Annexure V

NABL/ANCMT/2024/02/01 **13 February 2024**

Reference:

i) Document NABL 112 “Specific Criteria for Accreditation of Medical Laboratories”, Issue No. 04 Date: 11.02.2019, Amendment No. 01 Amendment Date: 26.04.2019

ii) ISO 15189: 2022 “Medical laboratories — Requirements for quality and competence”

Addendum to NABL 112 document in respect of ISO 15189:2022 version

Introductory requirements of ISO 15189:2022 - Medical laboratories — Requirements for quality and competence.

1. This standard promotes the welfare of patients and satisfaction of laboratory users.
2. The ISO 15189:2022 standard incorporates the requirements of Point-of-care-testing.
3. Requirements to plan and implement actions to address risks and opportunities for improvement in turn decreasing probability of invalid results.
4. The requirements of risk management are aligned with the principles of ISO 22367:2020-Medical laboratories - Application of risk management to medical laboratories.
5. The requirements for laboratory safety are aligned with the principles of ISO 15190-Medical laboratories- Requirements for safety.
6. The requirements for sample collection and transport are aligned with ISO 20658-Requirements for the collection and transport of samples for medical laboratory examinations.

Table specifying the applicability of this document to different clauses of ISO 15189:2022

ISO 15189: 2022 Requirement	Refer NABL 112 Issue No. 4 Requirements
5.1 Legal entity 5.2 Laboratory Director	Page No. 10 - Organization and management responsibility
6.7 Service agreements Agreement with laboratory users Agreement with POCT operators	Page No. 11 - Service Agreements
6.8.2 Referral laboratories and consultants 6.8.3 Review and approval of externally provided products and services	Page No. 11 - 4Examination by referral laboratories
5.3.3 Advisory activities	Page No. 12 - Advisory services
8.4 Control of records Creation of records Amendment of records Retention of records	Page No. 13 - Control of records
8.8 Evaluations	Page No. 14 - Evaluation and audits
6.2 Personnel	5.1 Personnel
6.3 Facilities and environmental conditions	5.2 Accommodation and environmental conditions
6.4 Equipment Equipment requirements Equipment acceptance procedure Equipment instructions for use Equipment adverse incident reporting Equipment records 6.5 Equipment calibration and Metrological traceability 6.5.2 Equipment Calibration 6.6 Reagents and consumables Receipt and storage Acceptance testing Inventory Management Instructions for use Adverse Incident Reporting	5.3 Laboratory equipment, reagents and consumables
7.2 Pre-examination processes Primary Sample collection and handling Sample transportation Sample receipt Pre-examination handling, preparation and storage	5.4 Pre-examination processes

ISO 15189: 2022 Requirement	Refer NABL 112 Issue No. 4 Requirements
7.2 Examination processes Verification of examination methods Validation of examination methods Evaluation of Measurement Uncertainty Biological reference interval and clinical decision limits Documentation of examination procedures	5.5 Examination processes
7.3.7 Ensuring the validity of examination results Internal quality Control External quality assessment Comparability of examination results	5.6 Ensuring quality of examination results
7.3 Post examination processes Reporting of results Post-examination handling of samples	5.7 Post examination processes
7.4.1 Reporting of results Critical result reports Special considerations for results Automated selection, review, release and reporting of results Requirements of reports Amendments to reported results	5.8 Reporting of results
7.4.1.2 Result review and release	5.9 Release of results
7.6 Control of data and information management Authorities and responsibilities for Information management Information Systems management Downtime plans Off site management	5.10 Laboratory information management