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Full-Automatic Chemiluminescence Immunoassay System for Aspergillus Galactomannan Detection

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Background: Aspergillus is one of the most common fungal Genus that led to severe invasive fungal infection. Due to lack of typical clinical manifestations and effective early diagnosis methods, Invasive Aspergillus (IA) has a mortality rate of 50% to 100%. Early diagnosis and treatment were the crucial factor to improve this situation. Aspergillus galactomannan (GM) is a widely recognized biomarker for the diagnosis of IA, and Platelia™ EIA was the routinely-used method. However, there was complexity requirements for experiment operation and requiring 2h to obtain the results. Thus, Aspergillus Galactomannan Detection Kit (CLIA), suitable for the open platform of Full-Automatic Chemiluminescence Immunoassay System (FACIS-I), was introduced to make GM test automated. This combination would maximum allow elimination of contamination origin from human operation, reduce the operational error, and get the accurate quantitative results within 40min.

Methods: 137 serums and 96 BAL fluids samples were involved. All samples were collected from Huashan Hospital hospitals following the standard procedures. The content of galactomannan was determined by both Platelia™ Aspergillus Ag (Manufactured by Bio-Rad Laboratories) and FungiXpert® Aspergillus Galactomannan Detection Kit (CLIA) (Manuctured by Genobio Pharmaceuticals Co., Ltd.). The final results were compared.

Results: Among 137 serum samples, 43 were shown both positive by Platelia™ and FungiXpert®, and 92 were shown both negative.1 Platelia™ positive sample showed negative with FungiXpert®, and 1 Platelia™ negative samples showed positive with FungiXpert®. Among 96 BAL fluid, 44 were shown both positive by Platelia™ and FungiXpert®, and 51 were shown both negative. The only inconsistent sample showed negative with FungiXpert® while Platelia™ showed positive. The coincident rate of 2 products was calculated. Compared with Platelia™, the serum positive coincident rate of FungiXpert® is 97.7% and the negative is 98.9%, the total rate is 98.5%. The BAL fluid positive coincident rate of FungiXpert® is 100% and the negative is 98.1%, the total rate is 99.0%.

Conclusions: The FungiXpert® exhibits high coincident results for serological diagnosis compared with routinely-used method, which indicated that GM diagnosis will be more rapid, simple and intelligent with the application of FACIS-I.