

10th Advances Against Aspergillosis and Mucormycosis

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Virtual Event

Clinical Performance Evaluation of a *Novel Monotest Galactomannan Detection* *in the Diagnosis of Invasive Aspergillus*

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FACIS-I

Fully automatic, great leap from 3h to 40min.



- Early
- Rapid
- Dynamic
- Quantitative
- Fully Automatic

Monotest Strip



- Monotest Detection
- Integrated reagents and consumables together
- Unique sample pretreatment system

1. BACKGROUND

Aspergillus galactomannan (GM) is a widely recognized biomarker for the diagnosis of IA, and *Platelia™ 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 Broncho Alveolar Lavage (BAL).

2. MATERIAL & 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.

3. RESULTS

Overall, the results were concordant in 251 of the 276 samples (90.58%) of the patients and 25/276 (9.06%) were discordant.

4. ANALYSIS OF THE INCONSISTENT RESULTS

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 1.

Genobio		Clinical Result		Total
		Positive	Negative	
FungiXpert®	Positive	14	8	22
	Negative	2	1	3
Total		16	9	25

Bio-Rad		Clinical Result		Total
		Positive	Negative	
Platelia	Positive	3	1	4
	Negative	13	8	21
Total		16	9	25

5. 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.