TARGET PRODUCT PROFILE FOR NEXT-GENERATION DRUG-SUSCEPTIBILITY TESTING AT PERIPHERAL CENTRES

Stop TB Partnership
New Diagnostics Working Group

World Health Organization

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Abbreviations and acronyms

AMK	amikacin
BDQ	bedaquiline
BPaL	bedaquiline-, pretomanid- and linezolid-based regimen
CFZ	clofazimine
DLM	delamanid
DCS	D-cycloserine
DR-TB	drug-resistant tuberculosis
DST	drug-susceptibility testing
EMB	ethambutol
FQ	fluoroquinolones
GDF	Global Drug Facility
HIV	human immunodeficiency virus
Hr-TB	isoniazid-resistant TB
INH	isoniazid
KAN	kanamycin
LFX	levofloxacin
LMIC	low- and middle-income countries
LPA	line probe assay
LZD	linezolid
MDR/RR-TB	multidrug-resistant or rifampicin-resistant tuberculosis
MDR-TB	multidrug-resistant tuberculosis
MXF	moxifloxacin
NDWG	New Diagnostics Working Group
NGS	next-generation sequencing
Pa	pretomanid
PPV	positive predictive value
pre-XDR TB	pre-extensively drug-resistant tuberculosis
PZA	pyrazinamide
RIF	rifampicin
RR-TB	rifampicin-resistant tuberculosis
R&D	research and development
TB	tuberculosis
TPP	target product profile
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Definitions

Drug-susceptibility testing (DST)[1] refers to in vitro testing using either phenotypic methods to determine susceptibility, or molecular techniques to detect resistance-conferring mutations to a particular medicine.

Rifampicin-susceptible, isoniazid-resistant tuberculosis (Hr-TB)[2] refers to *Mycobacterium tuberculosis* strains with resistance to isoniazid (INH) and susceptibility to rifampicin (RIF) confirmed in vitro.

Rifampicin-resistant tuberculosis (RR-TB)[2] is caused by *M. tuberculosis* strains that are resistant to RIF. These strains may be susceptible or resistant to INH (i.e. multidrug-resistant TB [MDR-TB]), or resistant to other first-line or second-line TB medicines. In these guidelines and elsewhere, MDR-TB and RR-TB cases are often grouped together as MDR/RR-TB and are eligible for treatment with MDR-TB regimens.

Multidrug-resistant tuberculosis (MDR-TB)[2] is caused by *M. tuberculosis* strains that are resistant to at least RIF and INH.

Pre-extensively drug-resistant tuberculosis (pre-XDR-TB)[3] is caused by *M. tuberculosis* strains that fulfil the definition of MDR/RR-TB and that are also resistant to any fluoroquinolone (FQ).

Extensively drug-resistant tuberculosis (XDR-TB)[3] is caused by *M. tuberculosis* strains that fulfil the definition of MDR/RR-TB and are also resistant to any FQ and at least one additional Group A drug.

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1 Implementing tuberculosis diagnostics: policy framework. (WHO/HTM/TB/2015.11). Geneva: World Health Organization. 2015 (https://apps.who.int/iris/bitstream/handle/10665/162712/9789241508612_eng.pdf?sequence=1&isAllowed=y).

2 WHO consolidated guidelines on drug-resistant tuberculosis: Module 4: treatment: drug-resistant tuberculosis treatment. Geneva: World Health Organization. 2020 (https://www.who.int/publications/i/item/9789240007048).

3 Meeting report of the WHO expert consultation on the definition of extensively drug-resistant tuberculosis, 27–29 October 2020. Geneva: World Health Organization. 2021 (https://www.who.int/publications/i/item/meeting-report-of-the-who-expert-consultation-on-the-definition-of-extensively-drug-resistant-tuberculosis).

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