Performance of Two Commercial Immunochromatographic Assays for Rapid Detection of Antibodies Specific to Human Immunodeficiency Virus Types 1 and 2 in Serum and Urine Samples in a Rural Community-Based Research Setting (Rakai, Uganda)

S. C. Kagulire,1* P. D. Stamper,3,4 P. Opendi,1 J. L. Nakavuma,2 L. A. Mills,1,3 F. Makumbi,1 R. H. Gray,4 D. Serwadda,1 and S. J. Reynolds3,5

Rakai Health Sciences Program, Kasiso, Uganda1; Makerere University, Kampala, Uganda2; Johns Hopkins University School of Medicine, Baltimore, Maryland3; Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland4; and NIAID, National Institutes of Health, Bethesda, Maryland5

Received 21 November 2006/Returned for modification 31 January 2007/Accepted 27 March 2007

Rapid detection of human immunodeficiency virus (HIV) antibodies is of great importance in developing and developed countries to diagnose HIV infections quickly and at low cost. In this study, two new immunochromatographic rapid tests for the detection of HIV antibodies (Aware HIV-1/2 BSP and Aware HIV-1/2 U; Calypte Biomedical Corporation) were evaluated in rural Africa to determine the tests’ performance and comparability to commercially available conventional enzyme immunoassay (EIA) and Western blot (WB) tests. This prospective study was conducted from March 2005 through May 2005 using serum and urine from respondents in the Rakai Community Cohort Survey. Nine hundred sixty-three serum samples were tested with the Aware blood rapid assay (Aware-BSP) and compared to two independent EIAs for HIV plus confirmatory Calypte WB for any positive EIAs. The sensitivity of Aware-BSP was 98.2%, and the specificity was 99.8%. Nine hundred forty-two urine samples were run using the Aware urine assay (Aware-U) and linked to blood sample results for analysis. The sensitivity of Aware-U was 88.7% and specificity was 99.9% compared to blood EIAs confirmed by WB analysis. These results support the adoption of the Aware-BSP rapid test as an alternative to EIA and WB assays for the diagnosis of HIV in resource-limited settings. However, the low sensitivity of the Aware-U assay with its potential for falsely negative HIV results makes the urine assay less satisfactory.

Nearly 25 million people in sub-Saharan Africa are infected with human immunodeficiency virus (HIV), and most of these people are unaware that they are infected (7). Knowledge of serostatus via antibody testing is the current entry point for most HIV prevention and treatment programs, and there have been recommendations to scale up HIV testing in developing countries to improve access to and utilization of antiretroviral care (2). However, the currently available conventional laboratory-based enzyme immunoassays (EIAs) require instrumentation (incubators, mechanical washing, and optical reading devices) and expertise, are expensive, and do not provide same-day results. Given the limitations of standard HIV tests, and the need for more expeditious point-of-care provision of HIV results, rapid HIV tests have been developed to be quicker, less expensive, and easier to perform. Rapid tests have been found to be cost-effective and to have increased the proportions of individuals receiving their HIV results (3, 4). However, there has been limited evaluation of some of the newly emerging HIV rapid tests. We therefore undertook an evaluation of two HIV rapid tests, Aware-BSP for blood and Aware-U for urine, in the Rakai District of southwestern Uganda. A preliminary evaluation of these tests in Thailand revealed good diagnostic properties (6). However, it was imperative to assess the performance of the new assays in a resource-limited rural sub-Saharan African setting, where different HIV clades are prevalent.

MATERIALS AND METHODS

Aware rapid assays. Calypte Biomedical Corporation has developed Aware rapid assays for the detection of HIV antibodies in blood (Aware-BSP) and urine (Aware-U). These are in vitro immunochromatographic rapid tests for the qualitative detection of antibodies to HIV type 1 (HIV-1) and HIV-2 in human serum, plasma, whole blood, and/or urine specimens. Both the blood and urine assays work on similar principles; however, the blood assay uses diluted samples for testing, while the urine assay does not require sample dilution. The test strip contains synthetic peptides representing the immunodominant regions of the HIV-1 gp41 and HIV-2 gp36 transmembrane proteins. A protein A antibody immobilized on the nitrocellulose membrane is used as a procedural control for the test and control zones. The endpoint of the assay is the visual detection of bound protein/colloidal gold conjugate on the nitrocellulose membrane. The control line will appear in all valid tests, indicating that a suitable sample was used and that the test functioned properly. The appearance of two lines on the test strip (i.e., test zone and control zone) is indicative of a positive reactive sample. The appearance of only one line on the test strip (in the control zone) indicates that the sample did not contain detectable HIV antibodies.

Study sample collection. This evaluation was conducted using specimens from a survey visit in an ongoing community cohort surveillance study in the Rakai District of southwestern Uganda. The Rakai Health Sciences Program previously called the Rakai Project has conducted cohort surveillance in 44 rural communities since 1994 (8). For this study, freshly collected urine and blood specimens were obtained between March and May 2005 from consenting adults (15 to 49 years of age). The samples were collected in participants’ homes, labeled with unique computer-generated identifiers, logged in, cross-checked, reviewed by another staff member as a quality control measure, and then transported in a cold box to the testing center at the program’s laboratory.
null
and emergency rooms is needed before the utility of the Aware-BSP test can be fully evaluated. The Aware urine-based rapid test demonstrated suboptimal sensitivity in our study, and thus, we have reservations about recommending its use.

ACKNOWLEDGMENTS

This work was supported by the U.S. National Institute of Allergy and Infectious Diseases International Centers for Excellence in Research Program (ICER).

We thank Calypte Biomedical Corporation and Intercross, Kenya, for freely offering the testing kits. We also thank all the Rakai staff and, most importantly, the cohort participants themselves.

REFERENCES

5. Reference deleted.