

# AMPATH LAB UPDATE

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## Molecular assay for the identification of clinically relevant *Mycobacterial* species directly from patient specimens



Non-tuberculous mycobacteria (NTM) are free-living ubiquitous organisms. More than 200 different species of NTM have been identified by using molecular techniques. The pathogenic potential of different NTM varies. Accurate identification to species level and discrimination from *Mycobacterium tuberculosis* complex is thus essential in determining the clinical relevance and guiding patient management. The GenoType CMdirect assay is a molecular test for the identification of *M. tuberculosis* complex as well as clinically relevant NTM directly from clinical specimens. This assay is an adjunct to *Mycobacterial* culture in any patient in which NTM disease is suspected and may be especially useful where microscopy of clinical specimens is positive for acid fast bacilli, but tuberculosis (TB) PCR is negative. Table 1 lists further details regarding the GenoType CMdirect assay.

**Table 1: The GenoType CMdirect assay.**

<i>Mycobacterium</i> species identified	<i>M. tuberculosis</i> complex	Identity will be confirmed by TB PCR and genotypic susceptibility testing will be performed if possible.
	<i>M. avium</i> complex <i>M. fortuitum</i> group <i>M. goodii</i> <i>M. malmoense</i> <i>M. interjectum</i> <i>M. szulgai</i> <i>M. kansasii</i> <i>M. xenopi</i>	Submit a sample for <i>Mycobacterial</i> culture if deemed clinically significant to perform susceptibility testing where relevant.
	<i>M. chelonae</i> <i>M. abscessus</i> complex	Submit a sample for <i>Mycobacterial</i> culture if deemed clinically relevant to confirm species identity and perform susceptibility testing.
	<i>M. scrofulaceum</i> / <i>M. intracellulare</i> <i>M. marinum</i> / <i>M. ulcerans</i>	The assay cannot distinguish these species with confidence. Submit a sample for <i>Mycobacterial</i> culture if deemed clinically relevant.
	<i>M. species</i>	No species specific banding pattern obtained but <i>Mycobacterial</i> species is present. Submit a sample for <i>Mycobacterial</i> culture if deemed clinically relevant.
Valid specimen types	Sputum, endotracheal aspirate, bronchoalveolar lavage, tissue, bone marrow, pus, fluid	
Turnaround time	72 hours	
Sensitivity	AFB smear positive: 100% <sup>1</sup> AFB smear negative: 63.6–75% <sup>1</sup>	
Specificity	AFB smear negative: 93.7–98.9% <sup>1</sup>	
Mnemonic	MOTTPCR	

<sup>1</sup> As compared to culture and/or sequencing

As NTM are environmental organisms, their isolation from patient samples may represent colonisation or contamination. The significance of these organisms needs to be determined by taking into account the clinical and radiological presentation, as well as the underlying immune status and other risk factors for NTM disease in the patient. These NTM are more likely clinically relevant if the same species is cultured or detected repeatedly, especially from a normally sterile site. *Mycobacterial* culture should form part of the laboratory work-up of a patient with suspected NTM disease, as this will aid in confirming the identification of the NTM, as well as enabling susceptibility testing to be performed.