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

**Your benefits with the NTM Product Series from Hain Lifescience**

- 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 GenoType CMdirect and GenoType 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 GenoType 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 GenoType Mycobacterium CM and GenoType 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 GenoType 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 CMdirect VER 1.0**

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

---

**Characteristics of GenoType CMdirect**

The GenoType CMdirect 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 GenoType CMdirect**

The GenoType CMdirect 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 GenoType CMdirect**

- **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.
Genotypy Mycobacteria CM VER 2.0
Molecular genetic assay for detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM

Characteristics of Genotypy Mycobacteria CM
The Genotypy Mycobacteria CM assay permits the simultaneous molecular genetic detection of:
- the *M. tuberculosis* complex
- more than 20 clinically relevant NTM species from cultivated samples.

Benefits of using Genotypy Mycobacteria 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.

Test principle of Genotypy Mycobacteria CM
The Genotypy Mycobacteria 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.

Genotypy Mycobacteria AS VER 1.0
Molecular genetic assay for detection of further 19 clinically relevant NTM

Characteristics of Genotypy Mycobacteria AS
The Genotypy Mycobacteria 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 Genotypy Mycobacteria CM test can be used for the hybridization.

Benefits of using Genotypy Mycobacteria 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 Genotypy Mycobacteria 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.

Test principle of Genotypy Mycobacteria AS
The Genotypy Mycobacteria 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.
GenoType NTM-DR VER 1.0
Molecular genetic assay for the detection of resistances to macrolides and aminoglycosides in various clinically relevant NTM

Characteristics of GenoType NTM-DR
The GenoType 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 rrl 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.

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 pneumonitis 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 connection with cervical adenitis and pulmonary diseases similar to TB
- M. simiae
  - Causes pulmonary diseases similar to TB
- M. shimoidei
  - Described in immunocompromised patients with pulmonary infections
- 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
  - M. abscessus subsp. abscessus
    - Profile of macrolide resistance depends amongst others from mutations in the erm(41) gene
  - M. abscessus subsp. bolletii
    - Subspecies respond in general less to therapy with macrolides
  - M. abscessus 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. gordonae
  - 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

Test principle
The GenoType 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.
**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 MTBDRs/ VER 1.0**  
Detection of *M. tuberculosis* complex and its resistances to fluoroquinolones, aminoglycosides/cyclic peptides and ethambutol from patient specimens or cultures

**GenoType MTBDRs/ 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

For further information please contact Hain Lifescience or your local distributor!