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MAJOR ARTICLE

Performance of the Bronchoalveolar Lavage Fluid *Aspergillus* Galactomannan Lateral Flow Assay With Cube Reader for Diagnosis of Invasive Pulmonary Aspergillosis: A Multicenter Cohort Study

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Background. The *Aspergillus* Galactomannan Lateral Flow Assay (LFA) is a rapid test for the diagnosis of invasive aspergillosis (IA) that has been almost exclusively evaluated in patients with hematologic malignancies. An automated digital cube reader that allows for quantification of results has recently been added to the test kits.

Methods. We performed a retrospective multicenter study on bronchoalveolar lavage fluid (BALF) samples obtained from 296 patients with various underlying diseases (65% without underlying hematological malignancy) who had BALF galactomannan (GM) ordered between 2013 and 2019 at the University of California, San Diego, the Medical University of Graz, Austria, and the Mannheim University Hospital, Germany.

Results. Cases were classified as proven (n = 2), probable (n = 56), putative (n = 30), possible (n = 45), and no IA (n = 162). The LFA showed an area under the curve (AUC) of 0.865 (95% confidence interval [CI] .815–.916) for differentiating proven/probable or putative IA versus no IA, with a sensitivity of 74% and a specificity of 83% at an optical density index cutoff of 1.5. After exclusion of GM as mycological criterion for case classification, diagnostic performance of the LFA was highly similar to GM testing (AUC 0.892 vs 0.893, respectively). LFA performance was consistent across different patient cohorts and centers.

Conclusions. In this multicenter study the LFA assay from BALF demonstrated good diagnostic performance for IA that was consistent across patient cohorts and locations. The LFA may serve a role as a rapid test that may replace conventional GM testing in settings where GM results are not rapidly available.

Keywords. hematologic malignancy; intensive care unit; respiratory diseases; solid organ transplant recipients; autoimmune diseases.

Aspergillus species cause over 300°000 cases of invasive aspergillosis (IA) annually, with a mortality rate ranging from 30 to 80% [1, 2]. Although patients with hematologic malignancies have been traditionally most affected by IA, the disease has emerged as an important cause of morbidity and mortality in other patient groups including those in the intensive care unit (ICU) with severe influenza [3] or—more recently—coronavirus disease 2019 (COVID-19) [4–6]. Prompt diagnosis and initiation of appropriate antifungal therapy are the 2 most important predictors of survival from IA [7, 8], although early diagnosis remains difficult to establish with culture showing limited sensitivity [9, 10]. The current gold standard for the diagnosis of IA is the detection of the fungal cell wall component galactomannan (GM) [11–13], a polysaccharide that primarily exists in the cell wall of *Aspergillus* species, via an automated enzyme-linked immunosorbent assay (ELISA) requiring a reader [14]. Although GM performance in BALF has been reliable, the test is limited by varying turnaround times dependent on the distance/duration of transport between the clinical setting and the laboratory where the test is performed and/or the number of specimens to be tested, as the test can only be set up in labs that receive a high volume of samples to support the ELISA [15]. Other molecular tests such as polymerase chain reaction (PCR) are also used [16, 17] but lack standardization [18] and have variable diagnostic performance across studies and settings [19, 20], particularly in the diagnosis of breakthrough infections [21] and in settings that use mold-active prophylaxis [22, 23]. Improved, more rapid, and simpler

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single sample diagnostics are thus needed to enable earlier diagnosis and targeted treatment of IA. Two rapid tests for the diagnosis of IA, including the IMMY sōna *Aspergillus* Galactomannan Lateral Flow Assay (LFA) (IMMY, Norman, OK, USA), are now available and enable more rapid diagnosis of IA.

The performance of the Communauté Européenne (CE)-marked IMMY sōna *Aspergillus* Galactomannan LFA in bronchoalveolar lavage fluid (BALF) has been evaluated in 4 studies [24–27], including 2 single-center studies evaluating its performance in both neutropenic and nonneutropenic patients, 1 multicenter study that did not include clinical classification of IA, and a multicenter study of patients with hematologic malignancy. Overall, sensitivity of the LFA across studies was 77% and specificity 81% for differentiating probable/proven IA versus no IA, with the vast majority of samples that have been evaluated to date stemming from patients with hematological malignancies, where sensitivity was 83% and specificity 87%. Although those studies mostly used a visual readout of test results, an automated digital cube reader that allows for quantification of results has recently been added to the test kits, and the test is currently undergoing Food and Drug Administration (FDA) approval.

