

P1018 Xpert MTB/RIF ULTRA vs. Xpert MTB/RIF: performance evaluation on respiratory and extrapulmonary specimens

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Background: The real time PCR is fundamental for rapid diagnosis in paucibacillary respiratory samples and for the detection of multidrug-resistant TB cases. The Xpert[®] MTB/RIF ULTRA (Cepheid, Sunnyvale USA) represents an improvement for rapid diagnosis, thanks to its limit of detection of 11,8 UFC/mL in sputum, which is much lower than the previous test Xpert[®] MTB/RIF (131 UFC/mL in sputum). The aim of this study was the comparison of performances of the two test on pulmonary and extrapulmonary specimens.

Materials/methods: We analysed the results with Xpert MTB/RIF on respiratory and non-respiratory samples collected from February 2017 to July 2017 (phase 1) and with Xpert MTB/RIF ULTRA from February 2018 to July 2018 (phase 2). The protocol for the Xpert PCR suggested by Cepheid was strictly followed for the all specimens. The samples, whose colture was contaminated (4.3%), were eliminated form the analysis. We compared retrospectively the Xpert results with culture results and medical records for clinical diagnosis of TB.

Results: We analysed 1313 respiratory and 310 non-respiratory samples with MTB/RIF (phase 1) and 1413 pulmonary and 357 extra-pulmonary samples with MTB/RIF ULTRA (phase 2). Their performances are shown in the following table.

Sample type (n°)	Pulmonary	Extra-pulmonary		
	MTB/RIF 1313.	MTB/RIF ULTRA (1413)	MTB/RIF 310.	MTB/RIF ULTRA 357.
Sensitivity %	87,18	92,47	69,23	87,04
Specificity %	100	99,24	100	100
Positive Likelihood Ratio	∞	122,06	∞	∞
Negative Likelihood Ratio	0,13	0,07	0,30	0,13

Conclusions: These data confirm that Xpert MTB/RIF assay is an accurate, sensitive (87,18%), and specific (100%) test for the rapid detection of pulmonary TB. The new MTB/RIF ULTRA assay has a higher sensitivity (92,47%) but a lower specificity (99,24%) mainly due to not confirmed traces of genomes of *M. tuberculosis complex* (9 cases) on following respiratory samples of the same patient. The increase of sensitivity is even bigger on extra-pulmonary specimens: 69,23% with the previous assay relative to 87,04% with the ULTRA. Our data suggest better performances of Xpert MTB/RIF ULTRA assay in term of sensitivity, and therefore its usefulness in diagnosing

pulmonary, and particularly in extra-pulmonary, tuberculosis.

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