

IVDR Laboratory Accreditation Checklist

Laboratory Safety & Infrastructure

- Designated zones for testing, prep, and waste handling
- Calibrated biosafety cabinets and spill control measures
- Emergency exits, eyewash stations, and hazard signage

Equipment & Calibration

- Instrument inventory with calibration certificates
- IQ/OQ/PQ completed for key diagnostic devices
- Software-driven instruments validated and maintained

Quality Control & Documentation

- Internal QC plans and external proficiency testing (PT)
- CAPA records tied to audits or deviations
- Documented sample retention and batch release policy

SOPs & Staff Competency

- Accessible, version-controlled SOPs
- Staff training logs linked to each SOP
- Verified staff qualifications and biosafety training

Regulatory Readiness

- IVDR conformity files with NB communication logs
- Inspection-ready QMS aligned with ISO 15189 or ISO 13485
- Secure LIMS with validated access controls and audit trails