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The comparison study between tachypleus tridentatus and limulus polyphemus with different experiment process for the diagnosis of invasive fungal diseases in China

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Background: The study aims to evaluate the performance of two different BG assays produced by different materials (*Tachypleus tridentatus* and *Limulus polyphemus*) with different operation methods (Tube format and microplate format).

Material/methods: Detection of (1-3)- β -D-Glucan in test samples is an indication of fungal infection that occurs in invasive fungal disease (IFD). The fungal cell wall component (1-3)- β -D-Glucan is detected with the two different BG assays which are Goldstream BG Test (Beijing Gold Mountainriver Tech Development Co., Ltd.) and Fungitell assay (Associates Cape Cod, Inc.) respectively using clinical serum specimens. Fungitell assay and Goldstream BG test use a positive cut-off value of 60-80 pg/ml. The Fungitell assay is set up on microplate with incubating microplate reader, Goldstream BG test is set up on test tube with Goldstream Kinetic Tube Reader (MB-80M). The concentrations for the five standards of Fungitell assay and Goldstream BG Test are all 31.25, 62.5, 125, 250 and 500pg/ml, respectively. While Fungitell assay makes standard curve for each experiment, Goldstream BG test imports the prepared standard curve into MB-80M and set quality control for each experiment. And there is no need to set parallel experiments on one sample when using Goldstream BG Test. The main reagent of Fungitell assay is produced by *Limulus polyphemus*, while the main reagent of Goldstream BG Test is produced by *Tachypleus tridentatus*. The experiment was done in China-Japan Friendship Hospital, 19 serum samples were detected with symptoms of suspected invasive fungal infection at hospital. Specific sample ID was assigned to each sample. Then all positive samples were also confirmed by blood culture. The results were compared and analyzed with a consistency assessment.

Results: Fungitell assay detected 7 positives, 12 negatives; Goldstream BG test detected 8 positives, 11 negatives; of which 7 positives is consistent, 11 negatives is consistent; the total coincidence rate is

18/19*100%=94.74%, the positive coincidence rate is 7/7*100%=100%, and negative coincidence rate is 11/12*100%= 91.67%. The experimental results are shown in the following table 1.

Table 1 Test results of Fungitell assay and Goldstream BG Test

Sample No.	Fungitell 1	Fungitell 2	Results	Goldstream (GKT-12M)	Results	Blood culture
1	>523.438	>523.438	P	428.62	P	<i>Candida albicans</i>
2	285.538	250.235	P	311.725	P	<i>Candida tropical</i>
3	45.559	58.679	N	<31.25	N	
4	42.52	30.989	N	<31.25	N	
5	282.369	248.27	P	190.41	P	<i>Candida kruseii</i>
6	245.91	183.226	P	272.11	P	<i>Candida albicans</i>
7	<7.812	<7.812	N	<31.25	N	
8	48.292	46.407	N	85.19	P	NYD
9	311.714	215.999	P	275.73	P	<i>Candida parapsilosis</i>
10	<7.812	<7.812	N	<31.25	N	
11	216.959	109.286	P	211.77	P	<i>Candida albicans</i>
12	93.131	75.212	P	85.19	P	<i>Candida parapsilosis</i>
13	48.292	46.407	N	43.89	N	
14	16.797	30.763	N	<31.25	N	
15	<7.812	<7.812	N	46.06	N	
16	24.294	34.211	N	39.59	N	
17	27.443	<7.812	N	44.18	N	
18	<7.812	<7.812	N	37.09	N	
19	<7.812	<7.812	N	40.81	N	

Conclusions: Although the two kits are produced by different materials and the operations are also different, the test results demonstrated that the performance of Goldstream BG test was highly consistent with that of Fungitell assay with the total coincidence rate of more than 90%. And the validation results obtained from blood culture proved that these two different BG assays were sensitive and reliable detection method which can be widely applied in the early diagnosis of invasive fungal disease. What's more, the tube-formated BG test produced by *Tachypleus tridentatus* maybe a little bit more sensitive than microplate-formated BG test produced by *Limulus polyphemus*.