

HANDBOOK



HIV DIAGNOSTICS

IMPROVING THE QUALITY OF HIV-RELATED POINT- OF-CARE TESTING:

ENSURING THE RELIABILITY AND ACCURACY
OF TEST RESULTS

DECEMBER 2015

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ABBREVIATIONS AND ACRONYMS

ISO International Organization for Standardization

NGO nongovernmental organization

TB tuberculosis

UNAIDS Joint United Nations Programme on HIV/AIDS

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DEFINITIONS

Connectivity

The ability to transmit data from testing conducted at the point-of-care site to a central database, such as a laboratory information system, for analysis and review. The data can be reviewed for the purposes of quality assurance. Connectivity may be through equipment-based testing devices that have connectivity capabilities or through future application of smartphone devices for non-equipment-based testing such as rapid diagnostic testing.

External quality assessment

Defined as a system for objectively checking the performance of a testing site (including the testers and the system used for testing) using an external agency. External quality assessment is sometimes used interchangeably with proficiency testing; however, external quality assessment can also be carried out using other processes such as retesting of samples by another accredited facility and site visits.

Point-of-care testing

Point-of-care testing has no universal definition; however, the core components of point-of-care testing are: (1) testing is carried out at or near the person being tested, (2) the results are returned to the person being tested during the same visit and (3) the results of point-of-care testing can be used immediately for patient care and referral. Point-of-care testing can be implemented in hospitals (critical care units, emergency care, surgery, maternity and neonatal units), laboratories, nursing homes, outpatient settings (physician's offices, pharmacies and remote locations) and in patients' homes. Different point-of-care tests are applicable at different levels of health-care systems; for example, non-equipment-based point-of-care rapid diagnostic testing has been fully decentralized to the community level (level 1), whereas equipment-based point-of-care testing (CD4 testing, future point-of-care early infant diagnosis testing and viral load testing) is suitable for point-of-care facilities down to primary health care facilities (level 2). This handbook refers

as well as point-of-care tests for monitoring people living with HIV who are receiving antiretroviral therapy such as CD4 testing and viral load testing. This handbook can also be used for other point-of-care testing programmes including tuberculosis (TB), sexually transmitted diseases, malaria and hepatitis.

Quality assurance

The continuous and systematic approach to monitor, evaluate and include actions to improve the quality of testing. Quality assurance is the core topic of this handbook and adapts many of the quality assurance principles that have been developed for laboratory testing. The continuous assessment of quality is described as encompassing various elements such as quality control, external quality assurance, documentation, supervision, safety and inventory management.

Quality control

Procedures used routinely to assure that a test run is valid and the test results are reliable and include internal kit controls and/or external quality control samples with well established results.

Quality corps

A group of volunteers hired temporarily to assist with quality assurance activities. This concept is based on a successful pilot programme in Africa to recruit volunteer personnel from the community where testing is carried out who are trained in specific elements of quality assurance and can undertake these activities such as expedited dispatch of proficiency panels, quality control specimens or standardized logbooks and rapid return of results, enabling deeper access and penetration at rural sites where testing is being carried out.

Quality improvement

An integral part of the quality assurance cycle that responds to the assessment and improvement activities, leading to better testing and health care outcomes using evidence-

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