Molecular Diagnostics

Tuberculosis and nontuberculous mycobacteria

DNA•STRIP detection of TB, NTM, and drug resistance

Innovation with Integrity

IVD

Established solutions with DNA•STRIP

DNA•STRIP technology provides rapid and reliable molecular solutions based on Line Probe Assays.

The DNA•STRIP test platform is based on low-cost implementation and supports our extensive GenoType product range.

Ability to combine multiple assays with each other during processing offers a streamlined and efficient workflow in laboratory routine.

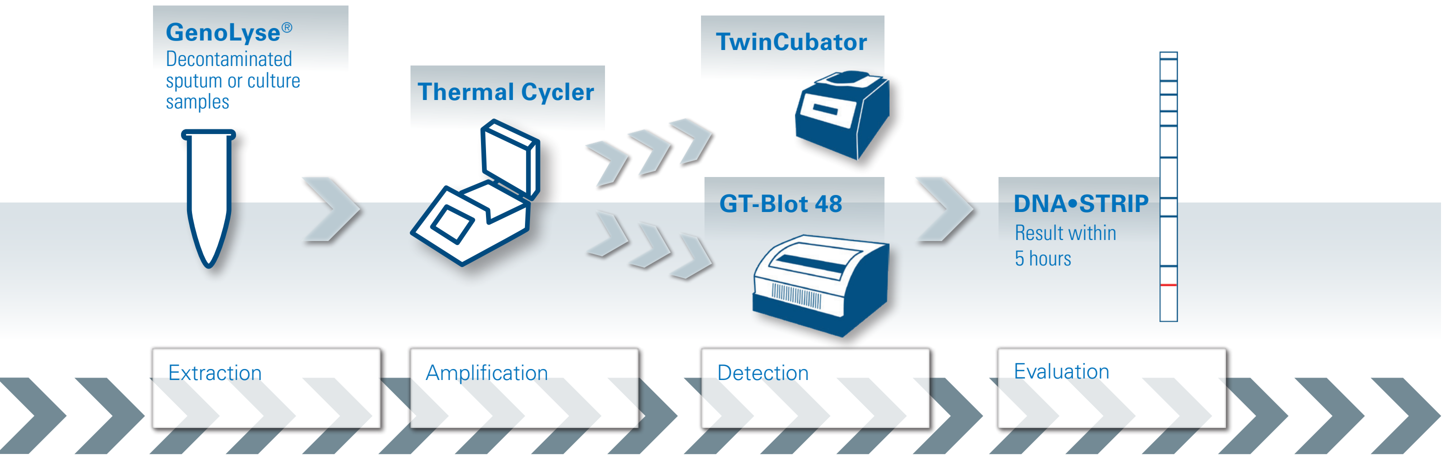
Your benefits with DNA•STRIP technology

- Fast and reliable results
- Robust and well-established assays
- Parallel processing for multiple assays possible
- Minimal equipment investment

Your benefits with GenoType product series

- Detection of *M. tuberculosis* complex, clinically relevant NTM and drug resistances
- Most comprehensive portfolio worldwide
- Use the same DNA extract for reflex testing
- Same day results compared to several weeks with conventional DST

Workflow



DNA extraction is performed manually in a few easy steps with the GenoLyse reagent.

PCR amplification takes place in our dedicated PCR cycler or a PCR cycler of your choice.

PCR product is hybridized onto the provided membrane strips.

Test result is evaluated using the test-specific template.

Tuberculosis Product Series

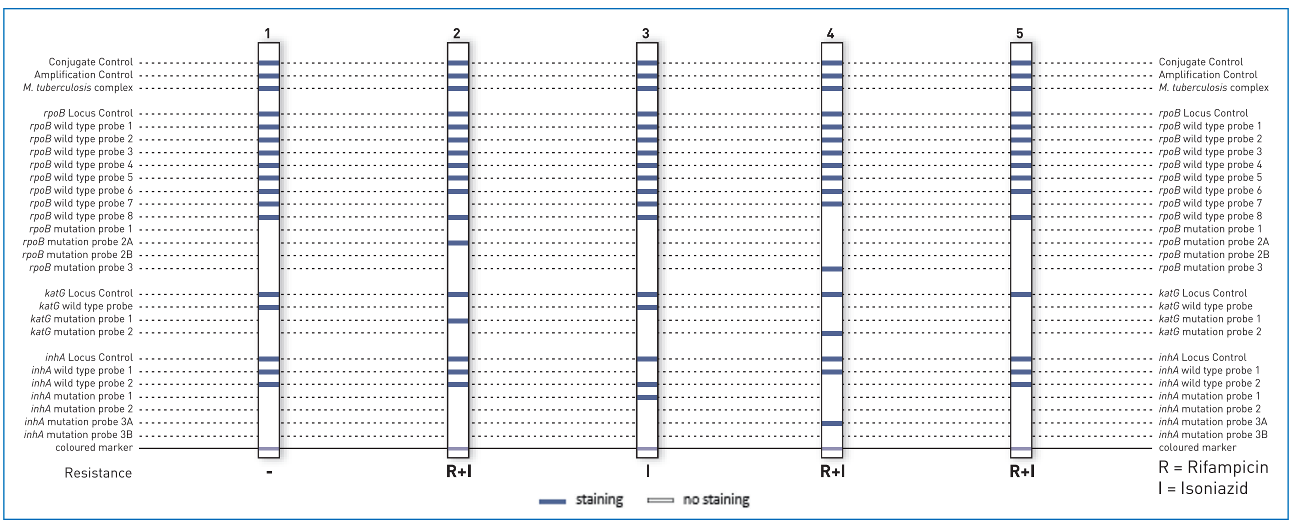
Early diagnosis of TB prevents the spread of the disease, ameliorates the chances of a successful therapy and prevents development of drug resistances.