To date, studies that evaluated this new test kit are lacking, as are multicenter studies that evaluated the LFA in other settings, such as ICU patients or solid-organ transplant (SOT) recipients. Further data on these populations are needed to help instruct how rapid tests such as the LFA can be used in these populations and define the role of the test is settings that do not have GM test results readily available.

We performed a retrospective multicenter study evaluating the performance of the LFA with automated digital Cube reader from BALF samples obtained from patients with varying underlying risk factors, including hematologic malignancy, solid organ transplant (SOT) recipients, and patients in the ICU or with other underlying diseases placing them at risk for IA.

METHODS

A total of 296 BALF samples obtained from 296 patients with various underlying diseases who had bronchoscopy performed and BALF GM ordered between 2013 and 2019 at the University of California, San Diego, United States, the Medical University of Graz, Austria, and the Mannheim University Hospital, Germany, were retrospectively analyzed.

IA was classified according to 2 criteria: (i) the revised EORTC/Mycoses Study Group (MSG) criteria with exclusion of serum beta-D-glucan (BDG) as mycological evidence [28]. Those without underlying hematological malignancies who did not fulfill probable or proven IA criteria were further classified using (ii) a slightly modified version of the clinical algorithm described by Blot and colleagues [3, 29, 30]. Following previous recommendations, the Blot algorithm was broadened by adding BALF GM >1.0 ODI as entry criterion, given that BALF culture was previously shown to have a sensitivity of only 58% for proven IA in ICU patients, whereas BALF GM > 1.0 ODI had a sensitivity of 85% (with a specificity of >90%) [3, 24, 31]. Breakthrough infections were classified according to recent MSG/European Confederation of Medical Mycology (ECMM) criteria [21].

GM (Platelia Aspergillus Ag ELISA; Bio-Rad Laboratories, Marnes-la-Coquette, France) and conventional mycological culture were routinely and prospectively performed in all BALF samples at each participating center before samples were stored, respectively. All remaining BALF samples were then stored at −70°C for up to 7 years. Stored BALF samples where thawed, vortexed, and tested with the *Aspergillus* Galactomannan LFA (IMMY, Norman, OK, USA) between January and April 2020 according to the manufacturer's instructions at each participating center. For the CE-marked *Aspergillus* galactomannan LFA, 300 µL of BALF samples were pretreated, heated, and centrifuged, before an aliquot was transferred to a second tube and mixed with a running buffer (same procedures for all BALF samples, including viscous and bloody samples). Test strips were than inserted into the sample running buffer aliquot and results read after 30 minutes based on the manufacturers recommendations, as described before [24, 25, 27, 32]. Positive test results create 2 lines (test and control lines) and negative results formed only 1 line (control line) (Supplementary Figure 1). Test lines intensities were read by an automated cube reader that was included with the test kits and displayed in optical density indexes (ODIs) [32]. Finally, the cube reader reported an invalid result in cases of a weak control line. The LFA tests were performed blinded toward the IA categorization and GM ELISA results.

Statistical analyses were performed at UCSD using SPSS 25 (SPSS Inc., Chicago, IL, USA). For continuous data, including BALF GM and LFA ODIs, receiver operating characteristic (ROC) curves analyses were performed and area under the curve (AUC) values were presented including 95% confidence intervals (95% CI) for the outcomes proven/probable/putative IA diagnosis (vs no IA) in the overall study cohort and subcohorts of patients with underlying hematologic malignancies, solid organ transplant (SOT) recipients, and patients in the ICU and/or with other underlying disease. Different LFA ODI cutoffs were compared by calculating sensitivity and specificity for proven/probable/putative IA versus no IA (exclusion of possible IA cases). Correlation between BALF GM and LFA ODIs was calculated using Spearman ρ correlation analysis due to the non-normal distributions. Two-sided *P*-value < .05 was taken as cutoff for statistical significance. The study protocol and all study-related procedures were approved by the Human Research Protections Program at the University of California, San Diego, United States (IRB Project #171104), the

Medical University of Graz, Austria (EC numbers 25–221 and 23–343) and Mannheim University Hospital, Germany (Ethics Committee of the Faculty of Medicine Mannheim, Heidelberg University, Germany; Reference 2012-320N-MA).

