

Field Evaluation of the Determine Rapid Human Immunodeficiency Virus Diagnostic Test in Honduras and the Dominican Republic

Palmer C J, Dubon J M, Koenig E, Perez E, Ager A, Jayaweera D, Cuadrado R R, Rivera A, Rubido A, and Palmer D A
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This study presents the results from a field evaluation of a rapid diagnostic test, the Determine test, which permits rapid detection of HIV infection. The test was evaluated using known HIV-seropositive samples at two independent laboratories in Honduras and the Dominican Republic to assess the performance of the Determine HIV rapid test and determine the level of agreement with in-country tests.

Tests were also performed with a bank of serum samples from HIV-positive individuals in the United States.

Abstract

Rapid detection of human immunodeficiency virus (HIV) infection can result in improved patient care and/or faster implementation of public health preventative measures. A new rapid test, Determine (Abbott, Abbott Park, Illinois), detects HIV type 1 (HIV-1) and HIV-2 antibodies within 15 minutes by using 50 µl of serum or plasma. No specialised equipment or ancillary supplies are required, and results are read visually. A positive result is noted by the appearance of a red line. An operational control (red line) indicates proper test performance. We evaluated the Determine rapid HIV detection test with a group of well characterised serum samples (CD4 counts and viral loads were known) and serum samples from HIV-positive individuals at field sites in Honduras and the Dominican Republic. In the field evaluations, the results obtained by the Determine assay were compared to those obtained by local in-country HIV screening procedures. We evaluated serum from 100 HIV-positive patients and 66 HIV-negative patients. All samples gave the expected results. In a companion study, 42 HIV-positive samples from a Miami, Fla., serum bank were tested by the Determine assay. The samples had been characterised in terms of CD4 counts and viral loads. Fifteen patients had CD4 counts <200 cells/mm³, while 27 patients had CD4 counts > 200 cells/mm³. Viral loads ranged from 630 to 873,746 log¹⁰ copies/ml. All samples from the Miami serum bank were positive by the Determine test. Combined results from the multicentre studies indicated that the correct results were obtained by the Determine assay for 100% (142 of 142) of the HIV-positive serum samples and 100% (66 of 66) of the HIV-negative serum samples. The Determine test was simple to perform and the results were easy to interpret. The Determine test provides a valuable new method for the rapid identification of HIV-positive individuals, especially in developing countries with limited laboratory infrastructures.

Results

Honduras and Dominican Republic – The sensitivity and specificity of the Determine test were 100%. The results for 100 of the HIV-positive serum samples and all 66 of the HIV- negative serum samples that were tested by the Determine test agreed with previous test results obtained by in-country test methods.

U.S.A serum bank – the Determine test was 100% sensitive in evaluating sera from patients with known CD4 counts and viral loads.

Discussion

The Determine HIV test fills all the suggested criteria for the rapid diagnosis of HIV infection:

- Rapid
- Inexpensive
- Highly sensitive and specific
- Easy to perform
- Easy to interpret
- Can be stored at room temperature for a long shelf life
- Requires no additional ancillary supplies or equipment.

The Determine test would therefore “provide a powerful tool for controlling HIV pandemic in developing countries worldwide.”

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