World Health Organization

HIV DRUG RESISTANCE

WHO/HIVRESNET HIV DRUG RESISTANCE

LABORATORY OPERATIONAL FRAMEWORK

DECEMBER 2017

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ACRONYMS AND ABBREVIATIONS

ART	Antiretroviral therapy
ARV	Antiretroviral drugs
BCCfE	British Colombia Centre for Excellence in HIV/AIDS
CDC	Centers of Disease Control and Prevention (United States)
CPR	Calibrated Population Resistance
CRF	Circulating recombinant form
DBS	Dried blood spot
DNA	Deoxyribonucleic acid
DPS	Dried plasma spot
DSS	Dried serum spot
EQA	External quality assurance
HIV	Human immunodeficiency virus
HIVDR	HIV drug resistance
HIVResNet	HIV Drug Resistance Network
MOH	Ministry of Health
NDRL	National HIV Drug Resistance Laboratory
PCR	Polymerase chain reaction
PP	Proficiency panel
PR	Protease
QA	Quality assurance
QC	Quality control
RDRL	Regional HIV Drug Resistance Laboratory
RNA	Ribonucleic acid
RT	Reverse transcriptase
SDRL	Specialized HIV Drug Resistance Laboratory
SOP	Standard operating procedures
WHO	World Health Organization

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EXECUTIVE SUMMARY

The World Health Organization (WHO) HIV Drug Resistance Network (HIVResNet) Laboratory Operational Framework describes how WHO HIVResNet laboratories function to support national, regional, and global HIV drug resistance (HIVDR) surveillance by providing accurate genotyping results in a standardized format according to WHO specifications. The aim of the WHO HIVDR Laboratory Operational Framework is to ensure:

- Accurate collection, handling, shipment and storage of specimens collected in countries implementing HIVDR surveillance;
- Availability of quality-assured HIV genotyping laboratory services producing comparable and reliable results at the national, regional and global level.

WHO recommends that all countries implementing HIVDR surveys send specimens for HIVDR genotyping to laboratories designated by WHO for this purpose. This document describes:

- The structure of the Laboratory Network;
- The roles and responsibilities of the different types of Network Laboratories;
- The requirements for application;
- The application review and evaluation process;
- The requirements for the submission of HIVDR data to WHO.

The WHO/HIVResNet Laboratory Operational Framework consists of the following four elements:

1. National strategy for HIVDR surveillance laboratory support;
2. WHO/HIVResNet Laboratory Network. The HIVResNet Laboratory Network is responsible for ensuring the delivery of quality-assured HIV genotyping data at the national, regional and global level. The Network includes different categories of membership, with different tasks and responsibilities:
   - National HIVDR Laboratories (NDRL; usually one per country);
   - Regional HIVDR Laboratories (RDRL; usually one per WHO region);
   - Specialized HIVDR Laboratories (SDRL).
3. Standards for specimen collection, handling, shipment, and storage. The Laboratory Network provides guidance documents and laboratory procedures to support standardization of all components of the Laboratory Operational Framework;
4. Laboratory technical support for capacity building.

Summary of updates

This document is an update of the WHO HIV Drug Resistance Laboratory Strategy published in 2010 and reflects the accumulated knowledge and experience of the Laboratory Network over the last

2. Minimum required criteria for a laboratory to apply for designation as a member of the Laboratory Network (Annex 4);
3. Addition of a "dry" proficiency panel

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