

ICMR-CDSCO/IVD/GD/PROTOCOLS/01/2024

Indian Council of Medical Research and Central Drugs Standard Control Organization
Department of Health Research and Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
Document No.: ICMR-CDSCO/IVD/GD/PROTOCOLS/01/2024

Subject: Inviting comments on standard IVD evaluation protocols drafted by ICMR and CDSCO

Licensure of In-Vitro Diagnostics (IVDs) under Medical Devices Rules 2017 requires a detailed evaluation protocol for the performance evaluation of IVDs to evaluate their quality and performance. To facilitate this process, the Indian Council of Medical Research (ICMR) and CDSCO have come together to draft standard evaluation protocols for use by IVD manufacturers testing labs in India. Currently, the following IVD evaluation protocols have been developed by ICMR and CDSCO:

1. Performance evaluation protocol for Chikungunya IgM ELISA
2. Performance evaluation protocol for Chikungunya IgM RDT
3. Performance evaluation protocol for Chikungunya real-time PCR
4. Performance evaluation protocol for Dengue NS1 RDT
5. Field evaluation protocol for Dengue NS1 RDT
6. Performance evaluation protocol for Dengue NS1 ELISA
7. Field evaluation protocol for Dengue NS1 ELISA
8. Performance evaluation protocol for Dengue IgM RDT
9. Performance evaluation protocol for Dengue IgM ELISA
10. Performance evaluation protocol for Dengue NS1/ IgM combo RDT
11. Field evaluation protocol for Dengue NS1/ IgM combo RDT
12. Performance evaluation protocol for Dengue real-time PCR
13. Field evaluation protocol for Dengue real-time PCR
14. Performance evaluation protocol for Zika virus real-time PCR

The protocols are now being placed in the public domain for comments from relevant stakeholders. This window of opportunity will close on 15th February 2025, and, once finalized, there will be minimal scope for change in these documents. Therefore, all interested stakeholders are requested to provide their comments before 15th February 2025, at ivdevaluation@gmail.com as per the enclosed format. Once the public consultation period concludes, all comments will be reviewed and considered in finalizing the draft protocols before final clearance by ICMR and CDSCO.

Dated: 31st December 2024

Place: New Delhi

STANDARD IVD PERFORMANCE EVALUATION PROTOCOL
STAKEHOLDER FEEDBACK FORM

S.N.	Name of the Protocol	Document No.	Page No.	Line No.	Current Text	Proposed Text	Explanation/Reference

Name: _____

Designation and Affiliation: _____