



BD MAX™
MDR-TB
Assay

Advance the standard of testing for multidrug-resistant tuberculosis (MDR-TB)

BD MAX™ MDR-TB

BD MAX™ MDR-TB is an integrated molecular assay for the detection of *Mycobacterium tuberculosis* complex (MTBc) and mutations associated with resistance to rifampin (RIF) and isoniazid (INH).

Supported by the World Health Organization (WHO)



The extent of the drug-resistant TB problem

Globally, about

10M

people get TB each year²

In 2020, there were

484K

new rifampin-resistant TB cases (RR-TB)²

78%

of these cases were multidrug resistant TB (MDR-TB)²

800K

patients are estimated to be rifampin-susceptible and isoniazid-resistant (Hr-TB)³

Globally, TB affects about 10 million people each year.¹

Drug-resistant forms of TB are responsible for 1/4 of annual deaths due to antimicrobial resistance (AMR) worldwide.²

What's more, drug-resistant TB can be difficult to diagnose and successfully treat, increasing overall costs and the risk of community spread.^{4,5}

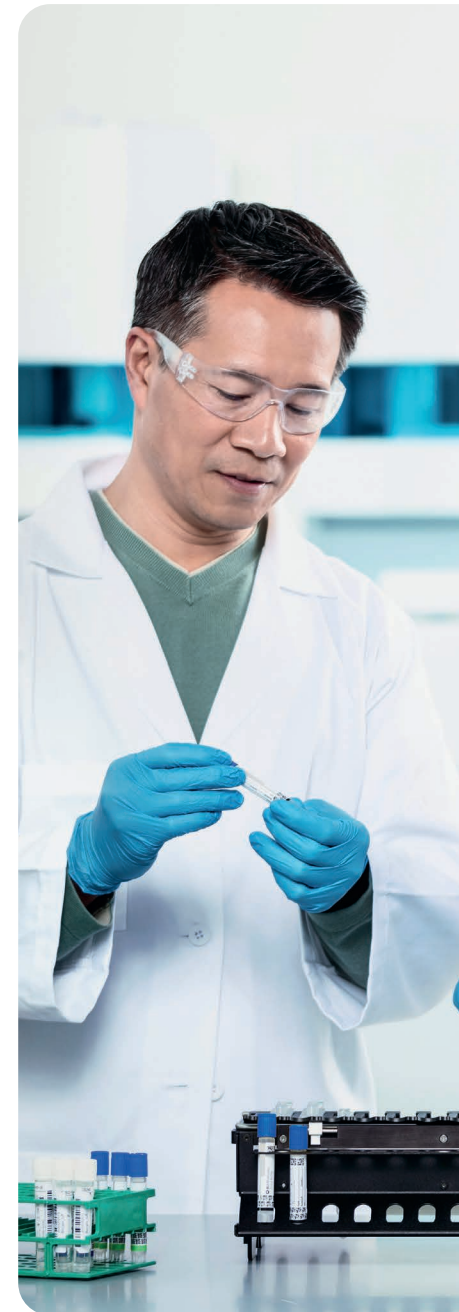
Drug-susceptible TB is associated with a 85% treatment success rate and a median cost of US\$973 per patient.⁴



The treatment success rate falls at 56% for MDR-TB, with a median cost of US\$6,430 per patient.⁴



Treatment success rate is only 39% for extensively drug-resistant TB (XDR-TB),⁴ and cost reaches a median of US\$26,292 per patient.⁵





Resistance to isoniazid without resistance to rifampin (Hr-TB) is associated with higher treatment failure and relapse rates, and it often remains undiagnosed or diagnosed after significant delays.⁶

The WHO recommends testing for genetic mutations associated with resistance to isoniazid (katG or inhA).⁷

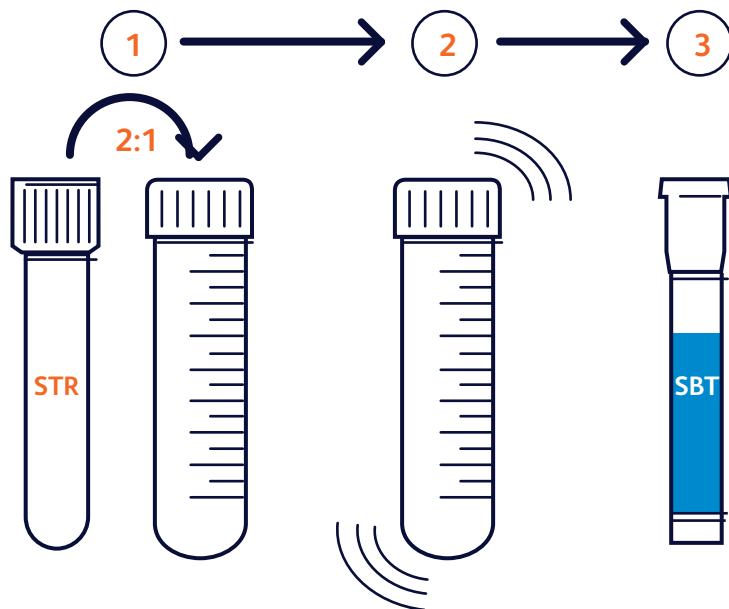
Widely used molecular tests today do not provide resistance results for both rifampin and isoniazid to report MDR-TB.⁶

