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Novel Diagnostic Method for Fungal Infection — (1,3)- β -D-Glucan Chemiluminescence Immunoassay

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Background: Globally, over 300 million people were afflicted with serious fungal infection, and Invasive Fungal Disease (IFD) is becoming one of its most serious categories. Nowadays, (1,3)- β -D-Glucan test (*Chromogenic Method*) (BG Test) is one useful method for IFD diagnosis and has been recommended by EORTC/MSG. However, there were high requirements for personnel operations for BG tests. Thus, introduced a novel (1,3)- β -D-Glucan detection kit manufactured by Beijing Gold Mountainriver Co, Ltd., which used *Chemiluminescence Immunoassay* (CLIA) technology to apply Full-Automatic Chemiluminescence Immunoassay System (FACIS-I) open platform. This combination would maximum allow elimination of contamination origin from human operation, reduce the operational error, and get the accurate qualitative and quantitative results within 40min.

Methods: Samples of all adult patients diagnosed with PCP (pneumocystis pneumonia), IA (invasive aspergillosis) and IC (invasive candidiasis) were enrolled in Ruijin hospital from January 2020 to December 2020. The patients' serum samples were applied to the FungiXpert[®] Fungus (1,3)- β -D-Glucan Detection Kit (CLIA) using FACIS-I to detect (1,3)- β -D-Glucan. In addition, the routinely-used *Chromogenic Method*, Fungus (1,3)- β -D-Glucan Detection Kit (Manufactured by Genobio Pharmaceutical Co., Ltd.) applying to microplate reader for comparative analysis.

Results: A total 139 patients with 41 PCP, 39 IA, 12 IC, and 47 controls including 20 patients with TB (*tuberculosis*) and 27 healthy volunteers were included in this analysis. At a cutoff value of >100 pg/mL, 95 showed positive in both FungiXpert[®] and Genobio, among them, 96.8% were diagnosis as IFD. 39 showed both negative, among them, 97.4% were confirmed no fungal infection. There were 2 cases that FungiXpert[®] showed positive while Genobio showed negative. 3 patients showed positive only in Genobio. The coincident rate of 2 products was calculated, compared with Genobio, the serum positive coincident rate of FungiXpert[®] was 97.9% and the negative was 92.8%, the total rate was 96.4%.

Conclusions: The FungiXpert[®] with *Chemiluminescence Immunoassay* exhibits excellent coincident rate results for serological diagnosis compared with routinely-used *chromogenic methods*, which indicated that a new (1,3)- β -D-Glucan detection method was emerged. Moreover, the application of FACIS-I makes the (1,3)- β -D-Glucan detection experiment full-automatic, rapid and intelligent.