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The AspDx range

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)

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CE IVD

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OLM-007-11-2018

Aspergillus Lateral-Flow Device (LFD)

AspLFD

(Code OLM1906)

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 (AspLFD)** 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.[3-22]

Test principle

The **OLM Diagnostics** Aspergillus **LFD** uses a monoclonal Ab conjugated to nitrocellulose beads (NCB) to detect *Aspergillus* diagnostic antigen. 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. 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.

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. Measure of accuracy of the BAL LFD tests in diagnosis of IA:

Summary of performance of the LFD in BAL fluid samples (publications from prototype LFD, through to CE-marked device), per sample, are depicted in Table 1. Data taken from Heldt et al (2017)[3] and extended to include publications from June 2017 to September 2018. 1032 BAL fluid samples tested.

Table 1. Per BAL fluid sample performance of the BAL fluid Aspergillus LFD for probable/proven IPA versus no evidence for IPA in all patient cohorts combined (percentage and absolute numbers).

Sensitivity	Specificity	PPV	NPV
71%	91%	61%	94%
(104/146)	(644/711)	(104/171)	(644/686)

PPV = positive predictive value, NPV = negative predictive value, (bracket) = absolute numbers
Data derived from published studies (4-21)

2. Measure of accuracy of the serum LFD tests in diagnosis of IA:

Summary of performance of the LFD in serum samples (publications from prototype LFD, through to CE-marked device) are presented in Table 2. Data are taken from a 2015 meta-analysis by Pan et al[22] and extended to include publications from April 2015 to September 2018. This incorporates data from the LFD development study[2], as well as the three studies that have evaluated the diagnostic performance of the LFD in serum samples from adult patients with haematological malignancies [21, 23, 24]. 284 serum samples tested.

Table 2. Per serum sample performance of the Aspergillus LFD for probable/proven IPA versus no evidence for IPA, in all patient cohorts combined (percentage and absolute numbers).

Sensitivity	Specificity	PPV	NPV
56%	90%	61%	88%
(30/54)	(170/189)	(30/49)	(170/194)

PPV = positive predictive value, NPV = negative predictive value, (bracket) = absolute numbers
Data derived from published studies (2, 21, 23-24)