseases
Indian Council of Medical Research,
V. Ramalingaswami Bhawan,
P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110029, India.

The EoI Document No. **"**ICMR/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024**"** along with the title of the EOI as "**EoI for Technology Transfer**" in **Bold** and complete address as above must be clearly mentioned on the sealed envelope.

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- RMRCNE Institute, Dibrugarh, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi (Details of Institute) has developed a technology entitled "**A CRISPR Cas based TB detection system**" (hereinafter) referred to as **"Technology".**

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 **A CRISPR Cas based TB detection system**, 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 **A CRISPR Cas based TB detection system,** which is useful for the detection of ***Mycobacterium tuberculosis***, for commercialization and marketing activities.

4. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking Transfer of technology - **A CRISPR Cas based TB detection system.**

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology **A CRISPR Cas based TB detection system** (Details of technology/Product is at schedule-A).

iii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on a **"Non-Exclusive"** basis with single/multiple companies to enable wider outreach of the product (Technology/Product) 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-RMRCNE Institute has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of '**A CRISPR Cas based TB detection system'.**

Role of ICMR:

i. ICMR- RMRCNE Institute will provide expert guidance & technical support for the production of '**A CRISPR Cas based TB detection system'** in all phases. Such technical oversight by ICMR-RMRCNE Institute 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 '**A CRISPR Cas based TB detection system'** 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.

vi. The company shall use the said system comprising of the **RapidBact DNA Kit, GlowTB$_{PCR}$ kit and the RapidGlow Device** only as a system and not as standalone products.

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 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) 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 the 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 co-development/further development & 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 partnership/collaboration/technology transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty, at the rate of 2% on net sales in line with "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 to 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)
General Criteria		
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	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.

	the past with a good track record.	
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 record and currently not black-listed/ barred by any Central / State Government / Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only).	Undertaking on the Letter Head of the 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
Specific Criteria (Based on the nature of the Proposal)		
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

For any queries related to the EoI, please send email to the following:

1. Dr Md Atique Ahmed
   Scientist C & DBT Ramalingaswami fellow
   ICMR-RMRCNE, Dibrugarh. Assam
   Email: ahmed.atique@icmr.gov.in and atiqbiotech@gmail.com

2. Dr. Hansraj Choudhary,
   Scientist B, Division of Communicable Diseases,
   Indian Council of Medical Research, New Delhi
   Email: choudhary.hansraj@icmr.gov.in

cc to:

1. Dr. Nivedita Gupta,
   Scientist G & Head,
   Division of communicable Diseases,
   Indian Council of Medical Research, New Delhi
   Email: guptanivedita.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 '**A CRISPR Cas based TB detection system'** for the detection of ***Mycobacterium tuberculosis***.

Ref: ICMR/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

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 last 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/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technology '**A CRISPR Cas based TB detection system'** for the detection of ***Mycobacterium 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:……

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/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

Sir,

It is hereby confirmed and declared that M/s……(Company Name) currentlyhas 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-Litigation

(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/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

Sir,

It is hereby confirmed and declared that M/s….....(Company Name) and owner of the firm / board of directors, do not have any litigation / arbitration pending/under trial in court.

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/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

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 ……. (Product details).

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/CD/TB/Diagnostics/EOI/2024 dated 12.09.2024

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 …… (Name ofTechnology/ Product), 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:**

The process incorporates an advanced diagnostic system utilizing a pre-amplification step coupled with high precision CRISPR-Cas12a technology for the qualitative detection of *Mycobacterium tuberculosis* complex at the nucleic acid level, facilitating the accurate and ultra-sensitive detection of tuberculosis. The system features the 'RapidBact DNA Kit,' a rapid DNA extraction kit from sputum, the 'GlowTB$_{PCR}$ Kit,' which leverages a pre-amplification step and CRISPR-Cas12a for precise tuberculosis detection, and the 'RapidGlow Device,' an integrated incubator cum real-time or end-point fluorescence reader designed for effective result interpretation. Together, these components form a comprehensive and user-friendly platform for rapid and reliable tuberculosis testing.

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

Tuberculosis (TB) remains a global health challenge, necessitating the development of accurate and rapid diagnostic tools for effective disease management. Current diagnostic methods often exhibit limitations in terms of sensitivity, specificity, speed and cost, emphasizing the need for innovative approaches.

