Government of India

Ministry of Consumer Affairs, Food and Public Distribution

Department of Consumer Affairs

LOK SABHA
UNSTARRED QUESTION NO. 5201
TO BE ANSWERED ON 02.04.2025

STANDARDIZATION OF LABORATORY PROCEDURES

5201. DR. AMAR SINGH:

Will the Minister of **CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION** be pleased to state:

(a) whether standardization of laboratory procedures and maintenance of accurate reference ranges is crucial to ensure consistent and comparable results across different laboratories;
(b) if so, the details of the steps proposed to be taken by the Government keeping in mind that clinicians desperately need accurate results that are uniformly comparable between different laboratories; and
(c) if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE
CONSUMER AFFAIRS, FOOD AND PUBLIC DISTRIBUTION
(SHRI B.L.VERMA)

(a) to (c) : Standardization of laboratory procedures and maintenance of accurate reference ranges are crucial for consistent and comparable results across different laboratories. It ensures that results produced by a laboratory are consistent, reproducible, and comparable with other standardized laboratories with minimum or no variability. Reference ranges are crucial to be defined with their basis recorded to serve the users and population served by the laboratories. The Government emphasizes consistency in test results for accurate diagnosis and treatment, increasing confidence and satisfaction among stakeholders.

To ensure consistent results that can help clinicians access accurate results that are uniformly comparable between different laboratories, the government encourages laboratories to obtain accreditation from the National Accreditation Board for Testing and Calibration Laboratories, which is a constituent Board of the Quality Council of India (QCI) and is the national accreditation body of India w.r.t. conformity assessment bodies offering testing (including medical/diagnostic testing), calibration, proficiency testing providers and reference material producers. NABL has been providing accreditation services to laboratories in accordance with international standards (ISO/IEC 17011), accepted uniformly for laboratories across the world, such as:

i. ISO/IEC 17025:2017 ‘General requirements for the competence of testing and calibration laboratories’
ii. ISO 15189:2022 ‘Medical Laboratories- Requirements for quality and competence’
iii. ISO/IEC 17043:2023 ‘Conformity assessment — General requirements for the competence of proficiency testing providers’
iv. ISO 17034:2016 ‘General requirements for the competence of reference material producers’
v. ISO 20387:2018 for ‘Biotechnology-Biobanking-General requirements for Biobanking’

NABL accreditation ensures the following:

i. that all the components of laboratories- facilities, testing environment conditions, resources including personnel, equipment, Reagents and consumables, external services, examination methods, Internal quality checks, external quality assurance participation and management system requirements fulfil to the requirements of standard. It ensures that reference ranges are defined with their basis recorded to serve the users and population served by the laboratories.
ii. periodic assessments, surveillance and continuous monitoring to assess the fulfilment of the requirements of the standard in the laboratories.
iii. third party assessment wherein competency, impartiality and consistent operation of the laboratory is assessed for specific test(s) performed
iv. validity of test results by means of participation in Proficiency Testing, Inter-laboratory comparison or Intra-laboratory comparisons
v. quality management system in place in accordance with the requirement as laid down in relevant International standard i.e. ISO/IEC 17025 or ISO 15189

NABL accreditation is already leveraged as a requirement for empaneling laboratories for regulatory or various government health services as a benchmark of quality and competence.

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