Tuberculosis (TB) is one of the leading infectious disease killers worldwide. Caused by bacteria within *Mycobacterium tuberculosis complex* (MTBC), TB is curable and preventable. Rapid detection of MTBC and drug resistance is essential for appropriate and successful treatment. An estimated 74 million lives were saved through TB diagnosis and treatment between 2000 and 2021[1]. World Health Organisation (WHO) recommends the use of molecular line probe assays for the detection of resistances to first- and second-line anti-TB agents[2].

[1] Global tuberculosis report 2022. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO
[2] WHO consolidated guidelines on tuberculosis. Module 3: diagnosis - rapid diagnostics for tuberculosis detection, 2021 update. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

GenoType MTBDR*plus* VER 2.0

Detect *M. tuberculosis* complex and its resistances to rifampicin and / or isoniazid.



Example results

Simultaneous detection 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 via common mutations in the *katG* gene and the promoter region of the *inhA* gene

from smear-positive or -negative sputum specimens or cultivated samples

Your benefits

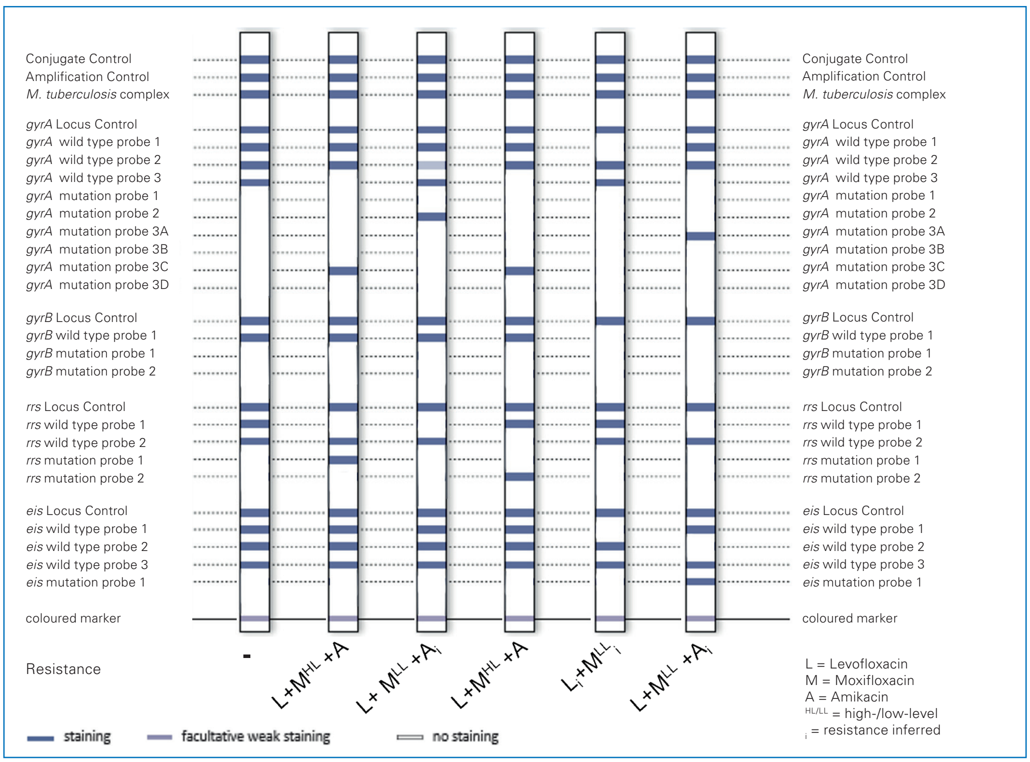
- **Same day results:** Detect MTBC and first-line resistances in patients suspected of TB infection within 5 hours
- **Streamlined workflow:** For reflex testing, reuse DNA extract for second-line resistance testing with GenoType MTBDR*sl* VER 2.0
- **Robust and reliable:** Integrated controls report validity of results, amplification and reverse hybridization

Bruker's tuberculosis GenoType product range facilitates streamlined workflow for comprehensive reflex testing.

