IVD

Hain Lifescience – a Bruker Company

Nontuberculous Mycobacteria

NTM diagnostics rapid, reliable and comprehensive!

Our molecular genetic test systems for mycobacteria differentiation and drug susceptibility testing allow comprehensive information from a single sample within a short period of time, thus making your diagnostics even more efficient!

The **Geno**Type **CM*direct*** enables simultaneous detection of the *M. tuberculosis* complex and more than 20 clinically relevant nontuberculous mycobacteria (NTM) directly from patient specimens. The **Geno**Type **Mycobacterium CM** provides the same information using culture as starting material. In case further NTM diagnostics from culture is required, the **Geno**Type **Mycobacterium AS** is the right choice. The **Geno**Type **NTM-DR** allows subsequent differentiation of relevant NTM and drug resistances from cultivated samples.

Your benefits with the NTM Product Series

- Fast and reliable results
- Detection of clinically relevant NTM and their drug resistances
- Time-saving compared to conventional methods
- CE-marked

NTM Product Series

Nontuberculous mycobacteria (NTM) are a group of ubiquitous bacteria in the environment. They are characterised by a wide variety of distribution and adaptation to specific environmental conditions. In contrast to *M. tuberculosis* and *M. leprae*, NTM are generally less pathogenic. However, especially in immunocompromised patients they can cause several clinical patterns. In the last few years, the incidence of nontuberculous mycobacterioses has increased worldwide, particularly in countries with low TB prevalence. Therefore, reliable and rapid molecular genetic diagnostics is the basis of an adequate therapy.

Differentiation

The distinction between tuberculosis (TB) pathogens and NTM is essential for diagnosis and treatment. There is no standard course of therapy for nontuberculous mycobacterioses. The choice of treatment depends on the respective mycobacteria species. Molecular genetic methods for species differentiation are valuable tools in NTM diagnostics and offer advantages compared to time-consuming conventional methods.

The PCR-based test systems **Geno**Type **CM*direct*** and **Geno**Type **Mycobacterium CM** enable reliable differentiation between *M. tuberculosis* complex and more than 20 clinically relevant NTM. Sputum or cultivated samples can be used as starting material. Less frequent NTM can be identified by using **Geno**Type **Mycobacterium AS**, which is based on the same technology. This test detects 19 additional clinically relevant NTM from cultivated material. The culture-based test systems **Geno**Type **Mycobacterium CM** and **Geno**Type **Mycobacterium AS** can easily be combined and therefore save time and effort.

Drug Susceptibility Testing

The treatment of nontuberculous mycobacterioses is often very challenging. Therapy usually depends on the respective NTM species and is often complicated by antimicrobial resistance. For an appropriate treatment it is therefore important to know the species and their susceptibility or resistance to certain antibiotic drugs. The molecular genetic assay **Geno**Type **NTM-DR** allows the simultaneous detection of important NTM and their resistances to macrolides and aminoglycosides. Culture samples are used as starting material. As results are available within a few hours, this test provides an enormous time advantage.

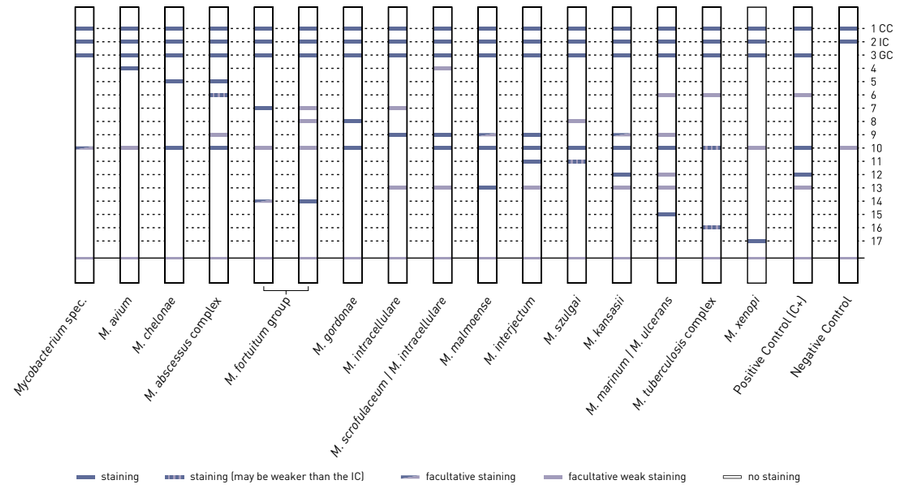
Test procedure NTM Product Series

DNA isolation | PCR | Detection | Results

GenoType **CM*direct*** VER 1.0

Molecular genetic assay for detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM

