IVD

Hain Lifescience – a Bruker Company

Tuberculosis

Rapid diagnostics of tuberculosis and its resistances

Our molecular test systems allow for an efficient TB screening and subsequent detection of MDR- or XDR-TB. **Fluoro**Type® **MTB** is the innovative test system for every lab and enables the direct detection of *M. tuberculosis* (MTB) complex. A resistance testing is possible with **Geno**Type **MTBDRplus** and **Geno**Type **MTBDRsl** – the globally established tests for MDR- and XDR-TB.

TBCheck **MPT64** is a robust test for the detection of *M. tuberculosis* complex directly from culture. After confirmation of MTB complex a PCR-based differentiation is possible with **Geno**Type **MTBC**.

Your benefits with the TB product series from Hain Lifescience

- Fast and reliable results
- Step-wise diagnostics
- Cost efficiency
- CE-marked

PCR/MYCOBACTERIA

Innovation with Integrity

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

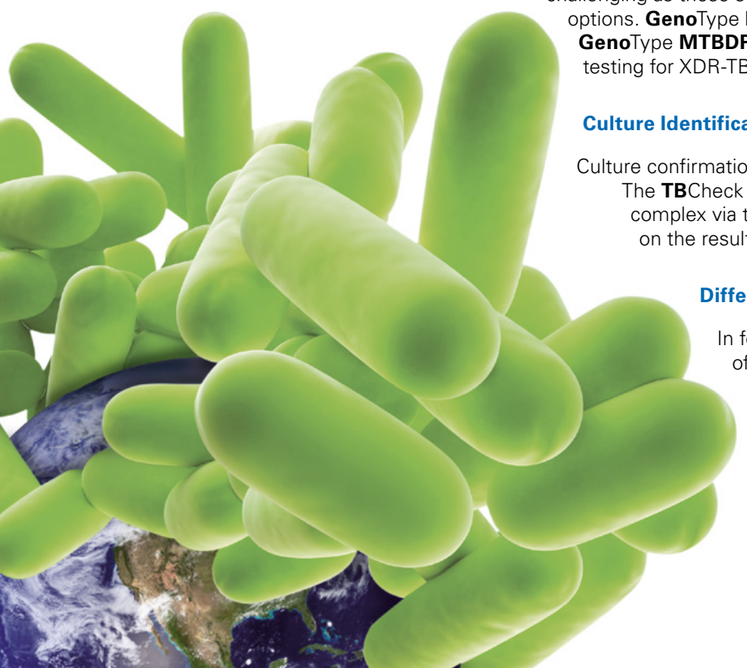
The TB product series from Hain Lifescience offers rapid, easy and cost-efficient diagnostic systems that are the prerequisite for an effective treatment and confinement of tuberculosis.

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 **Fluoro**Type® **MTB** test uses 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 **Fluoro**Type® **MTB** is the ideal TB screening test.

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. **Geno**Type **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. **Geno**Type **MTBDRsl** can be performed subsequently to **Geno**Type **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 **TB**Check **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. **Geno**Type **MTBC** is a PCR test for the differentiation of MTB complex from cultivated specimens.

FluoroType® **MTB**

Fluorescence-based molecular genetic assay for direct detection of *M. tuberculosis* complex

Characteristics of **Fluoro**Type® **MTB**

The **Fluoro**Type® **MTB** permits the molecular genetic identification of the *M. tuberculosis* complex directly from pulmonary and extrapulmonary patient specimens via the detection of the IS6110 element. The assay is rapid, simple and highly sensitive.

Test principle of **Fluoro**Type® **MTB**

FluoroType® **MTB** is based on PCR and the **Fluoro**Type® technology. Mycobacterial DNA is extracted from the patient specimen and specifically amplified via PCR. Then fluorescence-labelled probes are bound to single-stranded amplicons. Changes in fluorescence intensity are measured and displayed as a melting curve. The evaluation is done by the test-specific software. Amplification and detection run fully automated in the **Fluoro**Cycler® instruments. This ensures maximum user-friendliness and efficient diagnostics with reliable results at one glance.

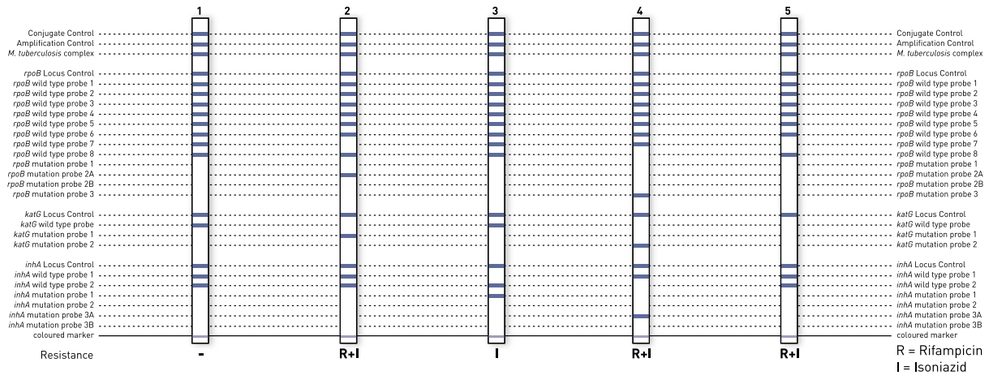
Benefits of using **Fluoro**Type® **MTB**

- **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 **Fluoro**Lyse or automated using the nucleic acid extraction instrument **Geno**Xtract®.

