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O1122 Evaluation of the LD Bio Aspergillus ICT lateral flow assay as a point-of-care test for serological antibody detection in chronic pulmonary aspergillosis

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Background: Measuring levels of Aspergillus-specific IgG is an important part of diagnosing chronic pulmonary aspergillosis (CPA). Existing assays are often cost- and resource-intensive and not compatible with resource-constrained laboratory settings. LD Bio Diagnostics has recently commercialized a lateral flow assay (Aspergillus ICT) that detects Aspergillus antibodies (IgG+IgM) in less than 30 minutes, requiring minimal laboratory equipment. Preliminary validation was conducted by the manufacturer using serum from a spectrum of Aspergillus diseases, including CPA (n=32). Herein, we conduct a larger-scale field evaluation for specific diagnosis of CPA, and assess whether the Aspergillus ICT result correlates with Aspergillus IgG titre.

Materials/methods: A retrospective, ongoing study was performed using 120 patient sera collected at the National Aspergillosis Centre (NAC, Manchester). Patient sera were selected based on a clinical diagnosis of CPA. Control sera (n=150) were obtained from the Peninsula Research Bank (Exeter). Aspergillus ICT was performed as per manufacturer's instruction. Results were read at intervals, and determined after 20 to 30 minutes as recommended (any line at the "T" marker considered positive), both manually and using the Qiagen ESEQuant LR3 lateral flow reader. Serological *Aspergillus* IgG titre was measured by ImmunoCAP.

Results: We found the Aspergillus ICT to have a sensitivity of 89.2% across 120 confirmed CPA cases, and a specificity of 98.7% for 150 control sera. In contrast, the ImmunoCAP assay routinely used at NAC exhibited 76.7% sensitivity for the same cohort. Comparison of manual result determination (by 'eye'), or peak detection by the Qiagen LR3, resulted in 95.8% agreement with manual result determination better able to detect weak positive results. Finally, we found no correlation between ImmunoCAP *Aspergillus* IgG titre and Aspergillus ICT test line intensity or rate of development (both measured by Qiagen LR3).

Conclusions: The Aspergillus ICT lateral flow assay exhibits excellent sensitivity for serological diagnosis of CPA. The assay is easy to perform however, may be challenging to read when only a very faint band is present (5/120 samples tested). In all, given the short run time, simplicity, and limited resources needed, the LD Bio Aspergillus ICT is a suitable diagnostic tool for CPA in resource-constrained settings.

	CPA	Control
ICT +	107	2
ICT -	13	148
Tested	120	150
Sensitivity	89.2%	---
Specificity	---	98.7%
$_{95\%}$ CI	82.2 - 94.1%	95.3 - 99.8%