RESULTS

The LFA produced a valid test result in 295 BALF specimens from 295 patients with proven (n = 2), probable (n = 56), putative (n = 30), possible (n = 45), and no IA (n = 162). The LFA did not yield a valid result in a single case with viscous BALF, which was subsequently excluded. Specimens with valid results originated from the University of California San Diego (n = 115), Medical University of Graz (n = 98) and Mannheim (n = 82). Overall, 104/295 BALF samples (34%) were obtained from patients with underlying hematological malignancies, 38/295 (13%) from SOT recipients, while 153/295 (52%) were obtained from patients in the ICU/with other underlying diseases. Demographic characteristics at each participating center are summarized in Table 1. Serum GM testing was performed in a subset of cases and had a trend toward a lower sensitivity in SOT and ICU/other underlying diseases (2/19; 11%) versus in cases with hematologic malignancies (9/25; 36%) (for fungal culture and other diagnostic test results, see Supplementary Table 1).

Both the LFA and GM ODIs were significantly higher among those with putative, probable or proven IA versus those with no IA and possible IA cases (Figure 1). The LFA with automated reader showed good discriminatory power for differentiating

Table 1. Demographic Data and Underlying Diseases of the Study Population in Each Participating Center

	Overall (n = 295)	University of California San Diego (n = 115)	Medical University of Graz (n = 98)	Mannheim University Hospital (n = 82)[a]	Probable/ Proven IA (n = 58)	Putative IA (n = 30)
Female (n, %)	104/232 (45%)	44 (39%)	49 (50%)	13/24 (54%)[a]	21/45 (47%)	13 (43%)
Male (n, %)	128/232 (55%)	71 (61%)	49 (50%)	11/24 (46%)[a]	24/45 (53%)	17 (57%)
Age, years (median, range)	60 (18–86)	59 (19–86)	61 (31–84)	60 (18–83)[a]	58 (23–79)	65 (29–84)
Classification of IA						
Proven IA [28]	2 (0.7%)	2 (1.7%)	0	0	…	…
Probable IA [28]	56 (19.0%)	32 (27.8%)	9 (9.2%)	15 (18.3%)	…	…
Putative IA [3, 29, 30]	30 (10.2%)	15 (13.0%)	15 (15.3%)	0	…	…
Possible IA [28]	45 (15.3%)	4 (3.5%)	4 (4.1%)	37 (45.1%)	…	…
No IA [28]	162 (54.9%)	62 (53.9%)	70 (71.4%)	30 (36.6%)	…	…
Primary underlying diseases/conditions (n, %)						
Lung transplant	32 (11%)	31 (27%)	1 (1%)	0	3 (5%)	5 (17%)
Other solid organ transplant	5 (2%)	2 (2%)	1 (1%)	2 (2%)	…	…
Acute myeloid leukemia	43 (15%)	7 (6%)	9 (9%)	27 (33%)	12 (21%)	…
Myelodysplastic syndrome	9 (3%)	6 (5%)	0	3 (4%)	5 (9%)	…
Acute lymphoblastic leukemia	12 (4%)	2 (2%)	1 (1%)	9 (11%)	2 (3%)	…
Chronic forms of leukemia (chronic lymphocytic leukemia and chronic myeloid leukemia)[a]	9 (3%)	0	0	9 (11%)	2 (3%)	…
Multiple myeloma	14 (5%)	4(3%)	2 (2%)	8 (10%)	5 (9%)	…
Non-Hodgkin lymphoma	9 (3%)	3 (3%)	2 (2%)	4 (5%)	5 (9%)	…
Hodgkin´s lymphoma	4 (1%)	3 (3%)	0	1 (1%)	2 (3%)	…
Oncological malignancy	29 (10%)	10 (9%)	16 (16%)	3 (4%)	3 (5%)	3 (10%)
Chronic obstructive pulmonary disease	20 (7%)	7 (6%)	13 (13%)	0	…	2 (7%)
Influenza related ICU admission	9 (3%)	1 (1%%)	8 (8%)	0	…	4 (13%)
Rheumatoid/autoimmune diseases with lung involvement	16 (5%)	5 (4%)	9 (9%)	2 (2%)	3 (5%)	3 (10%)
HIV/AIDS	4 (1%)	2 (2%)	0	2 (2%)	1 (2%)	…
Asthma	5 (2%)	4 (3%)	1 (1%)	0	…	1 (3%)
Interstitial lung disease	7 (2%)	5 (4%)	2 (2%)	0	1 (2%)	1 (3%)
Tuberculosis	2 (1%)	2 (2%)	0	0	…	…
Cystic fibrosis	3 (1%)	3 (3%)	0	0	…	…
ICU/other	58 (20%)	16 (14%)	32 (33%)	10 (12%)	9 (16%)	11 (37%)
Hematological malignancy/other	5 (2%)	2 (2%)	1 (1%)	2 (2%)	3 (5%)	…
Underlying disease category						
Hematological malignancy	104 (34%)	26 (23%)	15 (15%)	63 (77%)	35 (60%)	0
Solid organ transplant recipients	38 (13%)	34 (30%)	2 (2%)	2 (2%)	3 (5%)	6 (20%)
ICU /other	153 (52%)	55 (48%)	81 (83%)	17 (21%)	20 (34%)	24 (80%)

