MOLECULAR DIAGNOSTICS

Tuberculosis

Rapid diagnostics of tuberculosis and its resistances

Innovation with Integrity

PCR

TB Product Series

TB is the most prevalent infectious disease worldwide. A single patient with active TB may infect 10 to 15 other people each year. Four parameters are of crucial importance for the control of the disease:

- Early diagnostics
- Prevention of the spread of the disease
- Effective treatment with antituberculotics
- Prevention of the development of drug resistances

The TB product series from Hain Lifescience offers rapid, easy and cost-efficient diagnostic systems that are the prerequisite for an effective treatment and confinement of tuberculosis.

TB screening

Early and reliable diagnostics are the basis for a specific and thus successful tuberculosis treatment. Culture methods are time-consuming and laborious. In contrast, nucleic acid amplification tests, which allow for a fast screening have proven themselves in practice. The FluoroType® MTB VER 1.0 and FluoroType® MTB VER 2.0 tests use PCR and an innovative fluorescent-based technology for the detection of *M. tuberculosis* complex directly from pulmonary and extrapulmonary clinical specimens. The results are available within only three hours –therefore FluoroType MTB VER 1.0 and FluoroType® MTB VER 2.0 are the ideal TB screening tests.

Drug susceptibility testing (DST)

The increase of Multidrug-resistant (MDR-)TB is an alarming and ongoing global issue. MDR-TB is defined as TB that is resistant to at least rifampicin and isoniazid, the two most powerful first-line drugs. In order to prevent the further spread of resistant TB and offer the most appropriate therapy rapid and direct detection of MDR-TB is mandatory. GenoType MTBDRplus is based on PCR and the DNA•STRIP technology and allows the detection of *M. tuberculosis* complex and its resistance against rifampicin and isoniazid directly from clinical specimens. Extensively drug-resistant (XDR-)TB is defined as MDR-TB with further resistance to fluoroquinolones and a second-line agent (amikacin, kanamycin or capreomycin). Diagnostics and treatment of XDR-TB are even more challenging as those strains leave patients nearly without any treatment options. GenoType MTBDRsl can be performed subsequently to GenoType MTBDRplus using the same DNA isolate – thus an efficient testing for XDR-TB is possible.

Culture Identification

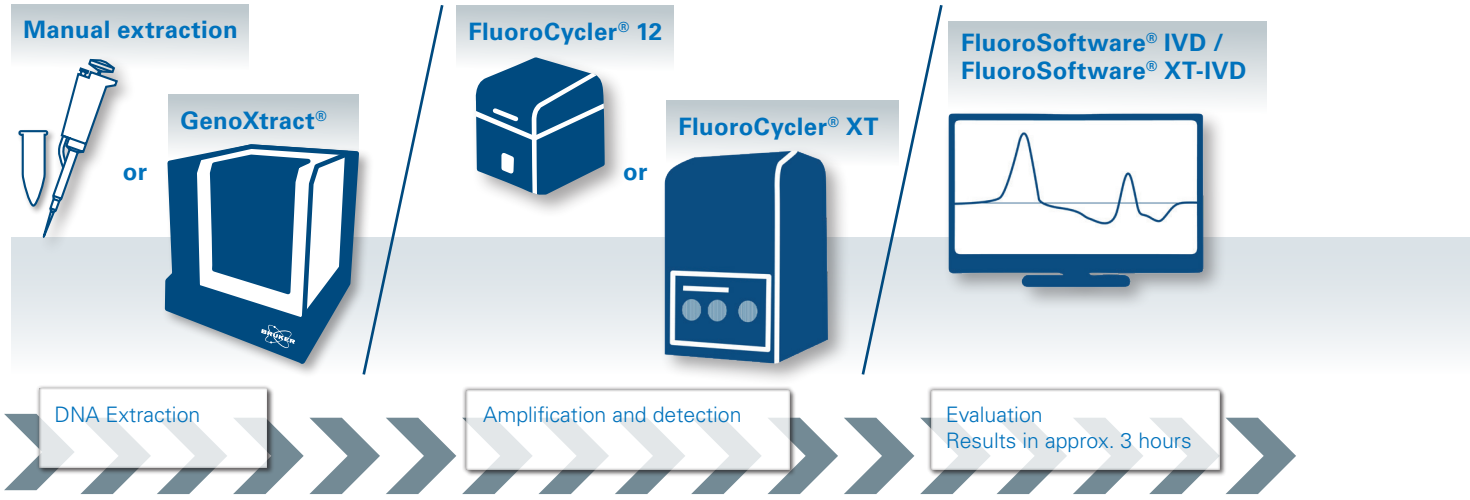
Culture confirmation still plays a considerable role in TB diagnostics. The TBCheck MPT64 assay detects and confirms *M. tuberculosis* complex via the MPT64 antigen from culture material. Depending on the results further diagnostics can be initiated efficiently.

