INDIAN COUNCIL OF MEDICAL RESEARCH
Department of Health Research - Ministry of Health & Family Welfare
Government of India

Rapid methods for antimicrobial susceptibility testing at point-of-care

Development of novel and/or improved diagnostic methods are sought to reduce the inappropriate and blind prescription of antibiotics and consumption with appropriate guidance and monitoring. We are aware that your research group has developed a point-of-care (POC) diagnostic which identify and facilitate the detection of drug resistant pathogens. ICMR is conducting a survey to understand the landscape of available indigenous diagnostics and efforts carried by scientist or private companies. This survey is meant to identify bottleneck or other challenges that are impeding the availability of good quality diagnostics in our health care system. Through this questionnaire we are seeking the information about developed diagnostic for antimicrobial susceptibility testing at POC and its validation.

1. What type of diagnostic/ assay/ method/ product is developed?

2. What is the intended use or application of the diagnostic?

3. Please provide the information of developer (s).

4. What is the principle (technology) of developed diagnostic?

5. Please describe the novelty of diagnostic.

6. What will be the beneficiary groups for the diagnostic?
   (e.g. POC, healthcare level, clinicians, nurses, hospital management, staff, patients, educationalists/socialist, technology experts and developers, local government and policy makers etc.)

7. What is the stage of development of diagnostic?
(e.g. Proof of concept or objective evidence)

8. Whether there was any association or partnership with industry or governmental organization for the development of diagnostic?

☐No ☐Yes, Please specify……

9. Whether any accreditation or mark or approval is obtained for the developed diagnostic?

☐ No ☐ Yes, Please specify……

10. How validation of diagnostic was performed (process of qualification)?
*(**Examples: For Instrument:** installation qualification (IQ), Operational qualification (OQ), Performance qualification (PQ), equipment details, service and maintenance*
***For assay:** protocol, specimen and antibiotics panel details, sample design, statistical advice/analyses, performance qualification, comparisons with alternative methods or with previously used test methods)*

Specimen used			
Targeted pathogen (s)			
Antibiotics panel used			
Testing population, sample size and design			
Gold standard or Reference followed or comparison (method currently or previously in use) used			
Parameter of validation met	Sensitivity (true positive)	☐ No	☐ Yes
	Specificity (true negative)	☐ No	☐ Yes
	Positive predictive value (PPV)	☐ No	☐ Yes
	Negative predictive value (NPV)	☐ No	☐ Yes
	uncertainty of measurement (UM)	☐ No	☐ Yes
	Limit of detection(LOD)	☐ No	☐ Yes
	Precision	☐ No	☐ Yes
	Linearity	☐ No	☐ Yes
	Accuracy	☐ No	☐ Yes
	Reproducibility (Robustness)	☐ No	☐ Yes
	Analytical sensitivity and specificity	☐ No	☐ Yes
	Limit of quantitation (LOQ)	☐ No	☐ Yes
	Any Other, if any		
Results Turnaround time			
How many tests can be performed (minimum & maximum) in a standard six hour working shift?			
Hands on time per unit test			

Stability/ shelf life tested	☐ No ☐ Yes, please specify……..
Any cross or collaborator laboratory test validation	☐ No ☐ Yes, please specify ……..
Quality control parameters met	
Is there any test results available for samples which challenge the performance of the method?	☐ No ☐ Yes, please specify …….
Any IPR/copyright issues worth mentioning?	
Limitation, if any	

11. Is developed diagnostic available in public domain in any form?
(e.g. published, controlled distribution, patent etc.)

12. Whether cost benefit analysis done or not?

13. Whether associated risk assessment evaluated or not?
(e.g. any risk of new procedure or additional hazards arise throughout the course of the evaluation which were not identified during the initial risk assessment?)

14. Any other information related to your developed diagnostic, you wish to provide.

Name:…….

Designation:……

Date:……...

Signature:…….