GenoType MTBDR*plus* VER 2.0 detects *M. tuberculosis* complex and its resistance to first-line drugs rifampicin and isoniazid from sputum specimens or cultures. Use the same DNA extract to subsequently test for second-line resistances to fluoroquinolones and second-line injectable drugs with **GenoType MTBDR*sl* VER 2.0**. Differentiate the species within *M. tuberculosis* complex in a positive culture with **GenoType MTBC VER 1.X**.

GenoType MTBDR*sl* VER 2.0

Detect *M. tuberculosis* complex and its resistances to fluoroquinolones and second-line injectable drugs.



Example results

Simultaneous detection of

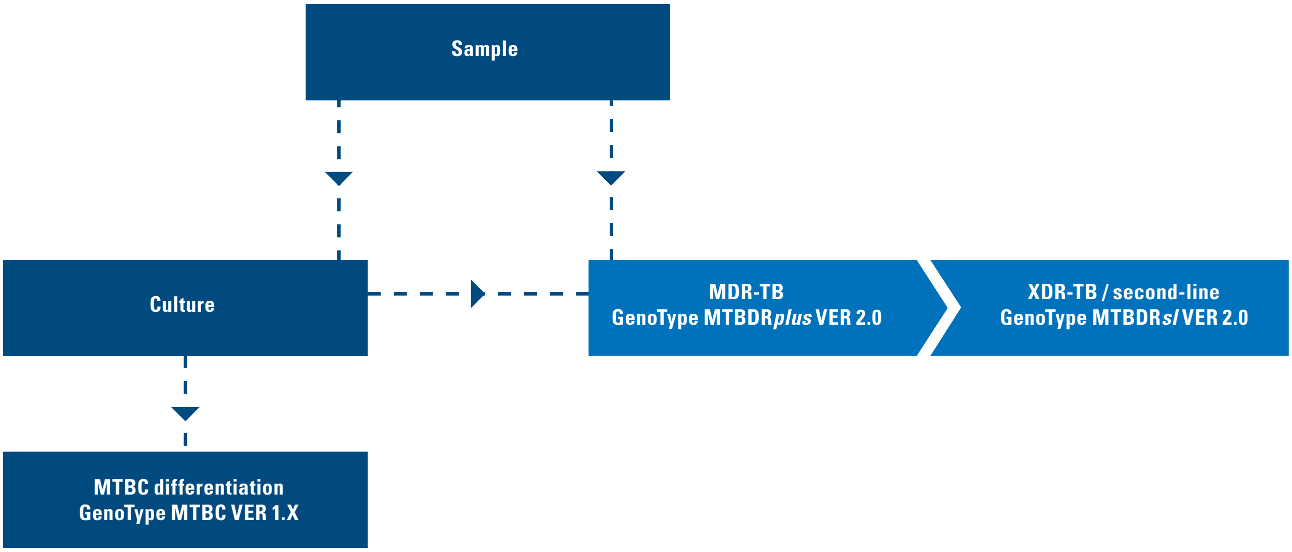
- the *M. tuberculosis* complex
- its resistance to the fluoroquinolones moxifloxacin and levofloxacin via common mutations in the *gyrA* and *gyrB* genes
- high- and low-level resistance to moxifloxacin via differentiation between specific mutations
- its resistance to second-line injectable drugs, such as amikacin, via common mutations in the *rrs* and *eis* genes