Differentiation

In former times the routinely performed differentiation of MTB complex was only possible with phenotypic and biochemical methods which are laborious and time-consuming. GenoType MTBC is a PCR test for the differentiation of MTB complex from cultivated specimens.

FluoroType® MTB

Rapid detection of *M. tuberculosis* complex directly from decontaminated sample material.



*Please contact your local representative for advice regarding workflow

FluoroType® MTB VER 1.0

FluoroType® MTB VER 1.0 offers rapid and reliable detection of *M. tuberculosis* complex from direct sample material, including decontaminated pulmonary and extrapulmonary patient samples. Thanks to its exceptional performance, FluoroType® MTB VER 1.0 has been endorsed by WHO for TB detection in pulmonary samples.

DNA extraction can be performed manually with a rapid three-step protocol or automated using the GenoXtract®. The DNA amplification and target detection of up to 12 samples takes place in the FluoroCycler® 12, with the option to run up to 4 units simultaneously with one computer. The flexibility of processing methods makes FluoroType® MTB VER 1.0 an assay of choice in small and large laboratories alike for MTBC detection.

FluoroType® MTB VER 2.0

FluoroType® MTB VER 2.0 offers a highly sensitive and semi-quantitative detection of *M. tuberculosis* complex directly from decontaminated sputum. Following manual DNA extraction with a rapid three-step protocol and DNA set-up, the subsequent DNA amplification and analysis of up to 96 samples takes place in the FluoroCycler® XT. The highly sensitive detection of MTB complex is ensured with two different targets integrated into the multiplexed PCR. Results at a glance ensure fast and reliable reporting for laboratories of any size.

The DNA extraction produced for this assay can further be used in a reflex-testing approach to evaluate MTBC-positive samples for drug resistance with FluoroType® MTBDR VER 2.0 and LiquidArray® MTB-XDR*.
*coming soon

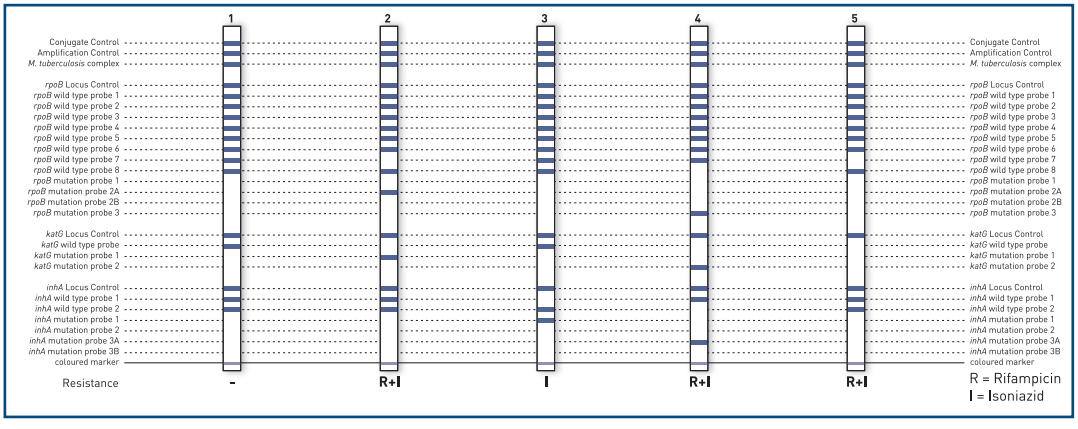
Benefits of using FluoroType® MTB

- Fast: The test system provides reliable results within three hours. This allows for an important time advantage in TB diagnostics.
- User-friendly: A ready-to-use amplification mix already containing the Taq polymerase is provided with the kit. Amplification and detection run fully automated in a closed system. Evaluation and result interpretation are done by the test-specific software. The test procedure is very simple and perfectly suitable for low to mid throughput.
- Flexible: DNA extraction can be performed either manually with FluoroLyse or automated using the nucleic acid extraction instrument GenoXtract®.