Abbreviations: HIV, human immunodeficiency virus; IA, invasive aspergillosis; ICU, intensive care unit.

[a]For Mannheim University Hospital age and sex only available from 24/82 participants.

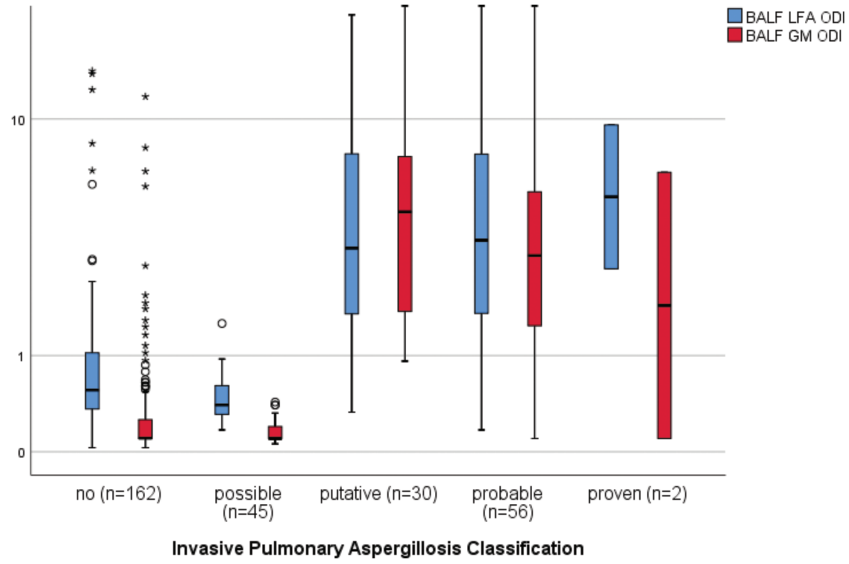

Figure 1. BALF, GM, and LFA ODIs by IA category. Abbreviations: BALF, bronchoalveolar lavage fluid; GM, galactomannan; IA, invasive aspergillosis; LFA, lateral flow assay; ODI, optical density index.

probable/putative or proven IA versus no IA with an AUC of 0.865 (95% CI .815–.916), including 88 with IA versus 162 without IA. Evaluation of cutoffs showed a sensitivity of 89% and a specificity of 44% when using a cutoff of 0.5 ODI, a sensitivity of 82% and a specificity of 73% with a 1.0 ODI cutoff, a sensitivity of 74% and a specificity of 83% with a 1.5 ODI cutoff, and a sensitivity of 69% and a specificity of 89% when using a cutoff of 2.0 ODI (Figure 2, Table 2).