GenoType **MTBDR*plus* VER 2.0**

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

Example results



Characteristics of **Geno**Type **MTBDR*plus***

The **Geno**Type **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 *rpo*B gene
- its resistance to isoniazid (For the detection of high level isoniazid resistance the *kat*G gene and for low level isoniazid resistance the promoter region of the *inh*A gene is examined.)

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

Test principle of **Geno**Type **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 **Geno**Type **MTBDR*plus***

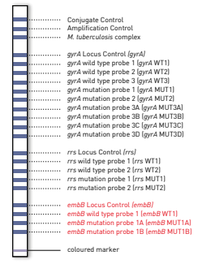
- **Efficient:** *M. tuberculosis* complex and its resistances to rifampicin and isoniazid are simultaneously detected in a single patient specimen. The test is therefore perfectly suitable for MDR-TB screening, for the identification of MTB complex and mono-resistances. Pulmonary patient specimens and 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***

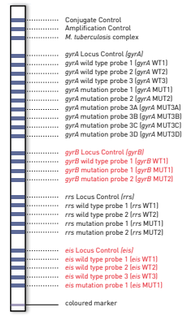
Molecular genetic assay for detection of *M. tuberculosis* complex and its resistances to fluoroquinolones and aminoglycosides/cyclic peptides (and ethambutol)

Example results

GenoType **MTBDR*sl* VER 1.0**



GenoType **MTBDR*sl* VER 2.0**



Differences between the two versions are marked in red

	GenoType **MTBDR*sl* VER 1.0**	**Geno**Type **MTBDR*sl* 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 *emb*B gene that are involved in ethambutol resistance	
	✓	–
Fluoroquinolone	Mutations in the *gyr*B gene that are involved in fluoroquinolone resistance	
	–	✓
Kanamycin	Mutations in the *eis* gene that are involved in kanamycin resistance	
	–	✓

Test principle of **Geno**Type **MTBDR*sl***

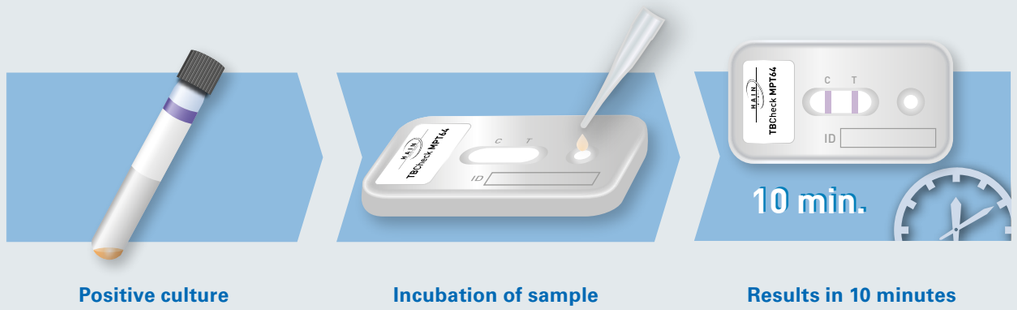
GenoType **MTBDRsl** is based on PCR and the DNA•STRIP technology. Mycobacterial DNA is extracted from the patient specimen or cultivated material, specifically amplified via PCR and detected on a membrane strip using reverse hybridization and an enzymatic colour reaction.

Benefits of using **Geno**Type **MTBDR*sl***

- **Sensitive detection:** The first version of **Geno**Type **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 **Geno**Type **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



Positive culture | **Incubation of sample** | **Results in 10 minutes**

Characteristics of **TB**Check **MPT64**

The **TB**Check **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 **TB**Check **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.

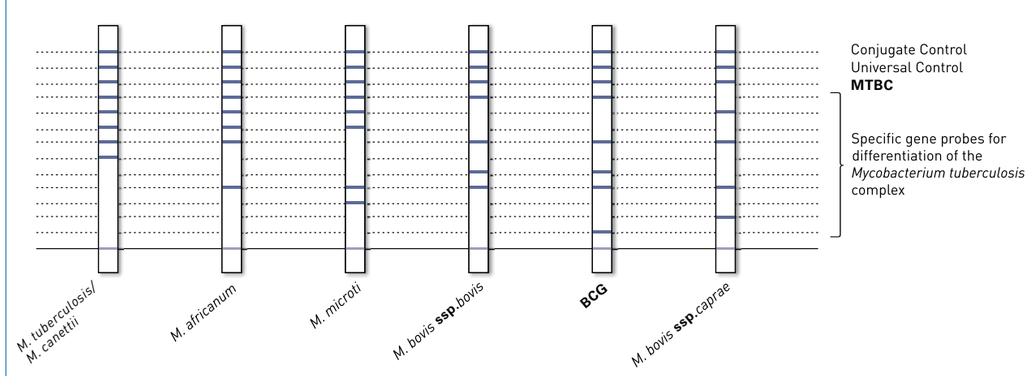
Benefits of using **TB**Check **MPT64**

- **Rapid detection: TB**Check **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 **TB**Check **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

Example results



Characteristics of **Geno**Type **MTBC**

The **Geno**Type **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 **Geno**Type **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 **Geno**Type **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

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
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

GenoType **MTBC VER 1.X**	Differentiation of *M. tuberculosis* complex from cultures
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

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

Please contact your local representative for availability in your country. Not for sale in the USA.

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