GenoType MTBDR*plus* VER 2.0

Molecular genetic assay for detection of *M. tuberculosis* complex and its resistances to rifampicin and/or isoniazid

Table 1
Example Result



Characteristics of GenoType MTBDR*plus*

The GenoType MTBDRplus enables the simultaneous molecular genetic identification of

- the *M. tuberculosis* complex
- its resistance to rifampicin by the detection of the most common mutations in the *rpoB* gene
- its resistance to isoniazid (For the detection of high level isoniazid resistance the *katG* gene and for low level isoniazid resistance the promoter region of the inhA gene is examined.)

from smear-positive or -negative pulmonary clinical specimens or cultivated samples.

Test principle of GenoType MTBDR*plus*

GenoType MTBDRplus is based on PCR and the DNA•STRIP technology. Mycobacterial DNA is extracted from the patient specimen or cultivated material, specifically amplified via PCR and detected on a membrane strip using reverse hybridization and an enzymatic colour reaction. Valid results are documented by internal controls, Conjugate and Amplification Control.

Benefits of using GenoType MTBDR*plus*

- Efficient: *M. tuberculosis* complex and its resistances to rifampicin and isoniazid are simultaneously detected in a single patient specimen. The test is therefore perfectly suitable for MDR-TB screening, for the identification of MTB complex and mono-resistances. Pulmonary patient specimens and cultivated samples can be used as starting material.
- Rapid: Results are available within five hours compared to several months with conventional DST.
- User-friendly: A ready-to-use amplification mix including the Taq polymerase is provided with the kit.
- Flexible: DNA extraction can be performed either manually or automated using the nucleic acid isolation instrument GenoXtract®. Amplification, detection and evaluation can also be automated. The test is thus suitable for low, mid and high throughput.
- Cost-efficient: For the implementation only minimum technical equipment is required, therefore an economical set-up is possible for laboratories of every potential size.

GenoType MTBDR*sl*

Molecular genetic assay for detection of *M. tuberculosis* complex and its resistances to fluoroquinolones and aminoglycosides/cyclic peptides (and ethambutol)

Table 2
GenoType
MTBDRsl VER 1.0

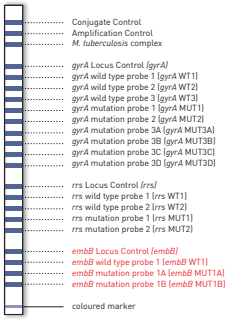
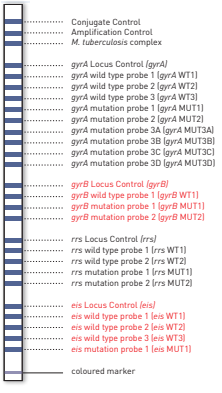


Table 3
GenoType
MTBDRsl VER 1.0



Differences between the two versions are marked in red

	GenoType MTBDRsl VER 1.0	GenoType MTBDRsl VER 2.0
Detection of	*M. tuberculosis* complex and its resistances to fluoroquinolones, aminoglycosides/cyclic peptides and ethambutol	*M. tuberculosis* complex and its resistances to fluoroquinolones and aminoglycosides/cyclic peptides
Sample Material	smear-positive pulmonary and cultivated samples	smear-positive and -negative pulmonary and cultivated samples
Ethambutol	Mutations in the *embB* gene that are involved in ethambutol resistance ✓	Mutations in the *embB* gene that are involved in ethambutol resistance -
Fluoroquinolone	Mutations in the *gyrB* gene that are involved in fluoroquinolone resistance -	Mutations in the *gyrB* gene that are involved in fluoroquinolone resistance ✓
Kanamycin	Mutations in the *eis* gene that are involved in kanamycin resistance -	Mutations in the *eis* gene that are involved in kanamycin resistance ✓

