

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





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# Abbreviations and acronyms

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

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# Definitions

**Drug-susceptibility testing (DST)**<sup>1</sup> 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)**<sup>2</sup> refers to *Mycobacterium tuberculosis* strains with resistance to isoniazid (INH) and susceptibility to rifampicin (RIF) confirmed in vitro.

**Rifampicin-resistant tuberculosis (RR-TB)**<sup>2</sup> 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)**<sup>2</sup> is caused by *M. tuberculosis* strains that are resistant to at least RIF and INH.

**Pre-extensively drug-resistant tuberculosis (pre-XDR-TB)**<sup>3</sup> 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)**<sup>3</sup> 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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<sup>1</sup> 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](https://apps.who.int/iris/bitstream/handle/10665/162712/9789241508612_eng.pdf?sequence=1&isAllowed=y)).

<sup>2</sup> 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>).

<sup>3</sup> 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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