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CLINICAL PERFORMANCE EVALUATION OF A NOVEL MONOTEST GALACTOMANNAN DETECTION IN THE DIAGNOSIS OF INVASIVE ASPERGILLOSIS

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Purpose:

Aspergillus galactomannan (GM) is a widely recognized biomarker for the diagnosis of IA, and PlateliaTM EIA (Bio-Rad) was the routinely-used method. However, it is a technology that requires batching and makes it very difficult to be used with individual samples as a single-test. A new monotest quantitative test - FungiXpert® Aspergillus Galactomannan Detection Kit with the chemiluminescence immunoassay (CLIA), developed by Genobio Pharmaceuticals Co., Ltd., could improve some of the limitations of Platelia. Here, a comparison was made between Platelia and FungiXpert performed simultaneously in serum and bronchoalveolar lavage (BAL).

Methods:

A total of 276 retrospective and prospective samples were simultaneously tested with Platelia and FungiXpert. Among the 276 cases, 106 collected retrospectively (20 from the control group, 96 from patients meeting the IA criteria), and the remaining 170 from daily request.

Results:

Overall, the results were concordant in 251 of the 276 samples (90.58%) of the patients and 25/276 (9.06%) were discordant. Among the 25 discordant cases 16 had IA and the remaining 9 did not. Platelia was positive in only 3 of 16 IA cases while FungiXpert detected 14. Of the 9 cases without IA, Platelia was negative in 8 and FungiXpert in 2.

Conclusion:

Both tests showed concordant results in more than 90% of the cases. In particular, FungiXpert can quickly detect and obtain quantitative test results within 40 minutes, which is more convenient for rapid detection of GM, and is more sensitive to the detection of IA cases when the results are inconsistent.