Quality Management Systems for non-laboratory settings – Toolkit

Environmental conditions to conduct testing

World Health Organization

Environmental conditions to conduct testing

Non-laboratory settings (e.g., community-based clinics, outreach sites, mobile units, health posts, and pharmacies) are increasingly used for delivering Point-of-Care Testing (POCT), particularly for infectious diseases like HIV, syphilis, hepatitis, malaria etc. These settings often lack the standard infrastructure, resources, and oversight of conventional laboratories. To ensure test reliability and operator safety, national guidelines must define minimum environmental and safety standards tailored to these decentralized contexts.

A. Environmental conditions for accurate testing

Read more: Module 3: testing environment, safety and IPC, from Pillar 2: workforce development

Category	***Details***
1. Temperature and Humidity Control	• RDTs and POCT devices must be stored and used within conditions specified by the manufacturer; in general the temperature (15°C–30°C) and relative humidity (≤60%) . • Use digital thermometers and hygrometers to monitor conditions where they are used. • Keep temperature logs and have a protocol in place if limits are exceed ed (e.g., relocate stock or discard). • In areas with unreliable electricity, use passive cooling, insulated boxes, or solar-powered fridges.
2. Ventilation and Lighting	• Ensure good ventilation to reduce aerosols and ensure comfort. • Use natural or bright artificial lighting, especially for reading line-based RDTs (e.g., HIV, syphilis). • Avoid placing testing stations in direct sunlight or near heat sources.
3. Cleanliness and Workspace Design	• Use non-porous, easy-to-clean surfaces and disinfect regularly (e.g., with 0.5% chlorine or 70% ethanol). • Designate separate workspaces for specimen prep, testing, and recordk eeping. • Keep workspace uncluttered to reduce errors and contamination.
4. Stock management Read more: Pillar 3: Testing Site Inventory Management and ordering process	• Store tests and reagents according to manufacturer's recommendation, in lockable, dustproof storage. • Maintain a stock register and follow FEFO (first-expire-first-out). • Calibrate or verify electronic POCT devices regularly.

B. Biosafety measures

Read more: Module 3: testing environment, safety and IPC, from Pillar 2: workforce development

Category	Details
1. Infection Prevention and Control (IPC)	• Country must conduct a risk analysis (disease and procedures) to decide appropriate Personal Protective Equipment (PPE) • Ensure consistent availability and use of PPE: gloves, masks, eye protection, and lab coats or aprons. • Provide accessible hand hygiene facilities (alcohol-based rubs or handwashing stations with clean water and soap). • Prohibit eating, drinking, smoking, or personal smartphone use at the workstation.
2. Biosafety and Biosecurity	• Store biological specimens in leak-proof, labeled containers. • Implement contamination control procedures with designated "clean" and "dirty" zones; restrict movement during testing.
3. Waste Management	• **Sharps**: Dispose of lancets, capillary tubes, and needles in puncture-proof, labeled containers. • **Biohazardous waste**: Dispose of used test devices, gloves, etc., in red or yellow bags as per national IPC standards. • **Decontamination and transport**: Train staff in on-site decontamination (e.g., 0.5% sodium hypochlorite) and safe waste transport protocols.
4. Emergency Preparedness and Response	• Develop SOPs for occupational exposure to blood or body fluids. • Provide an emergency first aid kit and display key emergency contacts (e.g., infection control officer, district supervisor, ambulance, Post Exposure Prophylaxis site). • Record and report any occupational exposure incidents • Conduct refresher training to assess emergency readiness.

C. Implementation Process

Step	Description
Step 1. Risk Assessment	Conduct structured risk assessments using a checklist to evaluate environmental and biosafety risks at each site. Prioritize sites based on test volume.
Step 2. SOP Development	Develop standardized SOPs for environmental monitoring, waste management, PPE use, and spill management, tailored to non-laboratory settings.
Step 3. Training and Mentorship	Train all non-laboratory testing personnel in IPC, biosafety, environmental standards, and emergency procedures. Use visual job aids and provide onsite mentoring.
Step 4. Supervision Read more: Supportive site supervision visit tools in Pillar 4: Process control, assessment and continuous quality improvement	Integrate environmental and safety indicators into national site supervision tools. Conduct regular supportive supervision and spot audits using mobile or paper-based checklists.
Step 5. Corrective and Preventive Actions (CAPA) Read more: Occurrence management and process improvement in Pillar 4: Process control, assessment and continuous quality improvement	Establish a clear mechanism for reporting deviations and implementing CAPA, with structured feedback to site staff and regional/national QA focal points.

D. Integration with National QA and IPC Systems

For testing activities to be safe, effective, and sustainable, it must be integrated into broader national frameworks for quality assurance (QA) and infection prevention and control (IPC). This integration ensures consistency in safety practices, supports regulatory oversight, and aligns facility-level actions with national health priorities.

- *Policy Linkages*

Testing implementation should not occur in isolation. Environmental and biosafety guidelines specific to testing must be harmonized with existing national IPC policies and Quality Management System (QMS) frameworks. For example, procedures for waste management, PPE use, and equipment decontamination in testing settings should be consistent with those applied in central laboratories and clinical care environments. Aligning these policies helps avoid fragmentation, ensures standardized safety measures, and promotes cohesive health system functioning.

- *Stakeholder Roles*

Clear delineation of roles and responsibilities is essential for effective implementation and oversight. Ministries of Health (MoH) must define how different departments, including laboratory services, IPC units, and primary health care divisions, collaborate to supervise

testing safety. Implementing partners, donors, and facility managers also play a role in ensuring compliance with IPC protocols, reporting breaches, and supporting capacity building. This coordination helps maintain accountability and ensures that safety is a shared, system-wide responsibility.

- *Monitoring Indicators*

Incorporating testing-specific safety indicators into national health dashboards or monitoring tools enables data-driven decision-making and continuous quality improvement. Examples of such indicators include:

  - % of testing sites with up-to-date temperature logs (ensuring storage conditions are maintained for diagnostic reagents).
  - Availability rate of PPE at testing sites (e.g., gloves, masks, disinfectants).
  - % of testing staff trained in biosafety and IPC protocols (ensuring that frontline health workers follow standard safety practices).

These indicators provide a snapshot of IPC compliance at decentralized testing sites and help identify areas that need corrective action or additional training.