from smear-positive or -negative sputum specimens or cultivated samples

Your benefits

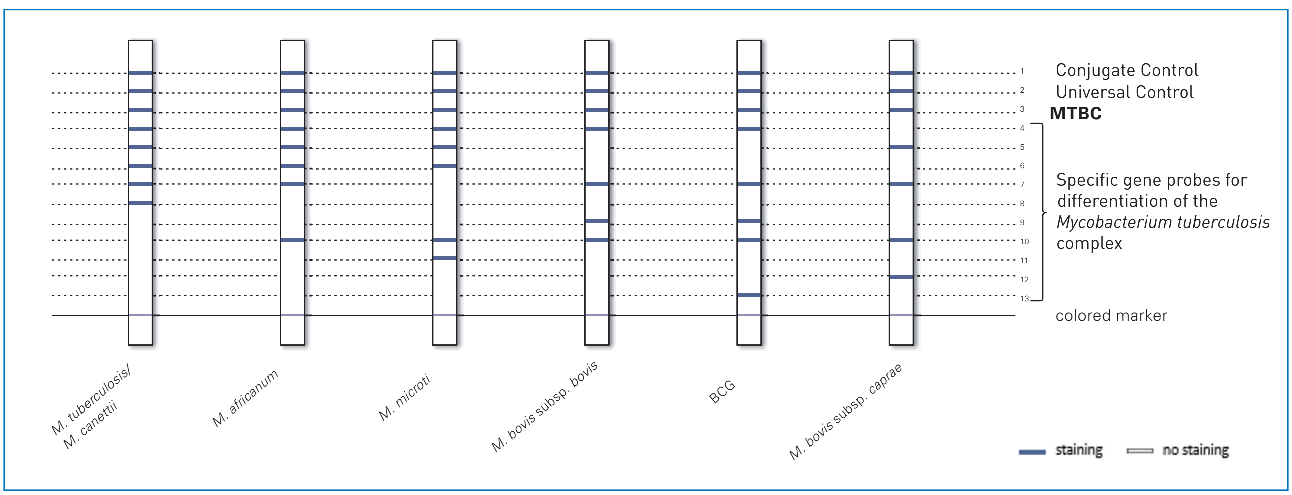
- **Same day results:** Detect second-line resistances in TB patients within 5 hours
- **Streamlined workflow:** For reflex testing, reuse DNA extract from first-line resistance testing with GenoType MTBDR*plus* VER 2.0
- **Robust and reliable:** Integrated controls report validity of results, including amplification and reverse hybridization

Bruker's tuberculosis assays offer efficient and flexible solutions for step-wise approach to TB and drug resistance testing.



GenoType MTBC VER 1.X

Detect and differentiate members of *M. tuberculosis* complex.



Example results

Simultaneous detection and differentiation of

- the *M. tuberculosis* complex
- Species: *M. tuberculosis*, *M. bovis* ssp. *bovis*, *M. bovis* ssp. *caprae*, *M. africanum*, *M. microti*, *M. canettii* and the vaccine strain *M. bovis* BCG

from solid or liquid culture samples

Your benefits

- **Same day results:** Identify causative species in TB patients within 5 hours
- **Streamlined workflow:** For reflex testing, reuse DNA extract from initial TB testing with GenoType MTBDR*plus* VER 2.0 (when cultured material is used)
- **Robust and reliable:** Integrated controls report validity of results and presence of mycobacteria

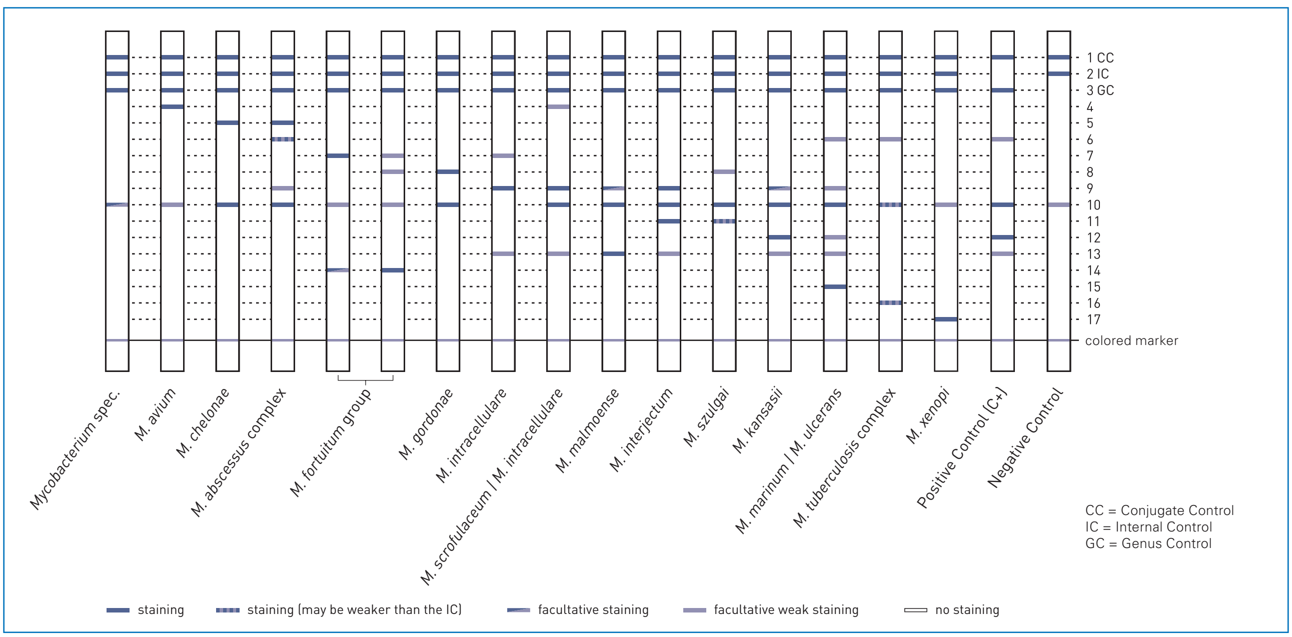
Nontuberculous Mycobacteria Product Series

Rapid and reliable identification of NTM and its drug resistances is essential for timely initiation of individualised therapy.

