

## The Use of Simple, Rapid Tests to Detect Antibodies to Human Immunodeficiency Virus Types 1 and 2 in Pooled Serum Specimens

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### Products Evaluated

Determine HIV-1/2 (Abbott Laboratories)  
Sero Strip HIV-1/2 (Saliva Diagnostic Systems, Inc.)

This study was carried out at the HIV Immunology and Diagnostic Branch, Division of AIDS, STD and TB Laboratory Research, National Centre for Infectious Diseases, USA.

The objectives of this study were to determine the ability of two lateral-flow rapid HIV tests to (a) detect HIV antibodies in pooled samples of various pool sizes; (b) detect recent infections in sample pools containing specimens from HIV seroconversion panels and (c) identify HIV antibody-positive pools equivalently to standard serological methods in prospectively collected samples.

### Abstract

**Background:** The use of pooled specimens has been proposed as a means of expanding testing for human immunodeficiency virus (HIV) antibodies in population studies and in blood screening, while reducing laboratory costs.

**Objectives:** To develop a strategic specimen pooling method to be used with rapid HIV antibody assays to detect positive specimens and to evaluate its performance in comparison with testing with commercial EIA and WB. **Study Design:** Two lateral flow rapid HIV antibody assays, Sero Strip HIV-1/2 and Determine HIV-1/2, were evaluated for their ability to detect HIV-1 antibodies in serum and/or plasma specimens pooled in sizes ranging from two to 20 following the respective manufacturers' protocols. One thousand prospectively collected specimens and 55 seroconversion specimens were prepared in pools of five for evaluation by the two rapid HIV assays. **Results:** Optimal detection and discrimination of HIV-1 antibody-positive and HIV-1 antibody-negative specimens was observed in pool sizes of five to ten for both assays. The ability of the two rapid assays to detect HIV-1 antibody-positive samples from commercial HIV-1 seroconversion panels contained in the pools was equivalent to that of commercial enzyme immunoassays (EIAs) and Western blot (WB) to detect HIV-1 antibody in the non-pooled samples. Application of the pooling method in prospectively collected specimens yielded excellent concordance with EIA/WB results in both sensitivity (98.88% for Sero Strip HIV-1/2, 100% for Determine HIV-1/2) and specificity (99.56% for Sero Strip HIV-1/2, 99.45% for Determine HIV-1/2). **Conclusion:** Use of a pooling strategy with either assay reduced the number of tests required by almost 50% and could provide substantial cost reductions for HIV screening in settings where HIV-1 prevalence is less than 10%.

### Results

Analysis of prospectively collected specimens by Sero Strip HIV-1/2 and Determine HIV-1/2

Rapid test	Specimen pools	HIV-1 antibody positive pools	Individual HIV-1 antibody positives	Individual HIV-1 antibody negatives	False reactive specimens <sup>a</sup>	False negative	Sensitivity (%) <sup>a</sup>	Specificity (%) <sup>a</sup>
Sero Strip	200	61	93	907	4	1	98.88	99.56
Determine	200	61	95	905	5	0	100	99.45
EIA/WB	200	60	90	910	0	0	100	100

<sup>a</sup> Compared with reference HIV-1 antibody testing by EIA/WB.

### Discussion

Neither Sero Strip HIV-1/2 nor Determine HIV-1/2 was significantly affected by specimen dilution in identifying a reactive HIV antibody specimen in pools of five specimens. The use of these tests with pooled specimens could be used for HIV screening in countries with limited health care resources as costs could be significantly reduced.