

ICMR-CDSCO/IVD/TB/PROTOCOLS/2025

Indian Council of Medical Research and Central Drugs Standard Control Organization

Department of Health Research and Drugs Controller General of India

Ministry of Health and Family Welfare

Government of India

Document No.: ICMR-CDSCO/IVD/TB/PROTOCOLS/2025

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 protocols for Tuberculosis have been developed by ICMR and CDSCO:

1. Analytical Performance Evaluation of In-Vitro Diagnostics for Pulmonary Tuberculosis
2. Clinical Performance Evaluation of In-Vitro Diagnostics for Pulmonary Tuberculosis
3. Clinical Performance Evaluation of In-Vitro Diagnostics for Pulmonary Drug Resistant Tuberculosis

These protocols are now being placed in the public domain for comments from relevant stakeholders. This window of opportunity will close on 7th **September 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 7th **September 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: 27th August 2025

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: _____