How can you achieve MAX impact?

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

BD MAX™ MDR-TB is an integrated molecular assay for the detection of TB complex and mutations associated with the resistance of Rifampin (RIF) and Isoniazid (INH).

Now supported by World Health Organization

BD

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

Globally, about
10 million[2]
people fall ill
with TB each year.[2]

In 2018, WHO
estimates there were
484,000
new cases with **resistance to rifampin** (RR-TB).[2]

78% of these cases
were **multi-drug resistant TB (MDR-TB).**[2]

800,000
patients are
estimated to be
rifampin-susceptible and isoniazid-resistant (Hr-TB).[3]

Drug-resistant tuberculosis can be difficult to diagnose and successfully treat, increasing overall costs and the risk of community spread

Globally, the latest available data show:

a treatment success rate of **85%** for **drug-susceptible TB** at a median cost of **(US) $973** per patient.[4]

a treatment success rate of **56%** for **MDR-TB** at a median cost of **(US) $6,430** per patient.[4]

a treatment success rate of **39%** for **XDR-TB**[4] at a median cost of **(US) $26,392** per patient.[5]

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

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 World Health Organization (WHO) recommends testing for genetic mutations associated with resistance to isoniazid (*katG* or *inhA*).[7]

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

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

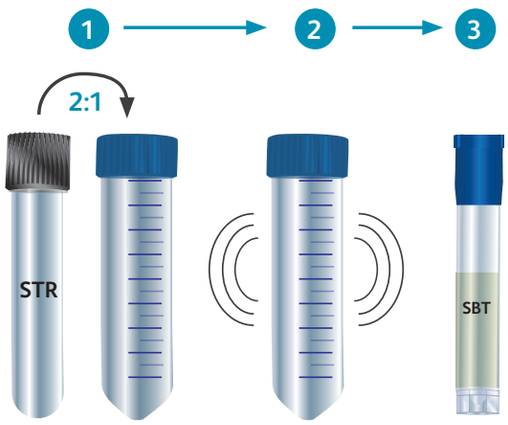
BD MAX™ MDR-TB assay delivers four results in one test!

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

Ability to report both inhA and katG gene mutations – the two most frequently reported mutations associated with Isoniazid resistance

Flexibility and efficiency for molecular TB testing 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

The BD MAX™ System provides a streamlined and efficient way to run molecular assays that improves turnaround time for fast, appropriate treatment decisions. The pre-filled reagent strips contain all the materials needed to complete the test per sample so there is no waste.

4

Add Sample Buffer Tube to rack

5

Load Unitized Reagent Strips with extraction and PCR reagents

6

Place a PCR cartridge in the reader

- Run up to 24 samples at a time • Less than 1.5 minutes hands on time
- Results in less than 4 hours

Clinical performance to support your testing needs

A recently published multi-center study found the BD MAX™ MDR-TB assay had high sensitivity and specificity for detection of Multi-drug resistant tuberculosis (MTB) and RIF and INH drug resistance and may be an important tool for rapid detection of TB and MDR-TB globally.[9]

Fresh MTB sensitivity stratified by Auramine O and Ziehl-Neelsen staining methods when performed from the raw portion[8]

	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%, 100.0%)	100.0% (176/176) (97.9%, 100.0%)	100.0% (149/149) (97.5%, 100.0%)	100.0% (147/147) (97.5%, 100.0%)
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 sequencing

	Raw sputum	Processed sputum
Overall sensitivity	94.1% (16/17)[a] (73%, 99%)	93.8% (15/16)[b] (71.7%, 98.9%)
Overall specificity	97.6% (200/205) (94.4%, 99%)	96.0% (191/199) (92.3%, 97.9%)

[a] Out of the 17 RIF resistant samples, 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 samples, 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.

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

	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%)

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

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

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

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

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

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

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

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

BD MAX™ System

Broad, comprehensive menu for a variety of testing needs

- Healthcare associated infections (HAI)
- Enteric solutions
- Women's Health and Sexually-transmitted infections (WH/STI)
- Respiratory infections

Visit www.advanced-diagnostics.eu to learn more

References: 1. World Health Organization. *Global investments in Tuberculosis research and development: past, present and future.* Geneva:2017. Accessed on June 30, 2020, at https://apps.who.int/iris/bitstream/handle/10665/259412/9789241513326-eng.pdf;jsessionid=9CB3038A3AF28FAE3659BB075C8F2F67?sequence=1. **2.** World Health Organization *Global tuberculosis reports.* (24 March 2020). Accessed on June 30, 2020 at 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*. Accessed on June 30, 2020, at https://www.who.int/tb/publications/2018/WHO_guidelines_isoniazid_resistant_TB/en/. **4.** World Health Organization. *Global tuberculosis report 2019*. Geneva: 2019. Accessed on June 30, 2020, at https://www.who.int/tb/publications/2018/WHO_guidelines_isoniazid_resistant_TB/en/. **5.** Pooran A, Pieterson E, Davids M, Theron G, Dheda K. What is the Cost of Diagnosis and Management of Drug Resistant Tuberculosis in South Africa? *PLoS ONE*. 2013;8(1):e54587. doi.org/10.1371/journal.pone.0054587. **6.** Gregory Olson G, Nathavitharana RR, Lederer PA. Diagnostic Delays and Treatment Implications for Patients with Isoniazid-Resistant Tuberculosis: A Case Report and Review of the Literature, *Open Forum Infect Dis.* 2019;6(6):ofz22. doi.org/10.1093/ofid/ofz222. **7.** World Health Organization. *WHO consolidated guidelines on drug-resistant tuberculosis treatment.* Geneva: 2019. Accessed on June 30, 2020, at https://www.ncbi.nlm.nih.gov/books/NBK539517/. WHO consolidated guidelines on drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO. **8.** BD MAX™ MDR-TB [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2019. **9.** Shah M, Paradis S, Betz J, Beylis N, Bharadwaj R, Caceres T, et. al. Multicenter Study of the Accuracy of the BD MAX Multidrug-resistant Tuberculosis Assay for Detection of Mycobacterium tuberculosis Complex and Mutations Associated With Resistance to Rifampin and Isoniazid [published online ahead of print, 2019 Sep 27], *Clin. Infect. Dis.,* 2019;ciz932. doi.org/10.1093/cid/ciz932.

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