

GenoType[®] Mycobacteria Direct

Molecular Genetic Test System for the Direct Detection of Five Clinically Relevant Mycobacteria Species from Patient Specimens



- simple
- safe
- fast
- easy to combine
- can be automated



CE -labelling
Quality management certified to ISO 9001



Ancient enemy – present threat

Although it was believed to have been overcome long ago, tuberculosis (TB) is advancing again. Both the incidence of the disease and especially the development of multidrug-resistance are increasing at an alarming rate – in particular in Eastern Europe and some developing countries. Tuberculosis has nevertheless become a rather rare disease in Germany in the meantime and practitioners do not think of TB at first. As a result the delayed diagnosis and therapy is detrimental to the success of the treatment and may lead to increasing mortality and transmission of the disease.

Identified too late?

The main focus in the field of TB diagnosis still lies with microscopic and cultural diagnostic methods. The microscopic detection of the pathogen can only provide an initial indication of the presence of an open TB, as it is a very insensitive and unspecific method. Due to the slow growth of many mycobacteria species cultivating on solid and

liquid media takes up to eight weeks before a final detection or safe exclusion of tuberculosis is possible.

Reliable differentiation

The fast and reliable identification of the mycobacteria species is an essential prerequisite for both a successful therapy of mycobacterioses and a reduction of the danger of infection. Until cultivation results are available, the direct detection of mycobacteria from patient specimens points the way for a TB treatment at an early stage. Molecular genetic methods smooth the way to achieve a fast diagnosis.

Hain Lifescience – Competence in mycobacteria diagnostics

Hain Lifescience is known as competent partner in mycobacteria diagnostics and as manufacturer of the **GenoType[®]** product series. The **GenoType[®] Mycobacteria Direct** now offers the molecular genetic direct detection of clinically relevant species of mycobacteria.

Based on the NASBA method and the **DNA-STRIP® Technology** the **GenoType® Mycobacteria Direct** is at present the only test which allows the simultaneous detection of tuberculosis pathogens and non-tuberculous mycobacteria from patient specimens.

- *M. avium*
- *M. intracellulare*
- *M. kansasii*
- *M. malmoense*
- *M. tuberculosis* complex

can be detected and differentiated. By analysis of mycobacterial RNA the direct detection method provides specific and sensitive results long before cultural results are available.

In addition to active case finding and reducing the risk of transmitting the disease, the quick and proper treatment of affected persons is of particular importance in fighting the mycobacterioses effectively. For mycobacteria belonging to the *M. tuberculosis* complex (with the exception of the BCG vaccine strain) treatment is mandatory.

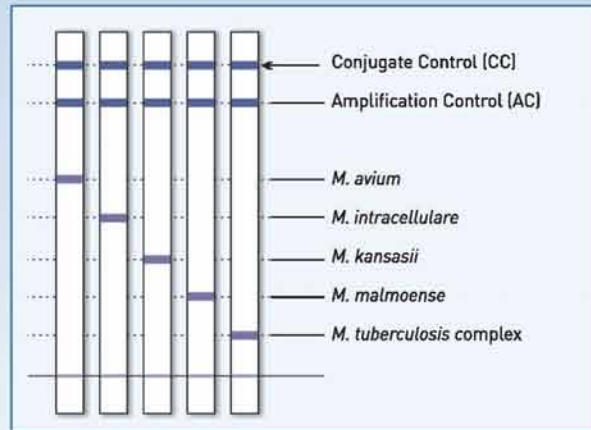


Fig. 1: Reaction zones of **GenoType® Mycobacteria Direct**

The **GenoType® Mycobacteria Direct** allows initial diagnosis within hours rather than days, thus giving a competitive edge of time.

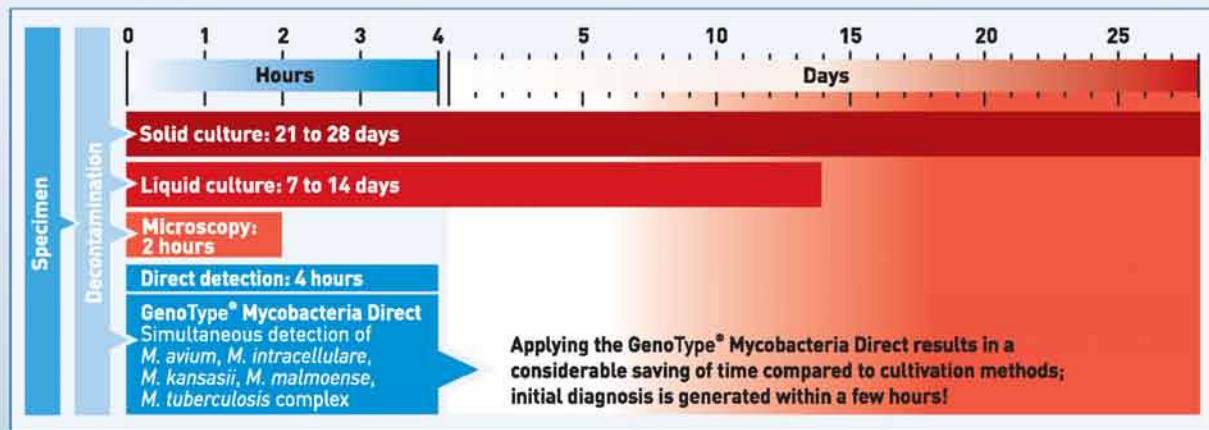


Fig. 2: Time-related comparison between classic procedures and the molecular genetic direct detection using the **GenoType® Mycobacteria Direct**

Benefits of GenoType® Mycobacteria Direct

- Simultaneous detection of the five most important and clinically relevant species of mycobacteria direct from patient samples based on a combination of NASBA method and **DNA-STRIP® Technology**
- Detection of RNA, i.e. of viable cells
- Highly specific RNA isolation using the "Magnetic Beads Capturing" method
- High sensitivity and specificity by applying the NASBA method and the detection via specific probes
- High diagnostic reliability by controls (internal amplification control, positive control)
- No expensive equipment required
- Processing of few specimens is possible

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