EoI No. ICMR/EoI/PM/09/Scrub Typhus/2026
Dated June 17, 2026

Invitation for Expression of Interest (EoI)

For

Transfer of Technology
Of
A Dipstick-based Test Kit for the Detection of *Orientia tsutsugamushi* and Method of Detection thereof
(Diagnostics)

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 Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof"** useful for D**etection of causative agent of scrub typhus (ST) i.e. Orientia tsutsugamushi (OT).**

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/09/Scrub Typhus/2026
Date of Publication	Date: June 17, 2026
Last date of submission	Date: July 08, 2026

Note:

Interested applicants are invited to submit their Expression of Interest (EoI) through the Medical Innovation Patent Mitra portal (https://patentmitra.icmr.org.in/companyeoiregistration/). 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-Regional Medical Research Centre Gorakhpur, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi has developed a technology entitled **"**A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof" (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 Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof"**, 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 Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof",** useful in detection of detection of causative agent of scrub typhus (ST) i.e. Orientia tsutsugamushi (OT).

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 **"A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof".**

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product entitled **"A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof".**

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 Technology/product entitled **"A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof**" 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-Regional Medical Research Centre Gorakhpur has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of the Technology/product entitled **"A Dipstick-based Test Kit for the Detection**

of Orientia tsutsugamushi and Method of Detection Thereof".

Role of ICMR:

i. ICMR-Regional Medical Research Centre Gorakhpur will provide expert guidance & technical support for the production of the Technology/product entitled **"A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof**", in all phases. Such technical oversight by **ICMR-Regional Medical Research Centre Gorakhpur** 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 Technology/Product "A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection thereof", 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 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 Partnership/Collaboration/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 @ 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 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 becomes 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 the past with a good track	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 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	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. Rajeev Singh
Email: rajeevbt22@gmail.com
Mobile No.: 8924936067

For Technical issues-
Medical Innovations Patent Mitra Team,
Email: 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 for the Technology entitled **"A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof"** and manufacturing, commercialization of the **"A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection Thereof.**

Ref: ICMR/EoI/PM/09/Scrub Typhus/2026 dated June 17, 2026

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/09/Scrub Typhus/2026 dated June 17, 2026

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Transfer of Technology entitled **"A dipstick-based test kit for the detection of Orientia tsutsugamushi and method of detection thereof**" and manufacturing, commercialization of the "A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection thereof".

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/EoI/PM/09/Scrub Typhus/2026 dated June 17, 2026

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/09/Scrub Typhus/2026 **dated** June 17, 2026

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/09/Scrub Typhus/2026 dated June 17, 2026

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 the Technology entitled **"**A Dipstick-based Test Kit for the Detection of Orientia tsutsugamushi and Method of Detection thereof"**.**

Yours faithfully,

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

*The Laboratory/ facility requirement will depend on the technology/ product

*The Laboratory/ facility requirement will depend on the technology/ product

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/09/Scrub Typhus/2026; dated June 17, 2026

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 of Technology/ 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/Product/Process:

The present technology is developed for the detection of causative agent of scrub typhus (ST); Orientia tsutsugamushi (OT). The invention pertains to the field of molecular diagnostics for the rapid and early detection of OT prevalent strains in India. The present technology is a rapid diagnostic test (RDT) which differs from a conventional polymerase chain reaction (PCR) or real-time PCR (RT-PCR) in that it is based on detection of OT nucleic acid at a single temperature accompanied by lateral flow strip end-point detection. This technology comprises of a primer pair; upstream and downstream primer and a crRNA with labelled ssDNA reporters or probe for isothermal detection of OT genome via CRISPR/Cas12a or Endonuclease IV based reaction respectively.

For CRISPR/Cas12a detection the isothermally amplified product using upstream and downstream primers was subjected to CRISPR/Cas12a:crRNA complex and single stranded DNA (ssDNA) reporters for OT signal detection. The CRISPR/Cas12a system recognizes the amplified targets with the help of crRNA. After the CRISPR/Cas12a: crRNA nucleoprotein complex identifies the target, form a ternary complex CRISPR/ Cas12a:crRNA. This complex activates CRISPR/Cas12a endonuclease which cleaves the target as well as any single stranded DNA (labelled with FAM-BHQ for fluorescence detection or FAM-Biotin for dipstick detection) present nearby. Upon cleavage, non-target DNA results in amplified fluorescent signal or lateral flow strip-based detection. Post-CRISPR/cas12a cleavage, the reaction product is added to the running buffer (analyte-specific solution) and a dipstick (LFS) is added from the end of the sample pad, is placed in the solution and the result is immediately interpreted after standing for 2 to 5 minutes. Due to the cleavage of the dual-labelled ssDNA reporters by CRISPR/Cas12a, the C-line develops, whereas the T-line diminishes. In dipstick-based detection absence of a T-line indicates a positive result. Upon cleavage, all cleaved reporters could travel to the C-line, leaving the T-line clear, hence indicating a positive test. Further, a faint or low T-line indicates a positive sample with a low concentration of the genome target.