Rapid, automated molecular multidrug resistance testing can enhance the diagnostic algorithm with liquid culture for drug-susceptibility testing and patient monitoring.⁶

“Without rapid testing for INH resistance, the appropriate implementation of a reliably effective regimen can be delayed...”⁶

BD MAX™ MDR-TB assay delivers 4 results in 1 test

The BD MAX™ MDR-TB assay is able to report both *inhA* and *katG* gene mutations – the two most frequently reported mutations associated with Isoniazid resistance.⁶



Tuberculosis

Multi-copy + single copy
genomic targets

Multidrug-resistant tuberculosis

RIFAMPIN
(*rpoB* gene) - RRDR

ISONIAZID
(*inhA*) promoter

ISONIAZID
(*katG*)

BD MAX™ MDR-TB workflow⁸

Specimen preparation in biosafety cabinet

1. Transfer BD MAX™ Sample Treatment Reagent (STR) to sputum specimen*
2. Mix (30 min. RT. Shake vial after 5 min.)
3. Transfer mixture to BD MAX™ Sample Buffer Tube

*Both raw and processed sputum are indicated for use

Clinical performance to support your testing needs

A recently published multicenter study found that the BD MAX™ MDR-TB assay had high sensitivity and specificity for detection of MDR-TB and RIF and INH drug resistance and may be an important tool for rapid detection of TB and MDR-TB globally.⁹

For many high-burden settings with a high-volume of testing, the BD MAX™ [MDR-TB] assay may represent an important automated tool for the rapid detection of both MTB and drug resistance.⁹

Fresh MTB sensitivity stratified by Auramine O and Ziehl-Neelsen staining methods when the staining method was performed from the raw sputum⁸

BD MAX™ MDR-TB Assay Performed on:	Auramine O Method ^a		Ziehl-Neelsen Method ^b	
	Raw sputum	Processed sputum	Raw sputum	Processed sputum
	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)	Percent (95% CI)
Sensitivity smear positive	100.0% (178/178) (97.9%, 100%)	100.0% (176/176) (97.9%, 100%)	100.0% (149/149) (97.5%, 100%)	100.0% (147/147) (97.5%, 100%)
Sensitivity smear negative	81.5% (97/119) (73.6%, 87.5%)	73.1% (87/119) (64.5%, 80.3%)	85.1% (126/148) (78.5%, 90.0%)	78.4% (116/148) (71.1%, 84.2%)

a Smear results were not available for 3 specimens with a Reference Method negative.

b Smear results were not available for 2 specimens with a Reference Method negative.

Fresh RIF performance overall compared to the composite RM culture/DST plus NAAT and bi-directional sequencing⁸

	Raw sputum	Processed sputum
Overall sensitivity	94.1% (16/17) ^a (73.3%, 99%)	93.8% (15/16) ^b (71.7%, 98.9%)
Overall specificity	98.5% (202/205) (95.8%, 99.5%)	97.4% (191/196) (94.2%, 98.9%)

Fresh INH performance overall compared to the RM (culture/DST)⁸

	Raw sputum	Processed sputum
Overall sensitivity	81.5% (22/27) (63.3%, 91.8%)	84% (21/25) (65.3%, 93.6%)
Overall specificity	100% (205/205) (98.2%, 100%)	100% (188/188) (98%, 100%)

^aOut of the 17 RIF resistant samps, 7 were DST RIF susceptible or non-evaluable, but Xpert MTB/RIF was RIF resistance detected and bi-directional sequencing confirmed the resistance. The resistance detected were L511P, D516y, D516F, H526N and L533P.

^bOut of the 16 RIF resistant samps, 6 were DST RIF susceptible but Xpert MTB/RIF was RIF resistance detected and bi-directional sequencing confirmed the resistance. the resistance detected were L511P, D516Y, D516F and L533P.



