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Presentation Title: M-1699 - Multicenter Evaluation of a Novel POC Assay for the Detection of Cryptococcal Antigen in HIV-Infected Persons

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Abstract: Background: Cryptococcal meningitis is a leading cause of death among people living with HIV. In sub-Saharan Africa, cryptococcosis is estimated to cause 20-25% of the HIV-attributable mortality which may equal or exceed mortality due to tuberculosis among persons living with HIV/AIDS. Early diagnosis is the key to effective treatment, particularly among patients in resource-limited countries. The new lateral flow assay (LFA) for cryptococcal antigen (CrAg) enables rapid and inexpensive diagnosis of cryptococcosis at or near the point of patient care. Methods: 750 clinical specimens were evaluated using the CrAg LFA among persons with and without cryptococcal disease. Serum, plasma, CSF, and urine specimens from HIV infected persons in South Africa and Uganda were prospectively evaluated using the CrAg LFA (IMMY, USA). The reference standard for comparison was CSF culture. Negative controls included HIV-infected persons presenting with suspected meningitis in Uganda, persons undergoing pre-ART CrAg screening in South Africa and persons without cryptococcosis in the United States. Results: The sensitivity and specificity of the CrAg LFA as compared to cryptococcal CSF culture are described in the table below.

Specimen Type	n	Sensitivity % (n)	Sensitivity 95% CI	Specificity % (n)	Specificity 95% CI
Serum	234	100% (76/76)	95-100%	96% (152/158)	92-98%
Plasma	74	100% (20/20)	84-100%	100% (54/54)	93-100%
CSF	150	100% (80/80)	95-100%	99% (69/70)	92-100%
Urine	292	99% (110/111)	95-100%	98% (178/181)	95-99%

Conclusions: The CrAg LFA was highly sensitive and specific in detecting cryptococcal antigen among HIV-infected persons with cryptococcal meningitis. Thus, the CrAg LFA could be effectively used in resource-limited settings as a point-of-care test to enable

earlier diagnosis and thereby treatment of persons with cryptococcal disease, which could save thousands of lives.