For endonuclease IV-based detection, the 5’ end of the downstream primer is modified with Biotin. The principle of detection lies in designing of the probe which is 46 base pair (bp) in length, 5’ end of which is 29 bp in length and modified by an antigenic label Fluorescein amidite (FAM); 30th base is modified by tetrahydrofuran (THF) residue; 3’ end of the probe is 16 bp long; modified with a polymerase extension

blocking group (Phosphate). The Apurinic/apyrimidinic (AP) endonuclease enzyme such as nfo/Endonuclease IV is a DNA repair enzyme which cleaves the abasic site (THF) introduced in target through the probe. The THF site is detected by nfo endonuclease, and cleaves it at AP site, upon cleavage the 5' end of probe acts as a forward primer, whereas the upstream and downstream primer pair amplifies the target region by recombinase polymerase activity initially. The amplification product generated by Probe as forward primer and downstream primer incorporates both label FAM and Biotin. Post-amplification the reaction product is added to the running buffer (analyte-specific solution) and a dipstick (LFS) is added from the end of the sample pad, is placed in the solution and the result is immediately interpreted after standing for 2 to 5 minutes. The dual label incorporated post amplification product (analyte), binds first to the gold-labeled FITC-specific antibodies in the sample application area of the dipstick. By capillarity the gold complexes diffuse over the membrane. Only the analyte captured gold particles will bound when they overflow the immobilized biotin ligand molecules at the test band and generate there a blue band over the time. Not-captured gold particles flow over the control band and will be fixed there by species-specific antibodies. With increasing incubation time, the formation of an intensely colored control band appears. Hence, the presence of test line (T-line) and a control line (C – Line) in the LFS is the positive indication of OT, however the presence of only C-Line indicates the specimen is negative for OT.

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

In India Scrub typhus (OT infection) accounts for more than 20% of cases of febrile episodes in AFI cases. OT can be difficult to diagnose clinically since its symptoms resembles with other acute febrile infections. If the ST has been left undiagnosed and untreated, it may lead to severe multiorgan failure, or acute encephalitis syndrome (AES) which may result in case fatalities upto 30% or even higher. Furthermore, ST has been established as an important aetiology associated with 60% of the acute encephalitis syndrome (AES) cases in the pediatric population. In such cases the unavailability of molecular rapid diagnostic tools (RDT) for early detection of Orientia tsutsugamushi results in delayed diagnosis thereby affecting delay in treatment especially in rural settings. There are no nucleic acid-based RDT available in India to counter-detect these strains. Given, the major endemic strains of OT from rural areas of India are Gilliam, and Karp and the lack of infrastructure, we have developed a platform named dipstick based isothermal nucleic acid detection of Orientia tsutsugamushi prevalent genotypes; Gilliam and Karp. This platform is rapid, sensitive, specific, ease-to-interpret and low-cost diagnosis test for early detection of Orientia tsutsugamushi in clinical samples with AES/AFI to initiate early treatment and cease the progression of the disease. The visual detection allows ease of use and interpretation of results in a time-efficient manner and eliminates the use of cumbersome instruments. Such a strategy for diagnosis is appropriate for onsite detection of OT, in simple,

peripheral and rudimentary mobile laboratories. This technology will primarily benefit the patients infected with OT from the remote location, where the treatment is delayed due delay in getting the reports from well-established laboratory. The disease left undiagnosed for longer period led to morbidity even mortality. Technology can enable the clinician to provide prompt on-time treatment of the disease. This can aid in reducing the burden of morbidity and mortality occurred due to delayed diagnosis of the ST. The platform can be readily deployed in field conditions, in simple and rudimentary mobile laboratories, and in some basic medical units, such as those in primary health care clinics in rural areas.

iii. **Technology Readiness level (TRL):** TRL – 4 (Technology validated in-house)

iv. Validation Status and outcome:

The technology has undergone in-house analytical and clinical validation at a single center using archived whole-blood clinical samples (n = 81) collected from suspected AES patients, where its performance was compared against conventional PCR targeting the 56 kDa gene. The validation included 43 PCR-positive and 38 PCR-negative samples, demonstrating 97.6% sensitivity and 100% specificity, with no observed cross-reactivity against other rickettsial pathogens, indicating high analytical specificity. The assay also showed a limit of detection of one gene copy per reaction, confirming strong analytical sensitivity. However, the validation was retrospective, single-site, and limited in sample size, with reliance on extracted DNA rather than simplified field-ready sample preparation, and no external or multi-center validation performed, indicating that the study represents an early-stage, proof-of-concept in-house validation rather than a full regulatory-grade clinical validation.

v. IP Filing Status/Publications

IP Filing: Indian Patent Application number 202311040300

Date of Filing: 13/06/2023

Name of Inventor(s): Dr. Rajeev Singh, Dr. Pooja Bhardwaj, Dr. Stitha Pragnya Behera, Dr. Rajni Kant, Dr. Smita Kulkarni

Publications:

i. Bhardwaj, P., Nanaware, N. S., Behera, S. P., Kulkarni, S., Deval, H., Kumar, R., Dwivedi, G. R., Kant, R., & Singh, R. (2023). CRISPR/Cas12a-Based Detection Platform for Early and Rapid Diagnosis of Scrub Typhus. Biosensors, 13(12), 1021. https://doi.org/10.3390/bios13121021

ii. Bhardwaj, P., Yadav, Y., Dhangur, P., Behera, S.P., Dwivedi, G.R., Singh, R., (2025). Sensitive and rapid visual detection of *Orientia tsutsugamushi* with Recombinase assisted dipstick detection platform. Diagnostic Microbiology & Infectious Disease. 116872. https://doi.org/10.1016/j.diagmicrobio.2025.116872

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