Nontuberculous mycobacteria (NTM) are closely related environmental bacteria within the *Mycobacterium* genus that can cause life-threatening infection in people. The incidence of NTM infection is on the rise and symptoms frequently resemble those of TB. Since treatment is species-dependent, early detection and identification of NTM species and its drug resistances is essential for optimal disease management.

GenoType CM*direct* VER 1.0

Detect *M. tuberculosis* complex and more than 20 clinically relevant NTM from sputum.



Example results

Simultaneous detection and differentiation of

- the *M. tuberculosis* complex
- *Mycobacterium* genus
- more than 20 clinically relevant NTM species

from decontaminated sputum samples

Your benefits

- **Same day results:** Detect common NTMs at species level within 5 hours directly from sputum
- **Streamlined workflow:** For reflex testing, reuse DNA extract from TB testing with GenoType MTBDR*plus* VER 2.0 (when using sputum samples)
- **Robust and reliable:** Integrated controls report validity of results, including efficient extraction, amplification and reverse hybridization

Overview Nontuberculous Mycobacteria

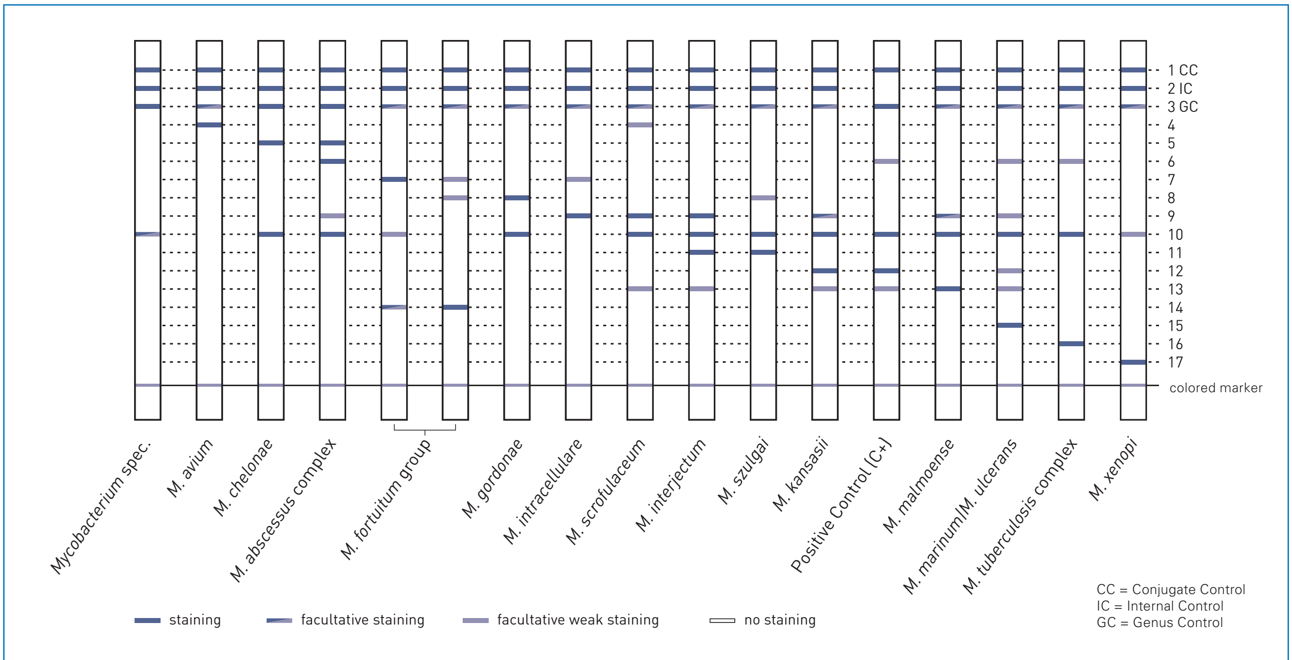
Slow growing mycobacteria (SGM)	
M. asiaticum	Described in patients with pulmonary infections, lymphadenitis, skin and soft tissue infections and bursitis
M. avium	Causes pulmonary and disseminated diseases in immunocompromised patients and lymphadenitis in children
M. celatum	Causative agent of pulmonary 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

Bruker's NTM GenoType product range facilitates streamlined workflow for comprehensive reflex testing.

