

Global first initiative and release of compendium of standard In-Vitro Diagnostics (IVDs) Evaluation protocol and minimum standard for high risk infectious disease IVDs and launch of IVD kit validation portal

Standardized In-Vitro Diagnostic (IVD) Evaluation Protocols, jointly developed by the Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organization (CDSCO) has been released by Smt. Anupriya Patel, Honourable Minister of State, Ministry of Health & Family Welfare and Chemicals & Fertilizers, Dr. Rajiv Bahl, DG-ICMR, Dr. Rajeev Singh Raghuvanshi, DCGI, Dr. Nivedita Gupta, Head, Division of Communicable disease, ICMR, Smt. Anu Nagar, JS DHR, Smt. Manisha Saxena, Sr. DDG-ICMR, and officials from IVD Division, CDSCO and ICMR on 11th September, 2025. This marks a significant milestone of the MoU between ICMR and CDSCO aimed at strengthening the IVD testing capacity. This edition includes 39 evaluation protocols of IVDs including 10 field evaluation protocols. Online portal for kit validation would ease the kit performance evaluation process and tracking for the stakeholders.



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FORWARD
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FOREWORD BY DIRECTOR-GENERAL, INDIAN COUNCIL OF MEDICAL RESEARCH

After the COVID-19 pandemic, the diagnostic industry of India has grown immensely, and is ready to contribute to the public health system by developing in-vitro diagnostic (IVD) kits for timely detection of pathogens causing critical infectious diseases. It is important to keep pace with the evolution of our diagnostic industry and create commensurate mechanisms for technical oversight, such as standard in-vitro diagnostic evaluation protocols, and a network of accredited laboratories for timely validation of new diagnostic kits and their introduction in the market.

The Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organization (CDSCO) are working tirelessly to create this ecosystem within the country to support in-vitro diagnostic kit validation. I am happy to note that the first batch of 39 standard IVD evaluation protocols are being unveiled. This includes protocols for performance evaluation of IVDs detecting Tuberculosis, Malaria, Dengue, Chikungunya, Zika virus, Typhoid fever, various respiratory viruses, Chlamydia virus and Nipah virus. I am sure that this landmark initiative will contribute immensely in strengthening the quality of IVDs in India, and also enable them to compete for global licensure.

I congratulate the ICMR and CDSCO teams for undertaking this excellent endeavor. I also understand that the process of standard protocol development will continue, and the scope will be expanded to cover other diseases and IVD formats.

Rajiv Bahl
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ICMR-CDSCO STANDARD PERFORMANCE EVALUATION PROTOCOLS

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