Test principle of GenoType MTBDR*sl*

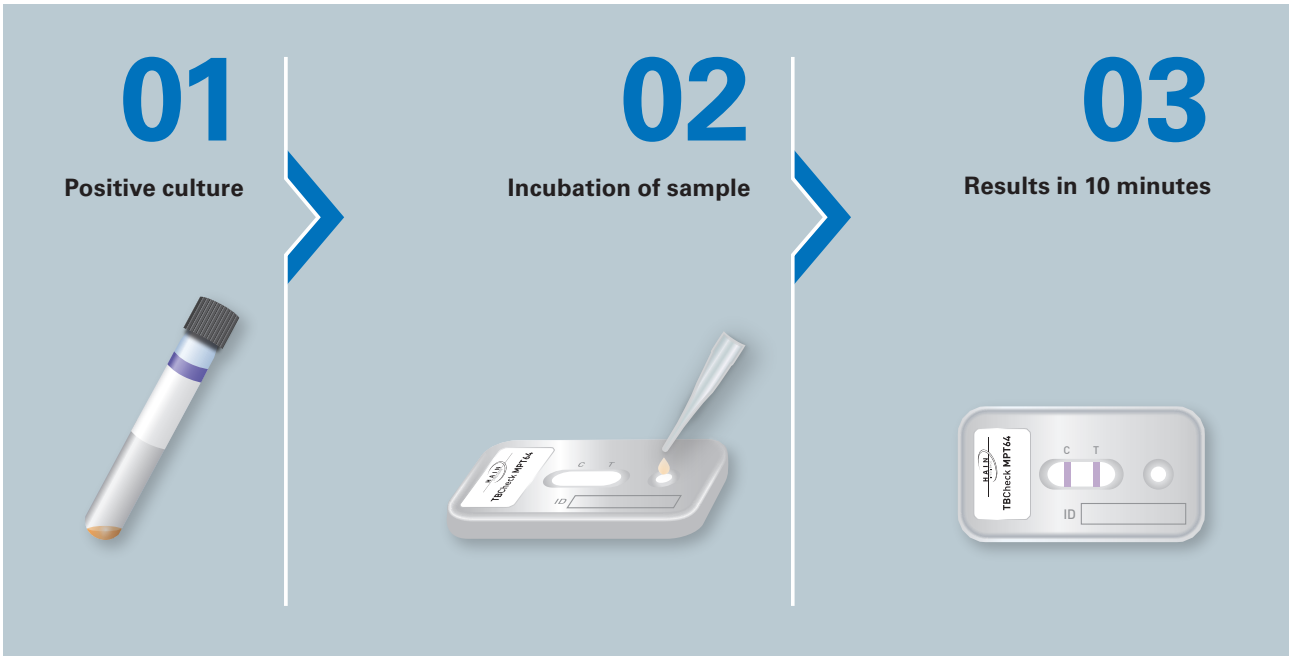
GenoType MTBDRsl is based on PCR and the DNA•STRIP technology. Mycobacterial DNA is extracted from the patient specimen or cultivated material, specifically amplified via PCR and detected on a membrane strip using reverse hybridization and an enzymatic colour reaction.

Benefits of using GenoType MTBDR*sl*

- Sensitive detection: The first version of GenoType MTBDRsl can be processed from smear-positive pulmonary or cultivated samples. The second version is even more sensitive and can therefore also be performed using smear-negative pulmonary samples.
- Efficient diagnosis: Both test systems are perfectly suitable for the detection of XDR-TB in patients previously diagnosed with MDR-TB. For step-wise diagnostics the test systems can be performed subsequent to GenoType MTBDRplus using the same DNA isolate.
- Rapid results: Results are available within five hours in comparison to several weeks when using conventional methods.

TBCheck MPT64 VER 1.0

Rapid immunochromatographic assay for detection of *Mycobacterium tuberculosis* complex



Characteristics of TBCheck MPT64

The TBCheck MPT64 assay allows the identification of the MPT64 antigen from cultivated liquid samples. This antigen is highly specific for *M. tuberculosis* complex and thus suitable for its identification directly from culture. As the MPT64 antigen is only present in MTB complex subsequent discrimination from nontuberculous mycobacteria is also possible.

Test principle of TBCheck MPT64

TBCheck MPT64 is based on an immunochromatographic assay principle. A droplet of the positive culture is placed on the lateral flow strip. On the strip the secreted MPT64 antigens are marked with gold and migrate to a specific binding site. This reaction leads to an accumulation of gold at the binding site and subsequently to a visible band on the strip. The control area shows the efficiency of the gold binding – therefore, valid results are always guaranteed.

