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P2402 Validation of the Anyplex MTB/NTM PCR assay for the detection of mycobacterial species from paraffin-embedded tissue samples

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Background: Both Mycobacteria tuberculosis (MTb) and other Mycobacterial species (MOTT) may cause extrapulmonary infections. Although culture is the standard method for diagnosis, the problem arises when Mycobacterial infection is not initially considered and is only suspected when subsequent histology shows evidence of such infection. In such cases, differentiation between MTb and MOTT infections is critical for adequate choice of treatment. Our goal was to evaluate the use of the Seegene Anyplex™ MTB/NTM assay for the detection of MTb and MOTT from formalin-fixed, paraffin-embedded (FFPE) tissue samples.

Materials/methods: The Anyplex™ MTB/NTM multiplex assay includes MTb-specific and pan-Mycobacteria targets. The assay was evaluated in two phases. In the first analytical phase, the sensitivity, specificity and Level off Detection (LOD) were evaluated using Mycobacteria-spiked samples. In the second phase, the assay was evaluated using FFPE tissue samples including MTb-positive samples, MOTT-positive samples and Mycobacteria-negative samples. MTb/MOTT-positive samples were selected based on the presence of 1) a positive culture and 2) compatible histological findings. DNA was extracted from FFPE samples using the QIAamp DNA FFPE Tissue Kit and amplification was done using the CFX96™ real-time PCR instrument.

Results: The assay correctly identified thirteen different isolates, of both rapid- and slow-growing Mycobacteria species with specificity of 100%. The LOD was as low as 10 CFU/sample for both the MTb and Mycobacteria components of the assay. The results of the FFPE phase of the study are presented in the table. The sensitivity for both MTb and MOTT were relatively low (<40%), despite the excellent analytical LOD. The specificity was excellent in both the analytical and FFPE evaluations, with the exception of one MOTT sample that was erroneously reported as MTb.

Conclusions: The Anyplex™ MTB/NTM assay showed excellent analytical sensitivity and specificity, but relatively low sensitivity when applied in FFPE samples. Hence, although this assay is useful in differentiating between MTb vs. MOTT, it cannot rule-out these infections when used on FFPE samples.

	MTb	MOTT	Negative	Total
Number of samples	23	25	10	58
Positive TMb PCR	8	1	0	9
Positive Mycobacteria PCR		8	0	8
Sensitivity	35%	32%		33%
Specificity			100%	100%