Example results



Characteristics of **Geno**Type **CM*direct***

The **Geno**Type **CM*direct*** assay permits the simultaneous molecular genetic detection of
- the *M. tuberculosis* complex
- more than 20 clinically relevant NTM species

from decontaminated sputum samples.

Test principle of **Geno**Type **CM*direct***

The **Geno**Type **CM*direct*** is based on PCR and the DNA•STRIP technology. Mycobacterial DNA is extracted from the patient specimen, 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 (CC). The Internal Control (IC) serves as an extraction and amplification control ensuring a secure test procedure. The Genus Control (GC) indicates that members of the genus *Mycobacterium* are present.

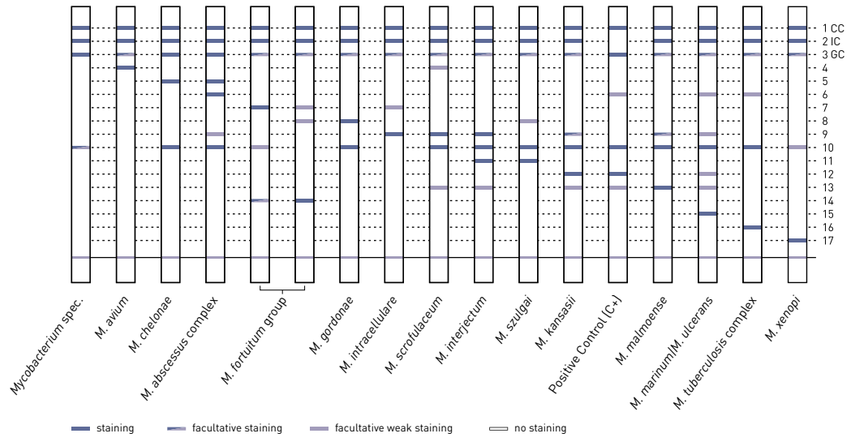
Benefits of using **Geno**Type **CM*direct***

- **Innovative:** The test can uniquely differentiate between *M. tuberculosis* complex and clinically relevant NTM directly from patient specimens.
- **Rapid and efficient:** Results are available within five hours directly from sputum. It is not necessary to wait for culture.
- **Safe and convenient:** Several controls are incorporated into the assay ensuring valid results. A ready-to-use amplification mix simplifies PCR setup.

GenoType **Mycobacterium CM VER 2.0**

Molecular genetic assay for detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM

Example results



Characteristics of **Geno**Type **Mycobacterium CM**

The **Geno**Type **Mycobacterium CM** assay permits the simultaneous molecular genetic detection of
- the *M. tuberculosis* complex
- more than 20 clinically relevant NTM species

from cultivated samples.

Test principle of **Geno**Type **Mycobacterium CM**

The **Geno**Type **Mycobacterium CM** 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 (CC). The Internal Control (IC) serves as an extraction and amplification control. Additionally, a positive IC indicates a correct processing.The Genus Control (GC) shows that members of the genus *Mycobacterium* are present.

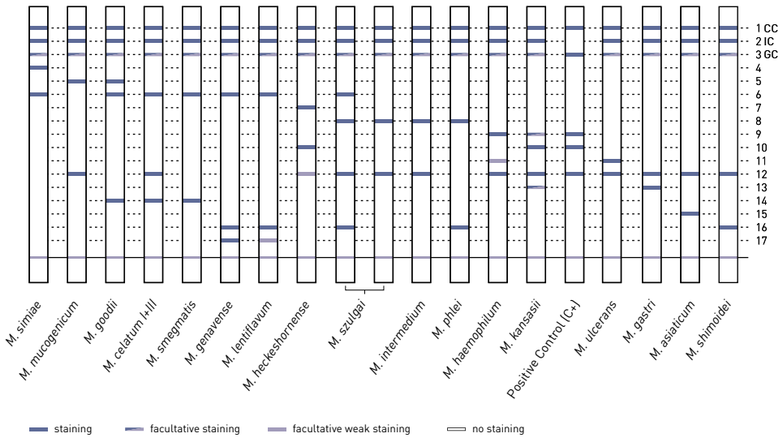
Benefits of using **Geno**Type **Mycobacterium CM**