Performance of the BALF LFA was not impacted by the presence of mold active antifungal prophylaxis or treatment at the time of bronchoscopy (38 cases, including 10 with probable/putative IA; 30/38 with underlying hematological malignancy, 8 SOT recipients). AUC in this subset for differentiating probable/proven versus possible/no IA was 0.975 (95% CI .933–1.000). Also, duration of storage did not impact LFA results, with similar AUCs (AUC 0.869) and also LFA ODIs in samples obtained before 2017 versus newer samples.

After exclusion of GM as mycological criterion, BALF LFA (AUC 0.892; 95% CI .822–.962) and BALF GM (AUC 0.893; 95% CI .822–.965) had good to excellent discriminatory power for differentiating probable/putative or proven IA (n = 34; including n = 32 with probable/putative IA and growth of *Aspergillus* spp. in BALF culture and n = 2 with proven infection) versus no IA.

BALF LFA ODI correlated significantly with BALF GM ODI Spearman r = 0.801 ($P < .001$) when the subset of negative BALF GM tests (ie, GM <0.5 ODI) for which exact levels were not available (n = 91) were coded as missing (Figure 3).

LFA Performance by Patient Group

The LFA with automated reader (Supplementary Figure 1) showed good to excellent discriminatory power for differentiating probable/putative or proven IA versus no IA in patients with hematological malignancies with an AUC of 0.917 (95% CI .847–.988, including 35 with IA vs 28 without IA), in SOT recipients with an AUC of 0.806 (95% CI .659–.953, including 9 with IA vs 24 without IA), and patients in the ICU/with other underlying diseases with an AUC of 0.867 (95% CI .797–.937, including 44 IA vs 109 no IA). ROC curves are displayed in Figure 2. Sensitivities and specificities depending on cutoffs are displayed in Table 2.

LFA Performance by Participating Center

Performance of the LFA with automated reader for differentiating probable/putative or proven IA versus no IA was similar across centers with an AUC of 0.853 (95% CI .781–.926) at the University of California San Diego (49 IA vs 62 no IA); an AUC of 0.866 (95% CI .765–.968) at the Medical University of Graz (24 IA vs 72 no IA), and an AUC of 0.844 (95% CI .712–.977) at Mannheim University Hospital (15 IA vs 30 no IA).

DISCUSSION

In this multicenter cohort study, we evaluated the diagnostic performance of the LFA assay with automated digital cube reader from BALF samples obtained from patients at risk for IA with various underlying risk factors, including patients with hematologic malignancy, SOT recipients, and patients in the ICU or with other underlying diseases, with the latter 2 categories representing 65% of our cohort. Our study addressed the need for performance data of the new LFA kit including cube reader as well as the need for providing data on the LFAs performance in patients without neutropenia or hematologic malignancy and is the largest study to date to evaluate the performance of