Streamlined integration into existing workflow with the BD MAX™ System family

- The BD MAX™ System family offers you a fully integrated, automated real-time PCR platform with a broad menu of molecular IVD and open-system tests.¹⁰
- The automated workflow and analytical performance help reduce the need for manual tasks, achieve more reliable and rapid results, and decrease the need for retesting.^{11,12}
- In particular, for MDR/TB detection systems, the BD MAX™ MDR-TB assay scored highest for ease of use, feasibility.¹³
- The compact and self-contained unitised reagent strips and the new reclosing septum cap help simplify waste management and reduce the risk of contamination.
- Reagents can be stored at room-temperature, making inventory and storage more convenient for you.¹²



Snap

Assemble unitised reagent strips with extraction and PCR reagents.



Less than **1.5 minutes** hands-on time
per sample¹²

Load

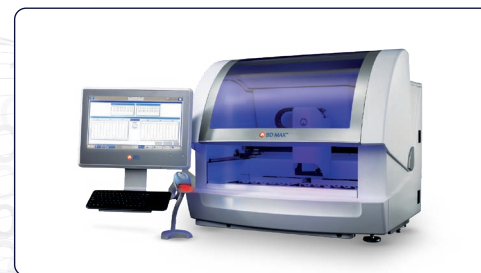
Load the Sample Buffer Tubes, racks and PCR cartridges.



24 patient results in **less than**
4 hours, on average⁸

Go

Come back in less than 4 hours
for results.⁸



Up to **24 samples at a time**⁸

BD legacy of trust in TB diagnostics

From specimen collection to final result, BD is here to support your needs for both genotypic and phenotypic testing.

Ordering information

Catalogue number: 443878

Assay name: BD MAX™ MDR-TB

Targets: Mycobacterium tuberculosis complex, RIF and INH resistance (katG and inhA)

Configuration: 24 Tests per box



Specimen collection with BD® Sputum Collection System



Digestion, decontamination, plating, staining and microscopy with BD BBL™ Mycoprep, BD BBL™ Acid Fast and Fluorescent Stains and BD BBL™ Prepared Media



BD MAX™ MDR-TB with a single test, one assay with four results: MTB, RIF-R, INH (katG and inhA) with BD MAX™ Automated Molecular System



Manual and fully automated liquid culture with BD BACTEC™ MGIT™ Systems



Direct, fast MTBc ID from culture with BD MGIT™ TBcID Identification Test*



SIRE and PZA first line antimicrobial reagents DST with BD BACTEC™ MGIT™ Systems



Data management and reporting tools with BD EpiCenter™ Data Management System with TB-eXIST Extended Individual Susceptibility Testing

For more information about BD MAX™ Molecular Diagnostic System, please visit: bd.com

AMR, antimicrobial resistance; CI, confidence interval; DST, drug susceptibility test; Hr-TB, isoniazid-resistant; INH, isoniazid; MDR-TB, multidrug-resistant tuberculosis; MTBc, Mycobacterium tuberculosis complex; NAAT, nucleic acid amplification test; PCR, polymerase chain reaction; RIF, rifampin; RM, reference method; RR-TB, rifampin-resistant TB cases; STR, Sample Treatment Reagent; TB, tuberculosis; WHO, World Health Organization; XDR-TB, extensively drug-resistant TB.

TB-eXIST* is not IVDR, check product market access for your specific markets:

References: 1. World Health Organization. *Global investments in tuberculosis research and development: past, present and future*. Geneva: 2017. 2. World Health Organization. *Global tuberculosis reports. (24 March 2020)*. Accessed June 30, 2020. https://www.who.int/tb/publications/global_report/en/. 3. World Health Organization. *WHO treatment guidelines for isoniazid-resistant tuberculosis: Supplement to the WHO treatment guidelines for drug-resistant tuberculosis*. Geneva: 2018. 4. World Health Organization. *Global tuberculosis report 2019*. Geneva: 2019. 5. Pooran A et al. *PLoS ONE*. 2013;8(1):e54587. 6. Olson G et al. *Open Forum Infect Dis*. 2019;6(6):ofz222. 7. World Health Organization. *WHO consolidated guidelines on drug-resistant tuberculosis treatment*. Geneva: 2019. Accessed June 30, 2020. 8. BD MAX™ MDR-TB [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2019. 9. Shah M et al. *Clin Infect Dis*. 2020;71(5):1161–7. 10. BD MAX™ System User's Manual. Becton, Dickinson and Company: Sparks, MD. 11. Mortensen JE et al. *BMC Clin Pathol*. 2015;15:9. 12. Hirvonen JJ et al. *Eur J Clin Microbiol Infect Dis*. 2015;34(5):1005–9. 13. David et al. *J Mol Diagn* 2023, 25: 46-56.



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