Indian Council of Medical Research, New Delhi
Department of Health Research
Ministry of Health & Family Welfare, Government of India

Division of Epidemiology and Communicable Diseases

'Call for Proposals on diagnostics for AMR especially for primary and acute care settings'

Antimicrobial resistance (AMR) is one of the major public health priorities in India. Rapid diagnostics enabling the early pathogen detection and antimicrobial susceptibility testing can equip healthcare professionals to understand the type of infection affecting the patient, analyse its scale and provide appropriate treatment in a timely manner. However, such reliable and quality validated rapid-diagnostics addressing needs of multi-tiered healthcare of India are lacking. Indigenously developed rapid diagnostics are urgently needed to fill this diagnostic gap and to contain AMR in country.

ICMR's taskforce on AMR diagnostics invites proposals from the innovators and developers who have developed a diagnostic test that can facilitate timely pathogen detection and susceptibility testing, to undertake systematic validation/feasibility study of the test. The diagnostics test should have crossed the proof of concept stage and should be ready for DCGI regulatory trials. The test should address the priority areas/pathogens listed below.

I. Interested Innovators and/or developers are invited to submit concept proposals pertaining to the following priority areas:

- **AMR diagnostics related to following high priority syndromes/conditions**
  - Respiratory tract infections (Lower and upper respiratory infections)
  - Differentiating bacterial from viral infections (including biomarkers)
  - Typhoid
  - Sepsis, Neonatal sepsis
  - Acute febrile illnesses
  - Urinary tract infections
- **AMR diagnostics related to following priority pathogens:**
  i. Carbapenem resistant bacteria
     - Enterobacteriaceae: *Escherichia coli, Enterobacter spp., Klebsiella spp.,*
     - *Acinetobacter baumannii*
     - *Pseudomonas aeruginosa*
  ii. Fluoroquinolone-resistant *Salmonella* Typhi
  iii. Penicillin non-susceptible *Streptococcus pneumoniae*
  iv. *Candida auris*
  v. Colistin resistant *Klebsiella*
  vi. Methicillin resistant *Staphylococcus aureus* (MRSA)
  vii. Vancomycin Resistant Enterococci (VRE): *Enterococcus faecium*

II. Application format for submitting the proposals

S.No.	Characteristics/Parameters
1	Name of Company/ Institution *(Details of the developer)*
2	Name of Test/technology
3	Principle (technology) and novelty of developed diagnostic *(Explain, how developed diagnostic address AMR)*
4	Evidence or Stage of development
5	Technology readiness level *(Present status of technology for use)* *Diagnostic should be at TRL 4 and above as per ICMR's Guidelines for Technology Transfer and Revenue Sharing for In-Vitro Diagnostics (Kits and Reagents). Guidelines can be accessed through link* https://main.icmr.nic.in/sites/default/files/upload_documents/ICMR_Technology_Transfer_and_Revenue_Sharing_Guidelines07072021.pdf
6	Internal and/or external validation done (Yes/No, explain)
7	Point-of-care test, or needs sample transportation (Yes/No, explain)
8	Whether each test to be done individually or in a batch
9	Number of test that can be done in a batch
10	Testing population, sample size and study design
11	Time taken from sample collection to results, Hands-on-time
12	Turnaround Time (TAT)
13	Specimen that can be tested
14	Sample volume
15	Sample storage and transport
16	Targeted pathogen(s)
17	Antibiotics panel used
18	If test detects resistance gene(s), enlist
19	Reference method/Gold standard used
20	Analytical parameter(s) tested
21	Specificity and Sensitivity
22	Result output format
23	Temperature and Operating conditions
24	Any calibration requirements, if yes, frequency of calibration
25	Sensitivity to sample variation
26	Stability/ shelf life of diagnostic tested (Yes/No, Explain)
27	Any major error or minor error
28	Intended use or targeted beneficiary of diagnostic test
29	Cost per test
30	Initial fixed cost for testing
31	Expected time for commercialization
32	Any limitation of developed diagnostic
33	Is test follow flexi-format for customization, Yes/No, please explain
34	Evidence on scalability of test available, if yes, please explain
35	Evidence on cost effectiveness, if yes, please explain

36	Any Target product profiles (TPP) consulted for diagnostic development
37	Standards or guidelines consulted to evaluate performance parameters
38	Time taken for diagnostic development (in years)
39	Approximate grant/funds receive/invested for diagnostic development
40	Diagnostic submitted in National Healthcare Innovations Portal (NHInP) (Yes/No)
41	Any association or partnership with industry/private or governmental organization for diagnostic development *(Yes/No, Explain)*
42	Diagnostic available in public domain *(e. g. published, controlled distribution, patent etc.)* in any form (Yes/No, enlist)
43	Any IPR/copyright issues

III. Who can apply?

This call is open for both the public and private innovators from India such that the diagnostics/tests should be developed and manufactured only in India.

The concept proposals are expected to adhere to the following instructions:

1. Proposals must provide a strong rationale for the diagnostic test developed, demonstrating a clear understanding of the context and needs of targeted level of healthcare.
2. The proposals should not be in research phase and must address the diagnosis of AMR infections.
3. Developed diagnostics should be innovative, indigenous and feasible for the Indian healthcare settings.
4. Proposals detailing the ready-to-use diagnostics will be considered only.

IV. How to apply?

Applicants should submit the proposal through e-mail to icmr.amrdx@gmail.com .
Proposals should be submitted in the format (point no. II) only.

V. Important Timelines

The **last date for submission** of concept proposals is **30-12-2022**.

For any query, contact: icmr.amrdx@gmail.com
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