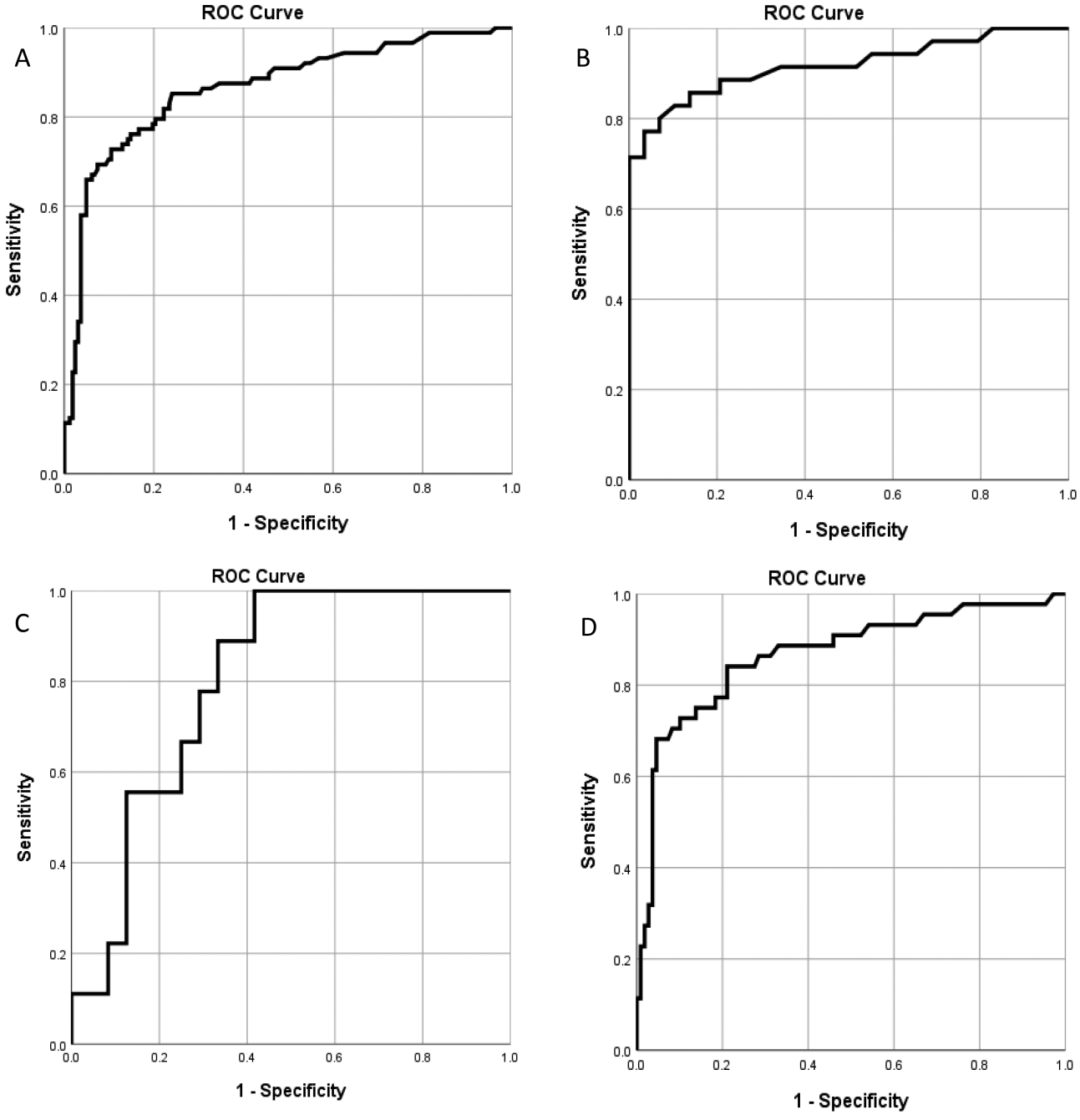

Figure 2. ROC analysis curves for BALF LFA for diagnosing proven/probable/putative IA versus no IA in the overall study cohort and subgroups. *A*, Overall study population. *B*, Hematological malignancy. *C*, Solid organ transplant recipients. *D*, ICU/others. Abbreviations: BALF, bronchoalveolar lavage fluid; IA, invasive aspergillosis; ICU, intensive care unit; LFA, lateral flow assay; ROC, receiver operating characteristic.

Table 2. Sensitivity and Specificity for the Bronchoalveolar Lavage Fluid Lateral Flow Assay for Diagnosing Proven/Probable/Putative Invasive Pulmonary Aspergillosis (IA) Versus No IA in the Overall Study Cohort and Subgroups. Evaluation of Different ODI Cutoffs

	0.5 ODI		1.0 ODI		1.5 ODI		2.0 ODI	
LFA Cutoff/Patient Group	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Overall	89% (78/88)	44% (71/161)	82% (72/88)	73% (117/161)	74% (65/88)	83% (134/161)	69% (61/88)	89% (144/161)
Solid organ transplant recipients	100% (9/9)	17% (4/24)	100% (9/9)	42% (10/24)	78% (7/9)	67% (16/24)	56% (5/9)	83% (20/24)
Hematological malignancies	89% (31/35)	54% (15/28)	80% (28/35)	89% (25/28)	74% (26/35)	96% (27/28)	71% (25/35)	96% (27/28)
ICU/ other	86% (38/44)	48% (52/109)	80% (35/44)	75% (82/109)	73% (32/44)	83% (91/109)	70% (31/44)	84% (92/109)

Abbreviations: IA, invasive aspergillosis; ICU, intensive care unit; ODI, optical density index.