To detect and differentiate clinically relevant NTM species, choose between **GenoType CM*direct* VER 1.0** for sputum specimens or **GenoType Mycobacteria CM VER 2.0** for cultures. Further test for less common NTM species and drug resistances in cultures with **GenoType Mycobacterium AS VER 1.0** and **GenoType NTM-DR VER 1.0**, respectively.

GenoType Mycobacterium CM VER 2.0

Detect *M. tuberculosis* complex and more than 20 clinically relevant NTM from culture samples.



Example results

Simultaneous detection and differentiation of

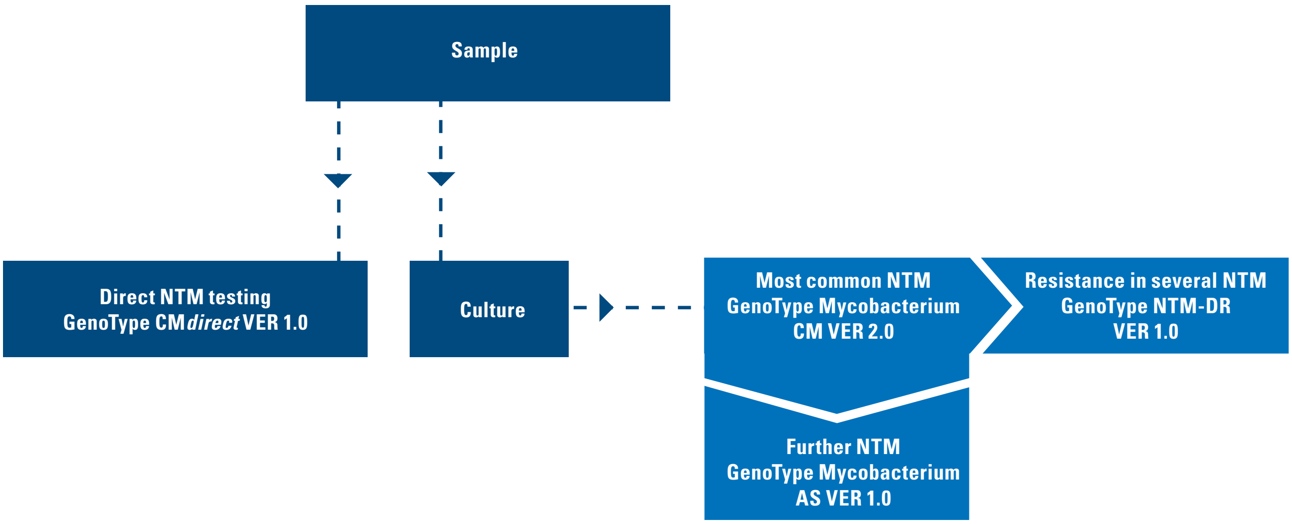
- the *M. tuberculosis* complex
- *Mycobacterium* genus
- more than 20 clinically relevant NTM species

from culture samples

Your benefits

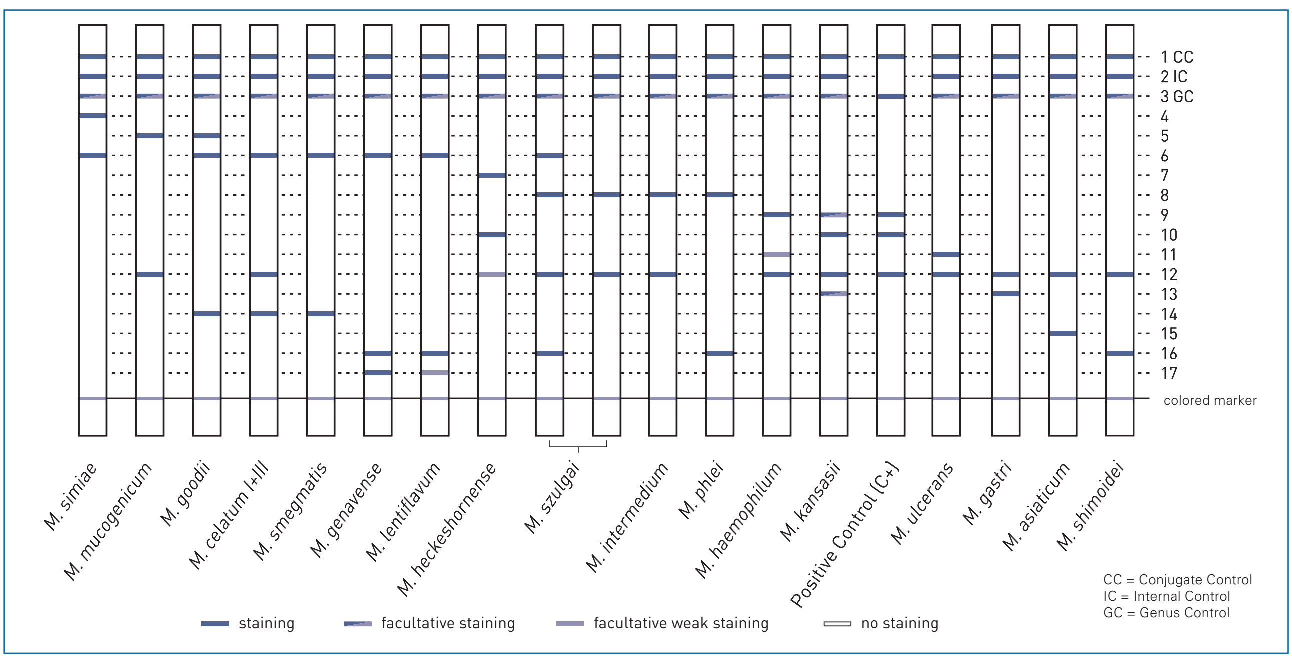
- **Same day results:** Detect clinically relevant common NTM at species level within 5 hours from culture
- **Streamlined workflow:** For reflex testing, reuse DNA extract for further NTM analysis with GenoType Mycobacterium AS VER 1.0 or GenoType NTM-DR VER 1.0
- **Robust and reliable:** Integrated controls report validity of results, including efficient extraction, amplification and reverse hybridization

