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 guidelines with respect to rapid tests for detection 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.

OBJECTIVE

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).

METHODS

HIV Stat-Pak and Sure Check HIV showed overall sensitivity of 99.8% (1,136/1,138) and 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.

RESULTS

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.

CONCLUSIONS

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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