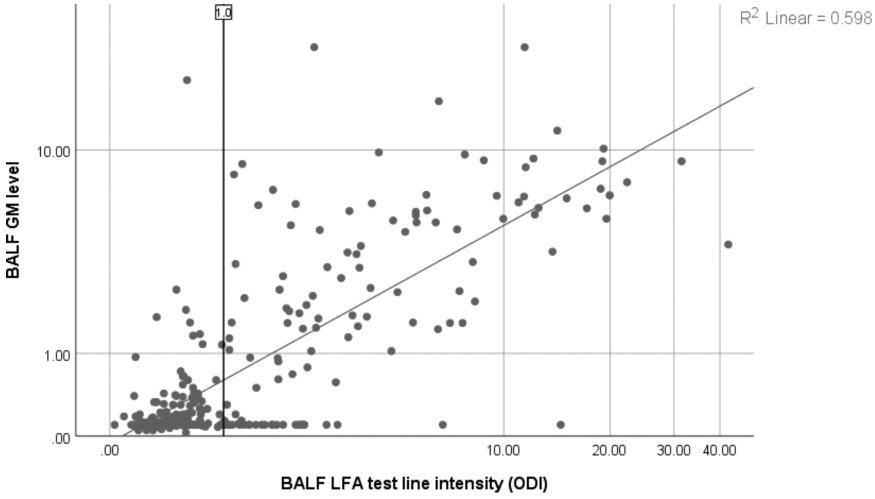

Figure 3. Scatter blots showing correlation between BALF, GM, and LFA ODIs in the study population. Samples with negative BALF GM results (ie, <0.5 ODI), for which exact GM levels were not available (n = 91) were coded as missing. When including all samples, BALF LFA ODIs were median 0.47 (IQR 0.33–0.71) in those with BALF GM <0.5 ODI (n = 191), and median 3.29 ODI (IQR 1.72–7.52) in those with BALF GM ODI ≥0.5 ODI (n = 104; $P < .001$). Abbreviations: BALF, bronchoalveolar lavage fluid; GM, galactomannan; IQR, interquartile range; LFA, lateral flow assay; ODI, optical density index.

the LFA assay from BALF samples. Our study reports several important findings. First, the LFA showed good overall performance in the mixed cohort as well as across the individual patient cohorts. Second, the LFA assay showed good correlation with GM from BALF, and—after exclusion of GM as mycological criterion—similar performance as GM for differentiating patients with probable/putative or proven IA compared to no IA. Finally, the performance of the LFA assay was similar across the three study sites.

In our study, the LFA showed good discriminatory power for differentiating probable/putative or proven IA (n = 88) versus no IA (n = 162), with an overall AUC of 0.865, which was slightly below the AUC of 0.92 reported for the LFA with an in-house reader for differentiating probable/proven IA versus no IA in a cohort of patients with hematological malignancies [26]. In previous studies, the combined overall sensitivity and specificity of the LFA assay with manual read was 77% and 81%, respectively [24–27]. The performance of the LFA in the mixed cohort in this study is similar to these previous studies when an ODI cutoff of 1.5 was used, with a sensitivity of 74% and a specificity of 83%, with a slightly higher sensitivity of 82% but lower specificity of 73% when an ODI cutoff of 1.0 was used, and a specificity of 89% with still an acceptable sensitivity of 69% with a cutoff of 2.0 ODI. In contrast, a lower cutoff of 0.5 ODI did not prove useful because of insufficient specificity (44%).