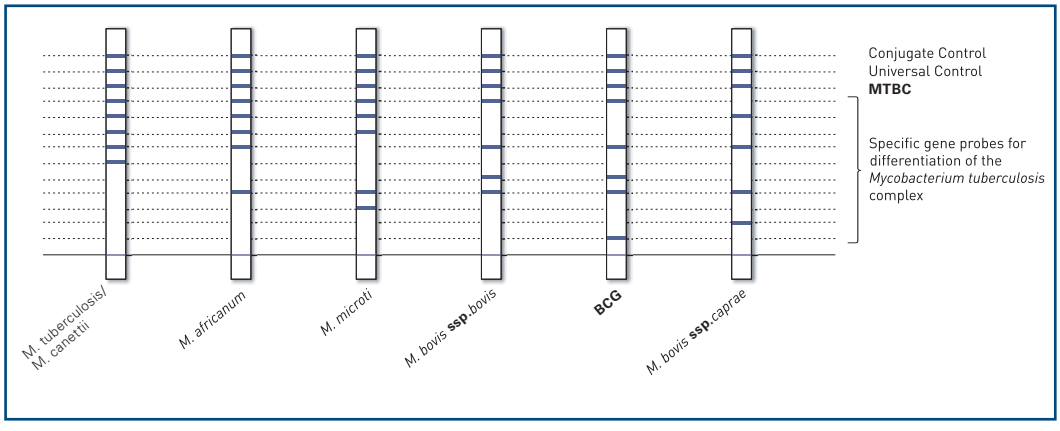
Benefits of using TBCheck MPT64

- Rapid detection: TBCheck MPT64 allows the rapid detection of *M. tuberculosis* complex and discrimination from NTM within 10 minutes. Therefore, rapid results are guaranteed and further testing is promptly possible.
- Indication for further diagnostics: The results of TBCheck MPT64 enable a sound choice for further diagnostics. Depending on the result, differentiation of *M. tuberculosis* complex or NTM is indicated.
- Confirmation: The assay can be used to confirm *M. tuberculosis* complex before drug susceptibility testing is performed.

GenoType MTBC VER 1.X

Molecular genetic assay for differentiation of *M. tuberculosis* complex

Table 4
Example Result



Characteristics of GenoType MTBC

The GenoType MTBC permits the molecular genetic identification of *M. tuberculosis*, *M. bovis* ssp. *bovis*, *M. bovis* ssp. *caprae*, *M. africanum*, *M. microti*, *M. canettii* and the vaccine strain *M. bovis* BCG (Bacille Calmette-Guérin) from cultivated samples.

Test principle of GenoType MTBC

GenoType MTBC is based on PCR and the DNA•STRIP technology. Mycobacterial DNA is extracted from cultivated material, specifically amplified via PCR and detected on a membrane strip using reverse hybridization and an enzymatic colour reaction. Valid results are documented by the Conjugate Control. The Universal Control displays the presence of mycobacteria and gram-positive bacteria with high G+C content. The MTBC control shows that members of the MTB complex are present.

Benefits of using GenoType MTBC

- Efficient: Simultaneous detection and differentiation of species belonging to the *M. tuberculosis* complex with a single processing. As starting material solid or liquid cultivated material can be used.
- Rapid: The results are available within five hours compared to several weeks with conventional methods.
- Reliable: Internal controls document valid results and thus ensure high diagnostic reliability.

Mycobacteria Product Series

TB screening	
FluoroType® MTB VER 1.0	Detection of *M. tuberculosis* complex from patient specimens
FluoroType® MTB VER 2.0	Detection of *M. tuberculosis* complex, from patient specimens, with ultra-high sensitivity
Drug susceptibility testing	
FluoroType® MTBDR VER 2.0	Single-tube detection of *M. tuberculosis* complex and its resistances to rifampicin and isoniazid from patient specimens or cultures
LiquidArray® MTB-XDR VER 2.0*	Detection of *M. tuberculosis* complex and its resistances to fluoroquinolones, linezolid, amikacin and ethambutol from patient specimens (sputum) or culture
GenoType MTBDRplus VER 2.0	Detection of *M. tuberculosis* complex and its resistances to rifampicin and isoniazid from patient specimens or cultures
GenoType MTBDRsl VER 1.0	Detection of *M. tuberculosis* complex and its resistances to fluoroquinolones, aminoglycosides/cyclic peptides and ethambutol from patient specimens or cultures
GenoType MTBDRsl VER 2.0	Detection of *M. tuberculosis* complex and its resistances to fluoroquinolones and aminoglycoside/cyclic peptides from patient specimens or cultures
Differentiation	
FluoroType® Mycobacteria VER 1.0	Detection and differentiation of 32 clinically relevant nontuberculous mycobacteria species and subspecies as well as the *M. tuberculosis* complex, from culture, in one well
GenoType CMdirect VER 1.0	Detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM from patient specimens
GenoType Mycobacterium CM VER 2.0	Detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM from cultures
GenoType Mycobacterium AS VER 1.0	Detection of 19 further NTM from cultures
GenoType MTBC VER 1.X	Differentiation of *M. tuberculosis* complex from cultures
Differentiation and drug susceptibility testing	
GenoType NTM-DR VER 1.0	Detection of important NTM and their resistances to aminoglycosides and macrolides from cultures
Culture identification	
TBCheck MPT64 VER 1.0	Rapid detection of *M. tuberculosis* complex from liquid cultures
Leprosy	
GenoType LepraeDR VER 1.0	Detection of *M. leprae* and its resistances to rifampicin, ofloxacin and dapsone from patient specimens

*coming soon

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Not for sale in the USA.

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