Bruker's NTM assays offer efficient and flexible solutions for NTM and drug resistance testing.



GenoType Mycobacterium AS VER 1.0

Detect a further 19 clinically relevant NTM.



Example results

Simultaneous detection and differentiation of

- *Mycobacterium* genus
- 19 clinically relevant less common NTM species

from culture samples

Your benefits

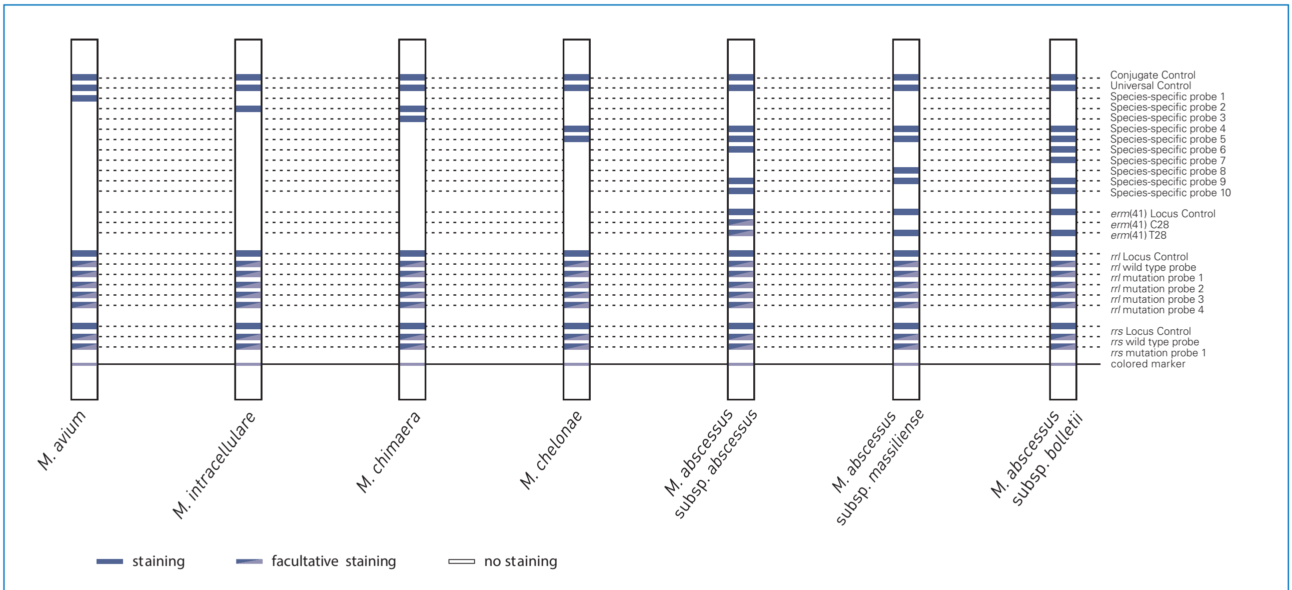
- **Same day results:** Detect clinically relevant NTM at species level within 5 hours from culture
- **Streamlined workflow:** For reflex testing, reuse DNA extract from GenoType Mycobacterium CM VER 2.0
- **Robust and reliable:** Integrated controls report validity of results, including efficient extraction, amplification and reverse hybridization

Detection of resistance to key drugs used to treat NTM infections is necessary for appropriate therapy selection early on.