The LFA showed a consistent performance across different groups of patients, with AUCs between 0.806 and 0.917. Compared to a combined sensitivity of 83% and specificity of 87% from previous studies in patients with hematologic malignancies [24–27], this study demonstrated a sensitivity of 80% and specificity of 89% at a 1.0 ODI cutoff and sensitivity and specificity of 74% and 96% at an ODI of 1.5. In SOT recipients, a cutoff of 1.5 ODI showed a sensitivity and specificity of 78% and 67%, which were higher than combined sensitivity and specificity of 50% and 48% from previous studies that evaluated a total of 29 cases including 8 with IA [24–27]. However, in contrast to patients with hematological malignancies, specificity of a 1.0 cutoff was only 42% and therefore insufficient in SOT recipients. Finally, in ICU patients and/or those with other underlying diseases, our study demonstrated a sensitivity of 80% and specificity of 75% at an ODI cutoff of 1.0 and sensitivity and specificity of 73% and 83% at an ODI cutoff of 1.5, which was an improvement compared to previous studies evaluating the LFA showing a combined sensitivity of 61% and specificity of 80% in a total of 53 cases including 18 with IA [24–27]. Thus, when using a cutoff of 1.0 or 1.5 ODI with of the LFA with cube reader the overall performance and the performance in patients with hematologic malignancy were similar to findings in previous studies. The improved diagnostic performance in SOT recipients and those in the ICU and with other underlying conditions observed in our study—particularly when using higher ODI cutoffs—may be explained by the simplification and objectivation of result readout by inclusion of the automated cube reader (previous studies used a visual readout) but also the limited number of cases that have been evaluated in previous studies.

The LFA had an excellent correlation with conventional GM from BALF, and both had good to excellent discriminatory power in differentiating probable/putative or proven IA from no IA when GM was excluded as mycological criteria for establishing a diagnosis of IA. Previous studies have shown excellent performance of the conventional GM from BALF [33,

34], also in nonhematologic malignancy patients [35–37], and our findings suggest that the performance of the LFA in these patients may be comparable, making this rapid test a viable option for diagnosis of IA in settings where conventional GM testing is not (rapidly) available. In addition, due to the inclusion of a standardized automatic reader, the performance of the LFA was very similar across the three study sites, suggesting that our findings would likely be reproducible at other medical centers.

Although mold active antifungal prophylaxis or treatment has been shown to impact the diagnostic performance of various diagnostic tests for IA including GM from BALF and serum [38], the BALF lateral flow device test (ie, the other rapid test for IA currently commercially available) [9, 38], culture and also *Aspergillus*-specific PCR [22] our findings indicate that the same may not be necessarily true for the LFA, which showed an excellent performance differentiating probable/proven versus possible/no IA in those receiving mold-active antifungals at the time of bronchoscopy (AUC 0.975). However, the number of breakthrough IA cases on mold active antifungals at the time of bronchoscopy was limited in this study (n = 10), and these findings have therefore to be interpreted with caution, especially because standing in contrast to a previous study, which reported lower sensitivity in hematologic malignancy patients on empiric antifungal treatment [26].

Our study has several limitations including the low number of proven cases of IA, despite its multicenter design. Given the difficulty in diagnosing proven IA, it is doubtful that a larger cohort of patients would easily be able to overcome this reality. Furthermore, as proven IA typically represents an advanced disease stage in IA, the diagnostic performance of assays such as the LFA may not easily translate to earlier stages of disease where the importance of a timely diagnosis of IA is greater. Importantly, the study was performed in banked samples, and prospective validation of our findings, ideally in a randomized setting with LFA informing clinical management versus standard of care is needed.

In conclusion, this large multicenter study provides evidence that the *Aspergillus* Galactomannan LFA with the Cube reader is a new and reliable test for the diagnosis of IA in BALF in patients at risk for IA, including those without underlying hematological malignancies. Diagnostic performance of the LFA was improved when utilizing higher cut-offs of 1.0 or 1.5 ODI, as opposed to the currently recommended cutoff of 0.5 ODI which showed limited specificity. Finally, the performance of the LFA was comparable to conventional GM from BALF, consistent across the 3 study sites and also not impacted by mold-active prophylaxis/treatment. The LFA may serve a role as a rapid test that may replace conventional GM testing in settings where GM results are not rapidly available.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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Disclaimer. *Aspergillus* galactomannan LFAs were provided by IMMY, Norman, OK, USA. They had no role in the study design, data collection, analysis, interpretation, decision to publish, in the writing of the manuscript, or in the decision to submit the manuscript for publication.

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