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)

BD

The extent of the drug-resistant TB problem

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

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]

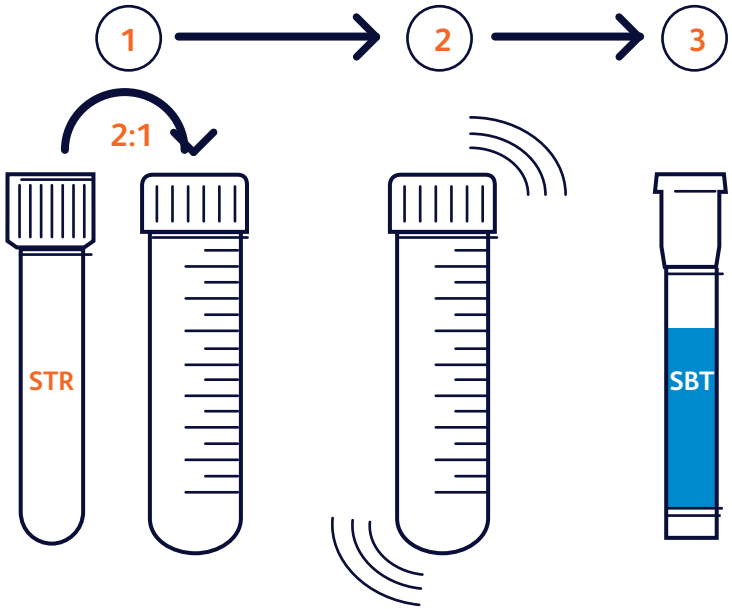
Widely used molecular tests today do not provide resistance results for both rifampin and isoniazid to report MDR-TB.[6]

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]



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[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 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]
- 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

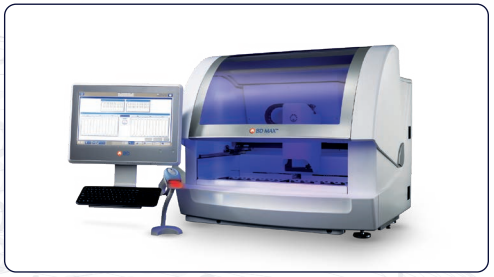
Assemble unitised reagent strips with extraction and PCR reagents.

Load

Load the Sample Buffer Tubes, racks and PCR cartridges.

Go

Come back in less than 4 hours for results.[8]



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

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

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™ 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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