Detection of HIV infection by HIV rapid tests in elite suppressors and individuals with antiretroviral drug-induced viral suppression

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Background

HIV rapid tests are commonly used to screen for HIV infection. Observational and cohort studies may use one HIV rapid test for screening while certain PREP trials may use two rapid tests or a combination of a HIV rapid test with a EIA- CIA test.

Objective

In the clinical trial In this study, we evaluated the performance of HIV screening tests for detection of HIV infection in HIV-infected adults who were virally suppressed

Methods

Three sets of samples were tested (plasma):

(1) 1,155 enrollment samples from men in the HPTN 061 study who reported no prior HIV diagnosis and had non-reactive OraQuick ADVANCE HIV-½ Antibody Test results (whole blood) obtained at study sites, Additional testing was performed at the HPTN Network Laboratory: Abbott ARCHITECT HIV-1 Ag/Ab COMBO test; a subset of the samples, including all samples that were reactive using the COMBO test, were tested using VITROS Anti-HIV 1+2 (EIA), Western blot, HIV RNA and an antiretroviral (ARV) drug screen.

(2) 22 samples from adults with natural viral suppression (elite suppressors[ES] who had undetectable HIV RNA for several years in the absence of antiretroviral treatment).

(3) 79 samples from HIV-infected adults on suppressive ARV treatment (ART, S-ART). Samples from ES and adults in the S-ART group were tested using the following assays: the Uni-Gold Recombigen HIV Test, the OraQuick ADVANCE HIV-½ Antibody Test, the INSTI Rapid HIV Test, and the VITROS Anti-HIV 1+2 Test (EIA).

Results

1) One (0.09%) of the 1,115 samples from HPTN 061 that had a negative OraQuick rapid HIV test had a reactive COMBO test and a reactive EIA. A second HPTN 061 sample that had a negative OraQuick rapid HIV test had a non-reactive COMBO test with a reactive EIA. Both samples had positive Western blots and had undetectable HIV RNA using two sensitive assays. ARV drugs were detected in one sample that were consistent with ART. No ARV drugs were detected in the other sample (this study participant was presumed to be an ES). Identical test results (for COMBO, EIA, Western blot, HIV RNA, and ARV detection) were obtained in both cases for samples collected 6 and 12 months after enrollment.
2) All 22 samples from the ES group had reactive/positive tests with all assays. Note: one ES sample did not have sufficient volume to perform all four tests.
3) All samples from the S-ART group had reactive/positive test results with these exceptions: one was non-reactive with the OraQuick test and one was non-reactive with the Uni-Gold test.

Overall, two (2%) of 101 samples from individuals with known viral suppression had negative test results using at least one HIV screening assay.

Results from one of the HPTN 061 ES when tested at the HPTN NL

OraQuick assay
Enrollment, 6 mo, 12 mo

UniGold assay
Enrollment, 6 mo, 12 mo

Notes

The OraQuick package insert includes a warning that infected individuals that are on highly active ART (HAART) may give false negative results with this kit.
The Uni-Gold package insert has a warning that immunosuppressed or immunocompromised individuals infected with HIV-1 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results in this instance and would not
be a reliable test method for such patients.
The INSTI package insert has a warning that patients who are receiving HAART may have undetectable levels of antibody to HIV-1 and give a false non-reactive INSTI™ HIV-1 Antibody Test result.

Conclusion

Individuals with viral suppression may have false-negative HIV rapid test results. Use of a single rapid test in certain settings may not identify HIV infections in individuals with natural or ARV-induced viral suppression; in some settings, it may be appropriate to use two screening tests in parallel to screen for HIV infection.

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