BD MAX™ MDR-TB

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

BD

The extent of the drug-resistant TB problem

Globally, about
10M
people get TB each year[2]

In 2018, 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.
Drug-resistant forms of TB are responsible for 1/4 of annual deaths due to antimicrobial resistance (AMR) worldwide.[1]

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]

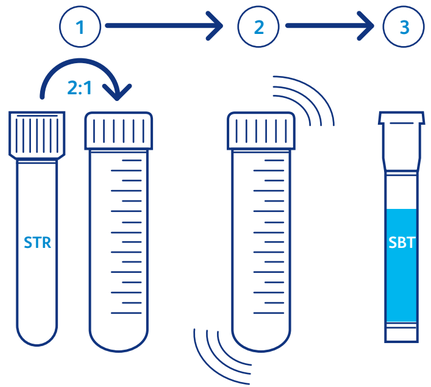
Widely used molecular tests today do not provide resistance results for both rifampin and isoniazid to report MDR-TB.[6]

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	Multidrug-resistant tuberculosis		
Multi-copy + single copy genomic targets	RIFAMPIN (rpoB gene) - RRDR	ISONIAZID (inhA) promoter	ISONIAZID (katG)

BD MAX™ MDR-TB workflow[8]

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 sputum[8]

BD MAX™ MDR-TB Assay Performed on:	Auramine O Method*		Ziehl-Neelsen Method*	
	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 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%)

Fresh RIF performance overall compared to the composite RM culture/DST plus NAAT and bi-directional sequencing[8]

	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%)

[a]Out 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.

[b]Out 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]
- The compact and self-contained unitized reagent strips and the new reclosing septum cap help simplify waste management and reduce the risk of contamination.

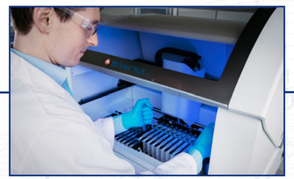
Snap

Assemble unitized reagent strips with extraction and PCR reagents.

Less than **1.5 minutes** hands-on time per sample[12]

Load

Load the Sample Buffer Tubes, racks and PCR cartridges.



24 patient results in **less than 4 hours,** on average[8]

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.

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 PZAfirst 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

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

For more information about BD MAX™ PLUS 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, refertence method; RR-TB, rifampin-resistant TB cases; STR, Sample Treatment Reagent; TB, tuberculosis; WHO, World Health Organization; XDR-TB, extensively drug-resistant TB.

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.

bd.com

BD Life Sciences, 7 Loveton Circle, Sparks, MD 21152-0999, USA Tel: 1.800.638.8663