RESEARCH ON THE DIAGNOSTIC PERFORMANCE OF SEVERAL DIFFERENT GALACTOMANNAN METHODOLOGIES FOR INVASIVE ASPERGILLOSIS

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Purpose:

Invasive aspergillosis (IA) is a growing threat to human health worldwide. The detection of IA represents a substantial challenge for many clinical laboratories. Molecular methods are favored because the majority can be executed quickly with high accuracy. However, there was no consensus has yet been reached about the single most optimal method. Nowadays, *Aspergillus* galactomannan (GM) is a recognized biomarker for the diagnosis of IA, ELISA is one useful method for GM detection. And many immunochromatographic (IC) methods have been developed and commercialized for rapid and precise detection. Chemiluminescence immunoassay (CLIA) technology have also been applied to GM detection. Here, several different methodologies of GM detection reagents are compared to study the diagnostic performance.

Methods:

FungiXpert® Aspergillus Galactomannan Detection K-Set (Lateral Flow Assay), Aspergillus Galactomannan ELISA Detection Kit and Aspergillus Galactomannan Detection Kit (CLIA), which all manufactured by Genobio Pharmaceutical Co., Ltd., these three different methodological reagents were used to conduct clinical comparative studies on the same sample at the same time to evaluate the sensitivity, specificity and coincidence rate.

Results:

The sensitivity and specificity for IC is 90.5-96.8% and 95.0-95.8% respectively. The sensitivity and specificity for ELISA is 92.1-96.9% and 92.5-96.2% respectively. The sensitivity and specificity for CLIA is 93.2-97.0% and 92.0-96.4% respectively.

Conclusion:

Different sensitivities had been showed of three methodologies, but each tests showed concordant results in more than 90% of the cases. To sum up, all 3 kits have high sensitivity and specificity, which can provide high diagnostic value for the IA. Moreover, it is recommended that samples from different sources better be submitted for clinical testing, and conditional laboratories should try to combine the three methods for simultaneous detection to strive for early diagnosis of invasive aspergillosis.