As NTM emerge as important pathogens frequently requiring intervention, identification of NTM species and their drug resistances in a time- and cost-efficient manner is essential for selection of an effective treatment.

GenoType NTM-DR VER 1.0

Detect resistances to macrolides and aminoglycosides in selected clinically relevant NTM.



Example results

Simultaneous detection and differentiation of

- *M. avium, M. intracellulare, M. chimaera, M. chelonae*
- *M. absessus* complex: *M. abscessus* subsp. *abscessus*, *M. abscessus* subsp. *massiliense, M. abscessus* subsp. *bolletii*
- their resistances to aminoglycosides via common mutations in the *rrs* gene
- their resistances to macrolides via common mutations in the *rrl* and *erm*(41) genes

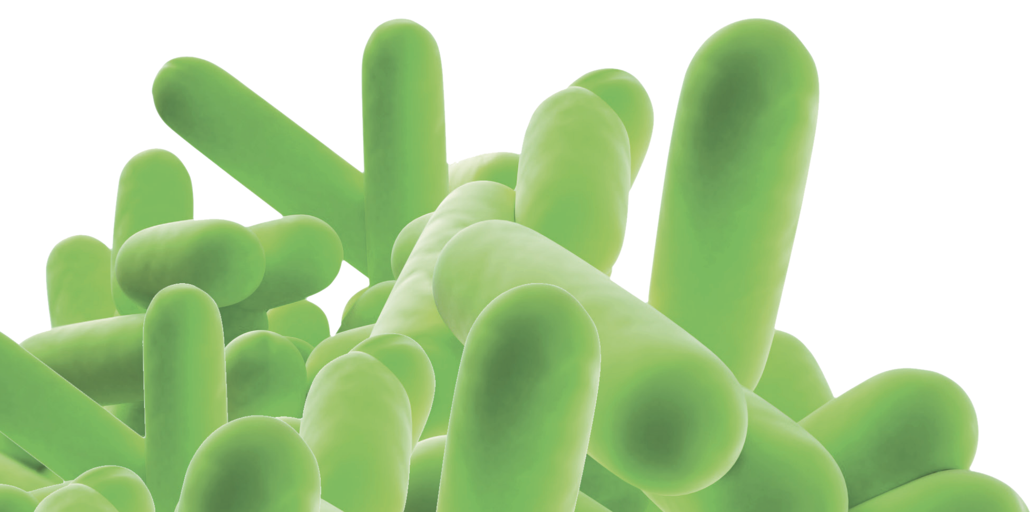
from solid or liquid culture samples

Your benefits

- **Same day results:** Detect selected NTM and relevant drug resistances within 5 hours from culture
- **Streamlined workflow:** For reflex testing, reuse DNA extract from GenoType Mycobacterium CM VER 2.0
- **Robust and reliable:** Integrated controls report validity of results, including efficient extraction, amplification and reverse hybridization

Mycobacteria Product Series

TB and drug resistance testing	
FluoroType® MTBDR VER 2.0	Detection of *M. tuberculosis* complex and its resistances to rifampicin and isoniazid from patient specimens (sputum) or cultures
LiquidArray® MTB-XDR VER 1.0	Detection of *M. tuberculosis* complex and its resistances to fluoroquinolones, linezolid, amikacin and ethambutol from patient specimens (sputum) or cultures
FluoroType® MTB VER 1.0	Detection of *M. tuberculosis* complex from patient specimens (pulmonary and extrapulmonary specimens)
GenoType MTBDR*plus* VER 2.0	Detection of *M. tuberculosis* complex and its resistances to rifampicin and isoniazid from patient specimens (sputum) or cultures
GenoType MTBDR*sl* VER 2.0	Detection of *M. tuberculosis* complex and its resistances to fluoroquinolones and second-line injectable drugs from patient specimens (sputum) or cultures
GenoType MTBC VER 1.X	Differentiation of *M. tuberculosis* complex species from cultures
NTM and drug resistance testing	
FluoroType® Mycobacteria VER 1.0	Detection and differentiation of 32 clinically relevant NTM species and subspecies as well as the *M. tuberculosis* complex, from culture, in one well
GenoType CM*direct* VER 1.0	Detection of *M. tuberculosis* complex and more than 20 clinically relevant NTM from patient specimens (sputum)
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 NTM-DR VER 1.0	Detection of important NTM and their resistances to aminoglycosides and macrolides from cultures
Leprosy and drug resistance testing	
GenoType LepraeDR VER 1.0	Detection of *M. leprae* and its resistances to rifampicin, ofloxacin and dapsone from patient specimens (skin)



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

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LiquidArray® MTB-XDR VER 1.0, FluoroType® MTBDR VER 2.0 are CE 0123 IVD

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