CLINICAL TRIAL OF TWO RAPID LATERAL-FLOW TESTS FOR THE DETECTION OF HIV ANTIBODIES IN FINGERSTICK WHOLE BLOOD, VENOUS WHOLE BLOOD, PLASMA AND SERUM

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OBJECTIVE

The objective of the clinical trial is to establish the performance characteristics of the Chembio rapid tests, HIV Stat-Pak and Sure Check HIV based on comparison to an FDA approved EIA for detection of antibodies to Human Immunodeficiency Virus. This trial assessed the performance of the assays in order to document that these products meet regulatory guidance with the respect to rapid tests for detection of antibodies of antibodies to HIV. The Chembio rapid tests are quick and single-use application and are intended for use in the field as well as professional use settings.

METHODS

The methods are outlined in Figure 1. Five geographically diverse clinical sites, all in the United States, enrolled a total of 2,700 participants from 3 risk group: Individuals known to be positive for HIV (1,101), individuals at high risk for infection (898) and individuals at low risk for infection with HIV (701). Each participant was tested with the HIV Stat-Pak and Sure Check HIV devices (Figure 2, 3 and 4) at the clinical sites. Four sample matrices were tested: whole blood from fingerstick, venous whole blood collected in EDTA, serum and plasma (collected in EDTA anticoagulant). Samples from each participant were sent to a reference laboratory for confirmatory (EIA1 and Western Blot) and discrepancy resolution testing (EIA1, EIA2, WB and NAT).

RESULTS

HIV Stat-Pak and Sure Check HIV showed and overall sensitivity of 99.8% (1,136/1,138) and an overall specificity of 99.9% (1,551/1,553) (Table 1). Sensitivity is derived from the known positive and High Risk population. Specificity derived from the Low Risk and High Risk population.

CONCLUSIONS

1. Both Chembio rapid tests, the HIV Stat-Pak and Sure Check HIV, achieved the study objectives.
2. The performance characteristic of Chembio tests were found to be over 99%
3. **These results have not yet been evaluated by FDA.**

Table 1. Sensitivity and Specificity of Chembio Rapid Tests

Sensitivity of HIV-1 Antibody Detection with Chembio Rapid Tests

Study Population	Total # of Samples Tested	Chembio Reactive	Licensed HIV EIA Repeatedly Reactive	Licensed HIV-1 Western Blot Reactive
HIV-1 Known Positive	1093	1087[1]	1089[2]	1089
HIV-1 High Risk	883	40[3]	40[4]	40
Total	1976	1127	1129	1129

[1] Two additional Chembio reactive samples (not shown) were non-reactive in the licensed EIA and Western blot and were excluded from sensitivity calculations.
[2] Two of the licensed EIA and Western blot reactive samples shown were Chembio non-reactive.
[3] One additional Chembio reactive sample (not shown) was non-reactive in the licensed EIA and Western blot, and one was EIA reactive and Western blot indeterminate. Both were excluded from sensitivity calculations.
[4] Two additional samples (not shown) were reactive in the licensed EIA and were non-reactive by Chembio and Western blot.

Sensitivity = 1127/1129 = 99.8% (95% CI = 99.4% - 100%)

Specificity of HIV-1 Antibody Detection with Chembio Rapid Tests

Study Population	Total # of Samples Tested	Chembio Non-Reactive	Licensed HIV EIA Non-Reactive	True Negative[5]
HIV-1 Low Risk	694[1]	689	687[3]	690
HIV-1 High Risk	883[2]	838	832[4]	839
Total	1577	1527	1520	1529

[1] Three low risk samples that were reactive in the Chembio tests and reactive in the licensed EIA and Western blot, and one that was non-reactive in the Chembio tests, non-reactive in the licensed EIA and indeterminate in the Western blot, were removed from specificity calculations.
[2] 40 high risk samples that were reactive in the Chembio tests, the licensed EIA and the Western blot were removed from specificity calculations.
[3] Three samples were reactive in the licensed EIA and were Western blot non-reactive.
[4] Seven samples were reactive in the licensed EIA, 6 of which were Western blot non-reactive and one of which was Western blot indeterminate.
[5] As determined by number of non-reactive EIA samples, plus any reactive EIA samples that were found to be non-reactive with licensed Western Blot assay.

Specificity = 1527/1529 = 99.9% (95% CI = 99.5% - 100%)

Figure 1. Clinical Trial Protocol

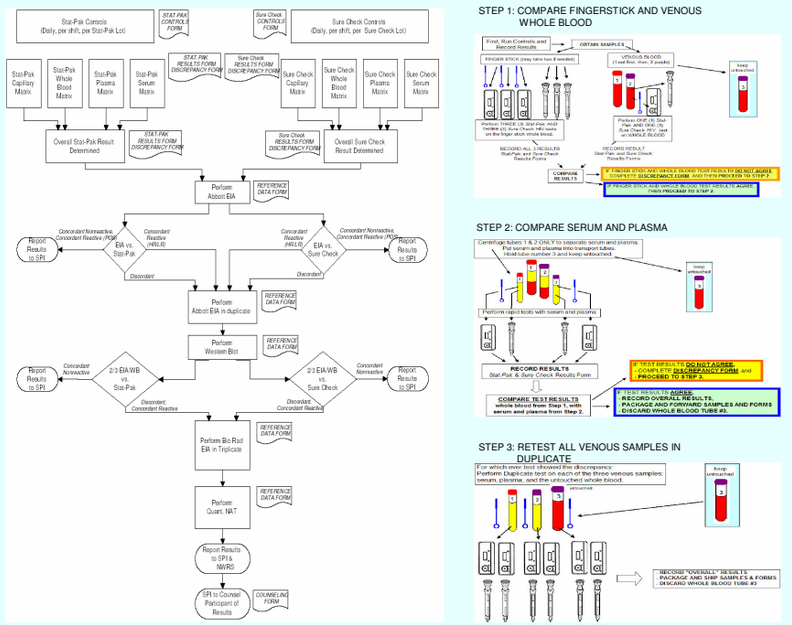

Figure 2. HIV Stat-Pak Test Procedure

Figure 3. Sure Check HIV Test Procedure

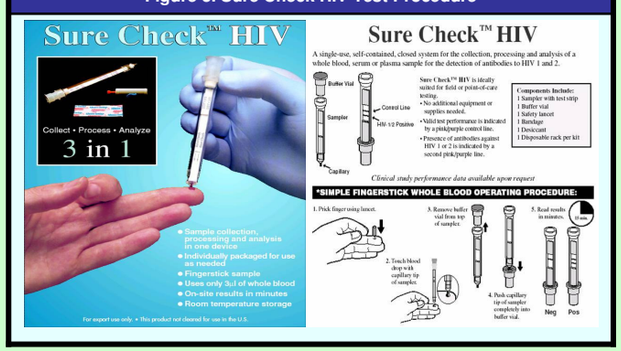

Figure 4. HIV Stat-Pak and Sure Check HIV Tests

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