

A new one-step direct-sampling HIV antibody rapid test.

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Abstract:

Background: The human immunodeficiency viruses 1 & 2 are the retroviruses that cause acquired immunodeficiency syndrome (AIDS). There are a number of tests that are used to determine whether a person is infected with HIV. They include the HIV antibody test, P24 antigen test and PCR test for HIV RNA or DNA. HIV antibody tests are the most appropriate test for routine diagnoses of HIV infections. Most people develop detectable HIV antibodies within 6 to 12 weeks of infection. There are many commercially available HIV antibody tests intended for use either in the laboratory or rapid tests for use at the point-of-care. Most rapid tests are multi-step in their operation requiring, for example, the addition of a chasing buffer or a pre-run dilution in order to complete the test. Each step possibly contributes to operator error and additional labour costs. However, a rapid test that is single-step in operation and requires only a small volume of whole blood and without the need of a sample transfer device, is ideal for point-of-care as well as self-testing for HIV infection. The objective of this study is to demonstrate the clinical utility of a new one-step HIV antibody test.

Principle: The ADEXUS-Dx HIV-1/2 Antibody Test was developed using a direct sampling immunoassay technology for whole blood, plasma or serum. HIV -1/2 recombinant antigens were employed for the detection of both HIV-1 and HIV-2 antibodies. A small sample volume (35µL) is required to run the test and no extra buffer is needed. Capillary blood from a finger tip can be directly applied to the test without any transfer device. When the sample is sufficient to fill a built-in receiving channel, it flows into a dry porous test strip composed of a membrane array with gold conjugated HIV antigens. The appearance of one or two visible purplish-red band(s) at the test region indicates the sample contains a detectable level of HIV antibodies for HIV-1 and/or HIV-2.

Performance: The ADEXUS-Dx HIV-1/2 Antibody Test requires less than 40µL of sample and was completed in 15 minutes without any additional step. Testing with the WHO HIV Antibody Reference Panel confirmed that the test recognized HIV-1 subtype A, B, C, E, Group O antibodies as well as HIV-2 antibodies. Clinical studies of the ADEXUS-Dx HIV-1/2 Antibody Test were conducted in three different countries: Brazil, Cameroon and Senegal. A total of 937 clinical samples (442 positive and 495 negative) were tested. There was 100% agreement for HIV antibody positive samples and 99.8% agreement for HIV antibody negative samples. Testing of a characterized 15 member low titer panel showed 14 positive samples.

Conclusion: The ADEXUS-Dx HIV-1/2 Antibody Test is a true one-step rapid test with excellent sensitivity and specificity. It is suitable for use in the detection of HIV infection at the point-of-care and for self-testing.