

Information

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TECO[®] Aspergillus Galactomannan Assay



Detection of Aspergillus galactomannan antigen for the diagnosis of Invasive Aspergillosis (IA)

The mortality rate of Invasive Aspergillosis is between 60 and 100% without timely treatment, thus reliable determination of galactomannan antigen may be essential.

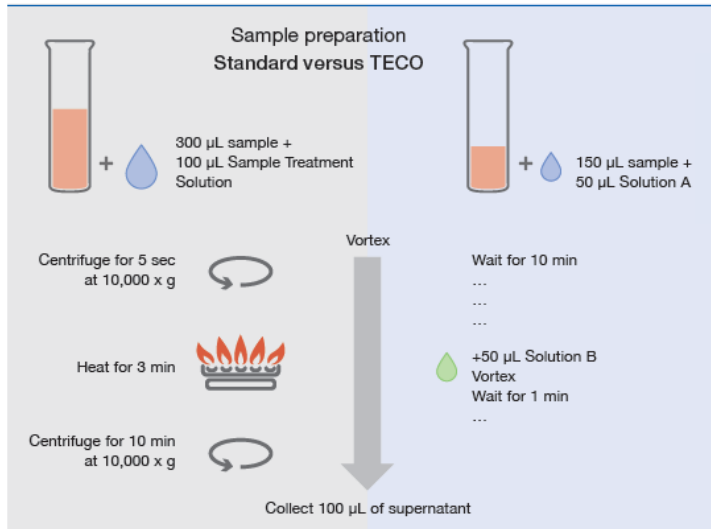
- Sandwich ELISA as diagnostic gold standard
- Validated for serum and BAL samples
- Significantly simplified sample preparation
- Only 150 µL sample volume required
- Limit of detection: 0.67 ng/ml (serum); 1.09 ng/ml (BAL)
- Automation possible from sample to final result

Reference method versus TECO[®] Aspergillus Galactomannan Assay:

Results	Coincidence rate (CI)	95% confidence interval	Number of samples
Positive coincidence rate (Diagnostic sensitivity)	94.11%	91.46-96.78%	272
Negative coincidence rate (Diagnostic specificity)	94.80%	93.26-96.24%	481

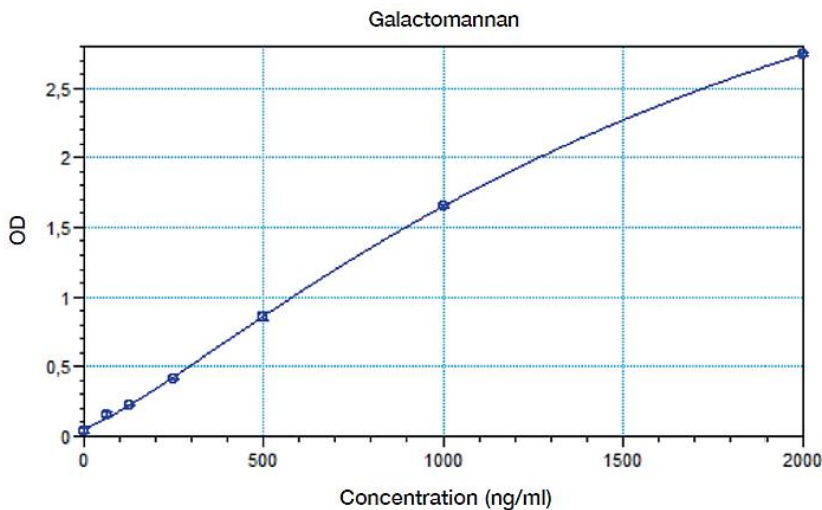
TECO® Aspergillus Galactomannan Assay

Detection of galactomannan antigens as indicators of Aspergillus spec. infection using anti-galactomannan monoclonal antibodies and HRP-mediated color reaction. Established diagnostic procedure, significantly simplified sample preparation



Coincidence rates of both sample preparation protocols:

Results	Serum	BAL
Positive coincidence rate (Diagnostic sensitivity)	96.7%	94.44%
Negative coincidence rate (Diagnostic specificity)	99.5%	97.06%
Number of samples:	297	52



Mean OD	ng/ml	Index
2.742	2000	8.62
1.652	1000	5.19
0.861	500	2.71
0.412	250	1.29
0.220	125	0.69
0.154	62.5	0.48
0.041	0	0.13

Qualitative and index-based detection after applying a WHO standardization.

Clinical comparison

BioRad Platelia and TECO® Aspergillus Galactomannan

For a small comparative study at the University Hospital AKH Vienna, Institute for Laboratory Medicine, Dept. Clinical Microbiology (Prof. Birgit Willinger), 20 serum and 11 BAL samples were tested with the Platelia Galactomannan ELISA (BioRad) and the TECO Galactomannan ELISA (TECOmedical) in parallel.

The major difference between both assays is the sample treatment, but also the antibodies used in the ELISAs.

Both assays use cut-off values, based on identical index value calculation.

BioRad Platelia Galactomannan:

Serum and BAL: ≥ 0.5 positive

TECO® Galactomannan.

Serum: ≥ 0.5 positive

BAL: ≥ 1.0 positive

300 μ l sample were heated at 100-110°C after addition of a test-specific reagent and centrifuged afterwards. 100 μ l of the supernatant have been used for the Platelia assay, results were reported as index values.

For the TECO ELISA, 150 μ l sample were used, and 2 different test-specific reagents were added with a defined timely delay. 100 μ l of this mixture was used for the TECO ELISA, and results were reported as index values.

Results are shown below. With one exception (BAL sample) all results indicated a similar diagnostic interpretation.

Lfd. Nummer	Material	TECO Aspergillus Antigen		Platelia Aspergillus Antigen		
		Wert (Index)	Interpr.	Wert (Index)	Interpr.	
01	Serum	1.075	pos	1.265	pos	
02	Serum	0.658	pos	0.602	pos	
03	BAL	14.24	pos	5.453	pos	
04	BAL	5.141	pos	4.498	pos	
05	BAL	0.116	neg	1.230	pos	*
06	Serum	0.097	neg	0.065	neg	
07	Serum	0.132	neg	0.304	neg	
08	Serum	0.12	neg	0.072	neg	
10	BAL	0.081	neg	0.051	neg	
11	BAL	0.097	neg	0.064	neg	
12	BAL	0.368	neg	0.046	neg	
13	Serum	0.058	neg	0.032	neg	
14	Serum	0.101	neg	0.043	neg	
15	Serum	1.133	pos	1.960	pos	
16	BAL	1.141	pos	1.549	pos	
17	Serum	0.166	neg	0.101	neg	
18	Serum	0.193	neg	0.188	neg	
19	Serum	0.104	neg	0.112	neg	
20	Serum	0.07	neg	0.061	neg	
21	Serum	0.65	pos	0.857	pos	
22	BAL	6.232	pos	5.502	pos	
23	BAL	3.075	pos	3.431	pos	
24	Serum	0.112	neg	0.081	neg	
25	Serum	2.19	pos	2.893	pos	
26	BAL	15.133	pos	7.063	pos	
27	BAL	7.988	pos	5.856	pos	
28	Serum	0.116	neg	0.036	neg	
29	Serum	0.097	neg	0.029	neg	
30	Serum	0.112	neg	0.043	neg	
31	Serum	0.251	neg	0.034	neg	
32	Serum	0.182	neg	0.046	neg	

* The result of sample #5 cannot be interpreted clearly. Further testings with BioRad Platelia and other lab parameters were negative, the patient also did not develop further signs of aspergillosis, but received preventive antimycotic treatment.

Catalog number: TE1067

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