

# Bronchoalveolar lavage lateral-flow device test for diagnosing invasive pulmonary aspergillosis in patients with haematologic malignancies: a multicentre study'



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**Background:** Timely diagnosis is a key factor in successful treatment of invasive pulmonary aspergillosis (IPA). Galactomannan testing from BAL represents a current gold standard. Limitations of galactomannan (GM) testing are varying turnaround time and availability. These limitations may be overcome by the Lateral- Flow Device (LFD) test, a single sample point-of-care test for native BAL testing that is based on the detection of an Aspergillus extracellular glycoprotein antigen by monoclonal antibody JF5. This multicenter study evaluates the LFD test by using bronchoalveolar lavage (BAL) samples.

**Methods:** A total of 74 BAL samples from 74 patients with underlying hematological malignancies were included at four University hospitals in Austria and Germany (41 samples from Graz, AT, 25 from Innsbruck, AT, and each 4 from Mannheim, DE and Vienna, AT). In Graz, Vienna and Mannheim sample collection was performed prospectively in 2013 while in Innsbruck LFD was tested in biobank samples collected within the past 5 years. The JF5 LFD results in qualitative data based on the test-line intensity ranging from strong positive (+++) to weak positive (+) or negative (-). A strong positive test result is shown in Figure 1.

30 had probable or proven IPA (3 Graz, 4 Mannheim, 21 Innsbruck, 2 Vienna). Diagnostic accuracy of LFD for probable/proven IPA was evaluated. For IPA grading fungal cultures as well as BAL GM (cut-off 1.0) were used. Other than that IPA was graded in accordance with the European Organization for Research and Treatment of Cancer Invasive Fungal Infections Cooperative Group (EORTC) and the Mycoses Study Group of the National Institute of Allergy and Infectious Disease (MSG) revised criteria.

**Results:** Sensitivity and specificity of LFD test for probable/proven IPA were 63.3% (Graz 66%, Mannheim 75%, Innsbruck 57%, Vienna 100%) and 86.4%, respectively. All six false positive results were observed among cases with possible IPA (n=13), while no false positive LFD result was observed among 30 cases without IPA. When patients with possible IPA were excluded PPV was 100%, NPV 73%. LFD resulted negative in 11 patients with probable/proven IPA. BAL GM was tested in two of those patients only and revealed levels of 1.24 and 0.1.

	Sensitivity	Specificity	PPV	NPV	DOR (95%CI)
Hematology pts (n=74)					
Probable/proven (n=30) vs possible/no IPA (n=44)	63%	86%	76%	78%	11 (3.5-34)
Probable/proven (n=30) vs no IPA (n=31)	63%	100%	100%	73%	107 (6-1916)

Table 1. Performance of LFD in hematology patients.

**Conclusion:** The LFD test of BAL specimens is performed easily and provides reliable and rapidly available results in patients with underlying hemato-oncological malignancies. Therefore, this new point-of-care test may be a very promising diagnostic approach for detecting IPA in BAL specimens from hematology patients.

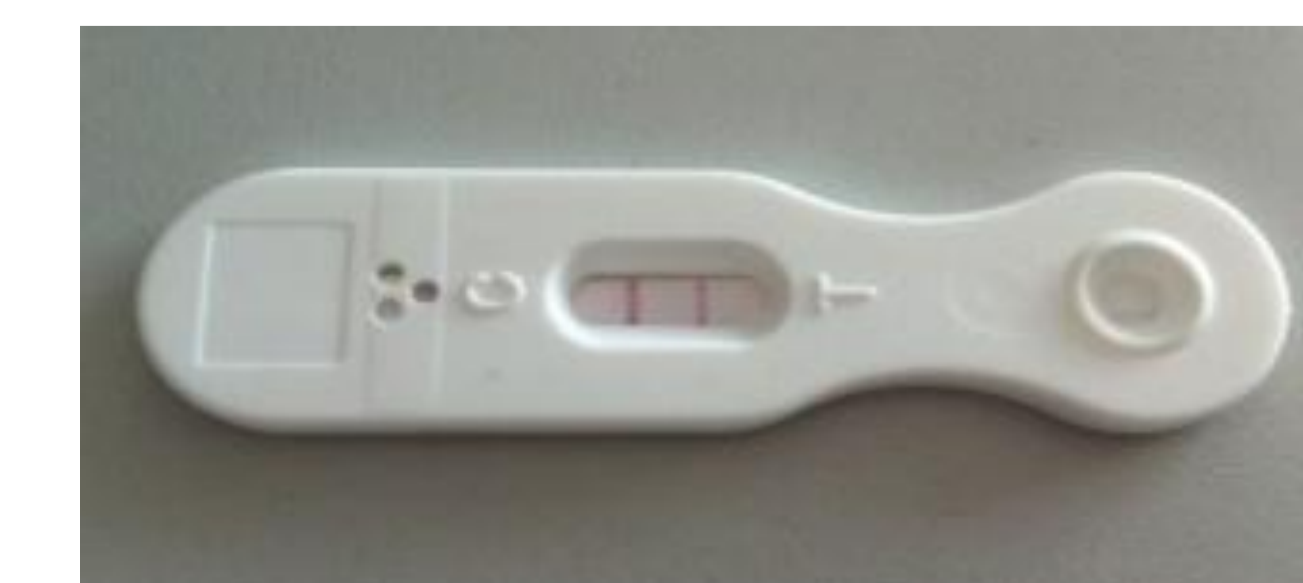


Figure 1: LFD result using BAL fluid showing strong positive (+++) test (T) line. Internal control line (C) indicates that the test has run correctly