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Performance of FungiXpert® Aspergillus Galactomannan Detection Kit (CLIA) on bronchoalveolar lavage fluid (BALF)

06. Fungal infection & disease
06b. Diagnostic mycology (incl. traditional, molecular and other methods)

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Background：FungiXpert® *Aspergillus* (Era Biology) is a novel chemiluminescence integrated reagent strip fully automated for galactomannan detection both in sera or BALF samples. Main advantages over Platelia™ *Aspergillus* (Bio-Rad) are simplicity, rapid turnaroud and possibility of carrying out individually without the need to group samples to adjust the cost. The aim of the study was to evaluate the performance of FungiXpert® *Aspergillus* on BALF samples.

Methods：All BALF submitted were routinely processed for bacterial, fungal and viral investigation and then subsequently frozen at -80 C. Fifty-five selected BALF were thawed in order to perform galactomannan detection in parallel with FungiXpert® and Platelia™. Furthermore, *Aspergillus* PCR were done with PerfeCTa SYBR® Green SuperMix (Quantabio) from eluates obtained with NucliSENS® easyMAG® (bioMérieux) following the Fungal PCR Initiative recommendations. Only Ct values <36 were considered positive. Electronic medical charts and microbiological records were reviewed to identify risk factors of invasive fungal disease and relevant microbiological findings. Probable invasive aspergillosis (PIA) and probable COVID-19-associated pulmonary aspergillosis (PCAPA) were considered in accordance to latest EORTC/MSGERC and ECMM/ISHAM criteria respectively. Prior antifungal treatment/prophylaxis or beta-lactam administration were not assessed.

Results：Results are sumarized in the table.

Considering 11 (20.0%) probable invasive aspergillosis, regardless risk factors and established criteria, FungiXpert® and Platelia™ showed overall sensitivities of 90.1% and 72.7% and specificities of 77,3% and 95.5% respectively. Focusing on patients with hematologic malignancy, FungiXpert® and Platelia™ displayed sensitivities of 75.0% and 50.0% and specificities of 75.0% and 92.8% respectively. Raising the cut-off from 0.5 to 1µl/L the specificity of FungiXpert® reaches 89% without affecting sensitivity.

Conclusions

Results according to risk group.					
	Positive FungiXpert® **n (%)**	**Positive Platelia™** **n (%)**	**Positive PCR** **n (%)**	**Aspergillus sp. positive culture** **n (%)**	**PIA or PCAPA** **n (%)**
Hematologic malignancy (32)	10 (31.3)	4 (12.5)	4 (12.5)	0 (0)	4 (12.5)
Pulmonary disease (13)	5 (38.5)	2 (15.4)	3 (23.1)	1 (7.7)	Not applicable (3 appears to have significance)
COVID (7)	3 (42.9)	2 (28.6)	2 (28.6)	2 (28.6)	2 (28.6)
Others: HIV, kidney transplant and solid organ tumor (3)	2 (66.6)	2 (66.6)	2 (66.6)	1 (33.3)	Not applicable (2 appears to have significance)

FungiXpert® seems to be a reliable alternative to Platelia™.