- **Efficient:** Detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM within a single procedure. As starting material, solid and liquid cultures can be used.
- **Reliable:** Several quality controls guarantee a high diagnostic accuracy. High sensitivity enables the differentiation of mycobacteria species from a single sample.
- **Rapid:** Results are obtained within five hours compared to several weeks with conventional methods.

GenoType **Mycobacterium AS VER 1.0**

Molecular genetic assay for detection of further 19 clinically relevant NTM

Example results



Characteristics of **Geno**Type **Mycobacterium AS**

The **Geno**Type **Mycobacterium AS** assay permits the simultaneous molecular genetic detection of
- 19 clinically relevant NTM species

from cultivated samples.

The DNA amplicon that is generated with the **Geno**Type **Mycobacterium CM** test can be used for the hybridization.

Test principle of **Geno**Type **Mycobacterium AS**

The **Geno**Type **Mycobacterium AS** 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 (CC). The Internal Control (IC) serves as an extraction and amplification control. Additionally, a positive IC indicates a correct processing. The Genus Control (GC) shows that members of the genus *Mycobacterium* are present.

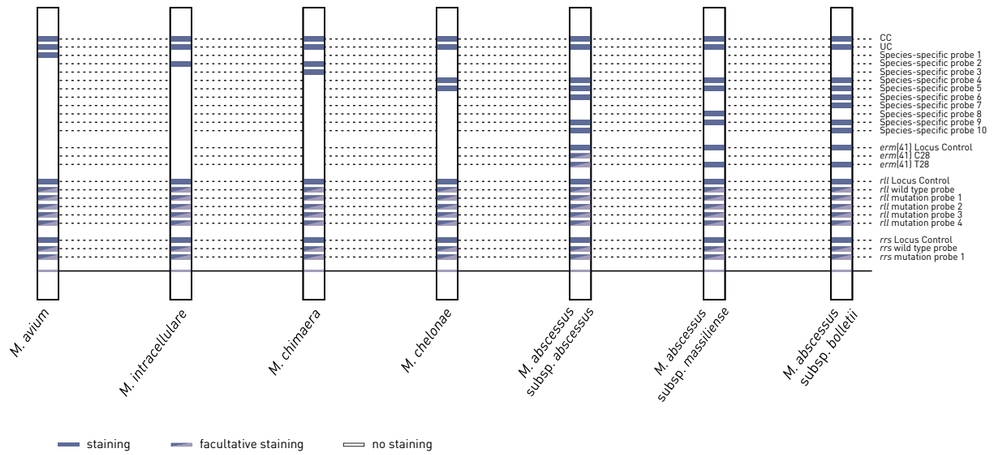
Benefits of using **Geno**Type **Mycobacterium AS**

- **Efficient:** Detection and identification of 19 clinically relevant NTM within a single procedure. DNA extraction and amplification is not necessary, since the DNA amplicon generated with **Geno**Type **Mycobacterium CM** can be used.
- **Reliable:** Several quality controls guarantee a high diagnostic accuracy. High sensitivity enables the differentiation of mycobacteria species from a single sample.
- **Rapid:** Results are obtained within five hours compared to several weeks with conventional methods.

GenoType NTM-DR VER 1.0

Molecular genetic assay for the detection of resistances to macrolides and aminoglycosides in various clinically relevant NTM

Example results



Characteristics of GenoType NTM-DR

The **Geno**Type **NTM-DR** assay permits the simultaneous molecular genetic detection
- of *M. avium*, *M. intracellulare*, *M. chimaera*, *M. chelonae* and the *M. abscessus* complex (*M. abscessus* subsp. *abscessus*, *M. abscessus* subsp. *massiliense* and *M. abscessus* subsp. *bolletii*), and
- their resistances to aminoglycosides via the detection of the most relevant mutations of the *rrs* gene
- their resistances to macrolides via the detection of the most relevant mutations of the *rrl* gene (Additionally, the *erm*(41) gene is analysed for the identification of macrolide resistance in members of the *M. abscessus* complex.)

from cultivated samples.

