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Point-of-care cryptococcal antigen screening – a case-control diagnostic accuracy study of the immuno-mycologics cryptococcal antigen lateral flow assay for screening finger-prick blood and urine among asymptomatic HIV-infected adults

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Introduction: Reflex laboratory screening of blood samples with CD4 counts of less than 100 cells/μl for cryptococcal antigen (CrAg) is being introduced nationally in South Africa. This enables identification of patients with sub-clinical cryptococcal infection and administration of pre-emptive fluconazole therapy to prevent life-threatening meningitis. However, access to laboratories may be limited in rural areas. The CrAg lateral flow assay (LFA) is ideally formatted for point-of-care (POC) use. Therefore, the accuracy of the CrAg LFA on finger-prick blood and urine samples performed in clinic settings by front-line health workers was determined.
Methods: Patients with asymptomatic cryptococcal antigenaemia detected by reflex laboratory-based CrAg screening were identified from HIV clinics in Johannesburg, along with CrAg-negative controls. A CrAg LFA was performed on finger-prick blood and urine samples by a nurse and repeated in a laboratory. Results of POC and laboratory-performed LFA tests were compared to the reference laboratory-based CrAg LFA test performed on plasma during the previous month. Testing was repeated on positive urine samples following centrifugation at 2000 rpm for 10 minutes.
Results: Fifty-three patients with known CrAg status (19 CrAg-positive: 34 CrAG-negative) were tested using POC and laboratory-based CrAg LFA. POC CrAg LFA on blood had a sensitivity of 89.5% (95% CI: 66.7–98.7%) and specificity of 100% (95% CI: 89.7–100%). Both CrAg positive patients who were tested as POC-LFA negative had very low CrAg titres. Sensitivity improved to 100% using laboratory-based testing. POC CrAg LFA on urine had a sensitivity of 84.2% (95% CI: 60.42–96.62%) and a specificity of 44.1% (95% CI: 27.2–62.1%), with no improvement using laboratory-based testing, or after centrifugation.
Conclusions: CrAg LFA on finger-prick blood is an appropriate POC method for screening HIV-infected adults commencing ART. This could reduce turn-around time and loss to follow up, particularly where laboratory access is limited. Urine samples should not be used due to a high rate of false positive results.

Abstract THPDB0201–Table 1. Sensitivity and specificity of the CrAg LFA used on blood/urine at the POC and in a laboratory, compared to laboratory LFA on plasma

	n, (Sensitivity, 95% CI)	n, (Specificity, 95% CI)
POC finger-prick blood	17/19 (89.47%, 66.86–98.7%)	34/34 (100%, 89.72%–100%)
Lab pipetted blood	19/19 (100%, 82.35–100%)	34/34 (100%, 89.72–100%)
POC dipped urine	16/19 (84.2%, 60.4–96.6%)	19/34 (44.1%, 27.2–62.1%)
Lab pipetted urine	15/19 (79.0%, 54.4–94.0%)	17/34 (50.0%, 32.4–67.6%)
Lab centrifuged urine	N/A	10/18 (55.6%, 30.7–78.5%)