

Hain Lifescience: Rapid, Comprehensive Diagnosis of MDR-TB

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Increasing antibiotic resistance requires rapid and comprehensive diagnosis. The new PCR-based FluoroType MTBDR test identifies tuberculosis (TB) pathogens as well as important antibiotic resistance characteristics within three hours. The technology was invented at Brandeis University (USA) and further developed into an in vitro diagnostic test by Hain Lifescience.

FluoroType MTBDR detects TB pathogens directly in patient samples. In addition, it can be used to detect multi-resistant TB (MDR-TB), i.e. resistance against Rifampicin and Isoniazid, the most important first line drugs. The test relies on FluoroType technology, which combines amplification by "Asymmetric excess PCR" (or LATE-PCR) and detection by fluorescence-labelled Lights-On/Lights-Off probes. This test is especially fast and provides results with a great depth of information.

The high degree of automation simplifies and speeds up testing and allows a throughput of up to 96 samples. The rapid detection of TB pathogens including antibiotic resistances directly from patient samples brings with it a time advantage in comparison with cultures, which often take several weeks. In addition, the test provides information about mono-resistances that may be present. This supports the immediate initiation of appropriate, personalised treatment.

FluoroType technology also supports the detection of rare or as yet unknown mutations in the target genes. The analysis is carried out automatically by the Fluoro-Software and is clearly presented in the results report. The scope of software can be extended by newly discovered mutants. In this way, FluoroType MTBDR helps to uncover new mutations and to integrate them into laboratory routines.

On 14 March 2017, FluoroType MTBDR was officially presented to a panel of experts, including representatives from the WHO, Stop TB Partnership, The Global Fund and the Foundation for Innovative New Diagnostics (FIND). For keynote speaker Prof. Rob Warren, leader of the research group on mycobacteriology at Stellenbosch University in South Africa, the advantage lies in the detection of Isoniazid resistances in particular: "This



allows for the differentiation between MDR-TB and Rifampicin mono-resistant TB thereby allowing adjustment in the treatment regimen."

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The new PCR-based FluoroType MTBDR test of Hain Lifescience relies on so-called FluoroType technology. The special features of this test are the rapid availability of results and the information depth that is achieved.