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The AspDx range

Developing the future of fungal diagnostics

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t: +44 (0) 191 375 9111
e: info@olmdiagnostics.com
w: www.olmdiagnostics.com

OLM Diagnostics, The Core, Science Central, Bath Lane, Newcastle Upon Tyne, NE4 5TF, England

AspLFD

Aspergillus Lateral-Flow Device (LFD)

For the rapid detection of Invasive Pulmonary Aspergillosis

- Highly specific and detects 'activity' only
- Single use assay with results in 15 minutes
- Proven efficacy in diagnosis of IPA in humans (serum and BAL)

CE IVD

OLM diagnostics

OLM-007-04-2018

Aspergillus Lateral-Flow Device (LFD)

AspLFD

Intended use

Rapid immunochromatography test for the qualitative detection of *Aspergillus* diagnostic antigen in human serum and bronchoalveolar lavage fluid; for use as an aid in the assessment and evaluation of patients with suspected **invasive pulmonary Aspergillosis (IPA)**.

Summary

IPA caused by the fungus *Aspergillus* is a frequently fatal disease of immuno-compromised humans such as haematological malignancy and bone marrow transplant patients.[1] Antigens produced by the fungus during infection can be used to diagnose the disease.

The ***Aspergillus* LFD (*Asp*LFD)** uses a monoclonal Ab that detects antigenic mannoproteins produced by the fungus during active growth[1,2] and can be used to detect the *Aspergillus* diagnostic antigen in human serum and BAL fluids.[3,4,5,6]

Test principle

The **OLM Diagnostics *Aspergillus* LFD** uses a monoclonal Ab conjugated to nitrocellulose beads (NCB) to detect *Aspergillus* diagnostic antigen.[1,2,3] The antibody-NCB conjugate binds specifically to *Aspergillus* diagnostic antigen in the patient sample to form a complex. The complex migrates along the strip until it is captured and concentrated on the test zone (T), where the same antibody has been bound. This causes a red line to appear on the strip.[1,2,3] If antigen concentrations are below detectable levels, no visible test line will be produced. Uncaptured NCB conjugate continues to flow towards the end of the strip where it is bound on the control (C) zone. Formation of a red C line indicates the test has been performed correctly.[1,2,3]

Intended use

Aspergillus antigen in human serum or BAL fluids indicates active infection by the pathogen since the antigen is a constitutively expressed mannoprotein produced from the hyphal tip of the fungus[1,2].

A positive result should be obtained with OLM Diagnostics *Aspergillus* Lateral-Flow Device when target antigen levels are greater than or equal to the cut off of ~30ng/ml serum determined using purified antigen[2].

Performance characteristics

1. In haematological malignancy patients using serum EORTC Proven/probable IPA (n=22) versus no IFD (n=59)

Published study conducted at School of Medicine, Cardiff University, Wales, UK6. LFD compared to Bio-Rad Platelia GM-EIA and real-time PCR.

Assay	Sensitivity	Specificity	NPV
LFD	81.82% (61.5-92.7)*	84.75% (73.5-91.8)*	92.59% (82.5-97.1)*
PCR	95.45% (78.2-99.2)*	72.88% (60.4-82.6)*	97.73% (88.2-99.6)*
GM-EIA	77.27% (56.6-89.9)*	81.36% (69.6-89.3)*	90.60% (79.8-95.9)*

* = 95% Confidence Intervals, NPV = Negative Predictive Value

2. In haematological malignancy patients and solid organ transplant recipients using BAL (n=37; 27 HM, 10 SOT; EORTC probable IPA n=12)

Published study conducted at Medical University of Graz, Austria4. LFD compared to Bio-Rad Platelia GM-EIA.

Sensitivity	Specificity	NPV
100%	81%	100%

GM levels in LFD negative BALs were significantly lower than in LFD positive BALs (n=22; median <0.4 ODI;[IQR] <0.4-<0.4 vs. n=17; median 1.50 ODI; [IQR] 0.72-11.33; p < 0.0001, Mann-Whitney U test) GM levels were also significantly lower in samples with weak LFD positives (n=8; median 0.97 ODI; [IQR] <0.4-1.23), than in moderate or strong positive LFD samples (n=9; median 4.66 ODI; [IQR] 2.8-19.3; p=0.0012, Mann-Whitney U test).