Test principle of GenoType NTM-DR

The **Geno**Type **NTM-DR** 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 (CC). The Universal Control (UC) displays the presence of mycobacteria and gram-positive bacteria with high G+C content.

Benefits of using GenoType NTM-DR

- **Efficient:** Simultaneous detection of several relevant NTM and their resistances to macrolides and aminoglycosides starting from solid and liquid culture.
- **Innovative:** The test system is based on a well-proven technology and can uniquely differentiate between *M. intracellulare* and *M. chimaera*.
- **Rapid:** Results are obtained within five hours compared to laborious and time-consuming conventional methods.

Overview Nontuberculous Mycobacteria

Slow growing mycobacteria (SGM)

M. asiaticum	Described in patients with pulmonary infections, lymphadenitis, skin and soft tissue infections and bursitis
M. avium	Causes pulmonary and disseminated diseases in immunocompromised patients and lymphadenitis in children
M. celatum	Causative agent of pulmonary infections in immunocompromised patients
M. chimaera	Identified amongst others in pulmonary samples from patients with respiratory disorders (e.g. COPD)
M. gastri	Described as a pathogen associated with peritonitis after dialysis
M. genavense	Species isolated from blood, bone marrow, lymph nodes, spleen and liver of patients with disseminated disease
M. gordonae	Described in association with pulmonary diseases and soft tissue infections
M. haemophilum	Mostly associated with skin infections in immunocompromised patients and lymphadenitis in children
M. heckeshornense	Causative agent of pulmonary infections, osteomyelitis and lymphadenitis
M. interjectum	Occurrence in chronic lymphadenitis mostly in children and sporadically in pneumonia
M. intermedium	Occurrence in chronic pulmonary diseases and described as skin pathogen
M. intracellulare	Causative agent of pulmonary diseases and disseminated infections, mostly in immunocompromised patients
M. kansasii	Described in pulmonary diseases, lymphadenitis, disseminated infections
M. lentiflavum	Frequently found in patients with cystic fibrosis and pneumonia
M. malmoense	Causative agent of pulmonary infections and cervical lymphadenitis
M. marinum	Causes skin and soft tissue infections particularly in limbs (fish tank granuloma)
M. scrofulaceum	Described in immunocompromised patients with pulmonary infections
M. shimoidei	Opportunistic lung pathogen often associated with pre-existing conditions of the lung
M. simiae	Causes pulmonary diseases similar to TB
M. szulgai	Described in connection with cervical adenitis and pulmonary diseases similar to TB
M. ulcerans	Causative agent of skin and soft tissue infections. Causes skin ulcerations, “Buruli ulcer” in particular in children
M. xenopi	Found in pulmonary diseases with existing COPD

Rapid growing mycobacteria (RGM)

M. abscessus complex	Members are often correlated with pulmonary infections in patients with cystic fibrosis; rarely in osteomyelitis and eye infections
– subsp. *abscessus*	Profile of macrolide resistance depends amongst others from mutations in the *erm*(41) gene
– subsp. *bolletii*	Subspecies respond in general less to therapy with macrolides
– subsp. *massiliense*	In general better prognosis in infections due to nonfunctional *erm*(41) gene
M. chelonae	Causes skin and soft tissue infections, in rare cases TB of the lung and disseminated infections
M. fortuitum	Described in empyema of the thorax, eye and surgical wound infections
M. goodii	Known infections after open bone fractures and surgery
M. mucogenicum	Causes post-traumatic wound infections and catheter sepsis
M. peregrinum	Causative agent of wound infections and pulmonary diseases
M. phlei	Isolated in infections associated with cardiac pacemaker and peritoneal dialysis
M. smegmatis	Described in pulmonary diseases, soft tissue and post-surgical infections

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 aminoglycosides/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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