Conventional diagnostic techniques for TB commonly rely on culture (which requires 42 days to confirm as TB negative), microscopy, and nucleic acid-based methods. These are time-consuming and may require sophisticated equipment. Additionally, some molecular diagnostic methods, while offering improved sensitivity, may lack the desired specificity or face challenges associated with cost and ease of handling.

In response to these challenges, the CRISPR-Cas12a-based molecular diagnostic system 'GlowTB$_{PCR}$ Kit,' combined with a pre-amplification step using a thermal cycler, alongside the RapidBact DNA Kit and the 'RapidGlow Device,' offers a promising solution.

The GlowTB$_{PCR}$ Kit targets two genes which are specific to the *M. tuberculosis* complex. It also includes a human gene which serves as an internal control. The overall diagnostic process takes between 2 to 3.5 hours (sample to result). This system is both highly sensitive and cost-effective, with the cost per test is ~155 INR and the device priced around ~10,000 INR.

Product features:

1. RapidBact DNA kit

a. Rapid: DNA extraction within 25 minutes.
b. High Yield and Purity; Comparable to commercial bacterial DNA isolation kit.
c. Low cost: ~ 50 INR per sample

2. GlowTB$_{PCR}$ Kit

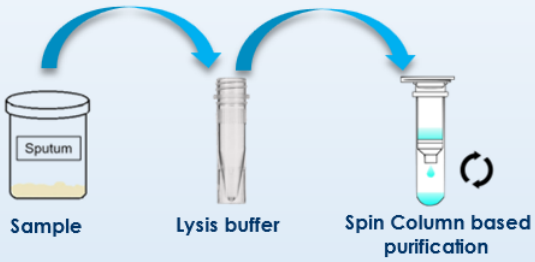
a. Rapid (~1.5 - 3 hours)
b. Can detect up to 2 copies/µl of DNA (Targets two genes of MTB)
c. Cost-effective (~105 INR per test, excluding DNA extraction)
e. Components in lyophilized form

3. RapidGlow Device

a. End-point and real-time fluorescence detector
b. Bench top
c. Light weight (~5 kg)
d. Portable
e. Runs in 12V DC
f. Scalability: 1 – 1536 samples in a single run
g. Low cost: ~ 10,000.00

Glow-TB$_{PCR}$ Workflow - A three Step Assay

Step 1: DNA Extraction



RapidBact DNA kit

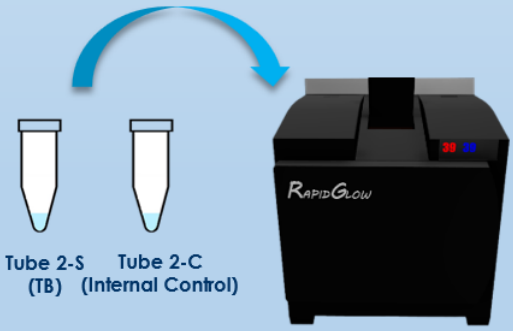
- 100µl Sputum into Lysis buffer
- Incubate @100°C, 10 mins
- Column-based purification
- Duration: 25 min

Step 2: Target Amplification

Glow-TB$_{PCR}$ kit

- 24µl resuspension buffer + 1µl DNA (Tube 1)
- Amplify using a thermal cycler
- Duration: 1 hour

Step 3: Fluorescence Detection

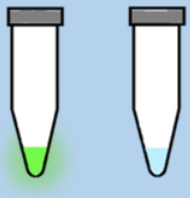


- 10µl of amplified product to Tube 2-S and Tube 2-C
- Incubate in RapidGlow device
- Duration: 30 mins-2 hour

Result Interpretation

Real-time detection

End-point detection



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

TRL 3

iv. **Validation Status and outcome:**

External validation will be done by ICMR HQ.

v. **IP Filing Status/Publications**

IP has been filed for:

i. RapidGlow device: incubator cum fluorescence reader with Indian Patent Application No. 202411016083.

ii. Glow-TB_{PCR}–a Rapid, near Point-of-Care CRISPR-Cas-based Ultra-Sensitive Molecular Detection kit for *Mycobacterium tuberculosis* complex" has been filed with patent Application No. 202411043686.

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