Rapid point of care (POC) testing has been increasingly deployed as an aid in the diagnosis of human immunodeficiency virus (HIV) infection, due to its ability to deliver rapid, actionable results while the healthcare provider is in direct contact with the patient being tested. Specifically, the OraQuick® ADVANCE™ HIV 1/2 Antibody Test has been widely used to identify HIV infection in resource-limited settings, due to its simplicity, ease of use and the ability to use oral fluid as an alternative specimen to blood. The OraQuick® ADVANCE™ HIV 1/2 Rapid Test has been widely used in STD clinics and community outreach centers (hospital emergency departments) as well as in identifying HIV infection among pregnant women⁴ 9, and to manage occupational exposure to infection.⁵

**Methods**

The OraQuick® HIV test is a visually read, qualitative, lateral flow immunoassay for the detection of antibodies to HIV-1 and HIV-2. HIV-1 and HIV-2 antibodies are immobilized on a single test line on a nitrocellulose strip and antibodies reactive with these antigens are visualized by colloidal gold labeled with protein-A. Oral fluid samples are collected directly on a swab (a reusable swab or a sterile swab) or a plastic disposable swab and mixed in a vial of pre-measured developer solution before inserting the device in the vial. Reactive results generate a reddish-purple band at the test zone. A second control line which detects human IgG ensures that patient specimens are intact and have not been diluted or contaminated. If a single line (indicating the presence of target antibodies in the sample) and no control line appear, the test is invalid. A control line is considered valid (one at the C (control) triangle and another at the T (test) triangle). Sensitivity for HIV antibodies was compared to a 3rd generation EIA and the OraQuick® test, for a sensitivity of 100% (Figure 2). Among the 30 seroconversion panels tested (average time between bleeds = 5.5 days), 3rd generation EIA was slightly more sensitive than OraQuick® for the detection of HIV antibodies, although the differential was small, with an average differential in time to detection of -2.5 days (95% CIs: -1.2 to -3.8 days) (figure 3). All 401 HIV positive plasma specimens were detected by both HIV EIA and the OraQuick® test, for a specificity of 100%. A total of 3,135 oral fluid screening results from 89 public health testing centers in the U.S., were analyzed by re-analysis with western blot. Blister was 99.84% (99.85-99.99%).

**Results**

All 401 HIV positive plasma specimens were detected by both HIV EIA and the OraQuick® test, for a sensitivity of 100% (Figure 2). Among the 30 seroconversion panels tested (average time between bleeds = 5.5 days), 3rd generation EIA was slightly more sensitive than OraQuick® for the detection of HIV antibodies, although the differential was small, with an average differential in time to detection of -2.5 days (95% CIs: -1.2 to -3.8 days) (figure 3). All 401 HIV positive plasma specimens were detected by both HIV EIA and the OraQuick® test, for a specificity of 100%. A total of 3,135 oral fluid screening results from 89 public health testing centers in the U.S., were analyzed by re-analysis with western blot. Blister was 99.84% (99.85-99.99%).

**Conclusions**

1. Clinical performance of the OraQuick® ADVANCE™ HIV test for detection of HIV antibodies was comparable to current, state of the art, laboratory-based tests. A second control line which detects human IgG ensures that patient specimens are intact and have not been diluted or contaminated. If a single line (indicating the presence of target antibodies in the sample) and no control line appear, the test is invalid. A control line is considered valid (one at the C (control) triangle and another at the T (test) triangle). Sensitivity for HIV antibodies was compared to a 3rd generation EIA and the OraQuick® test, for a sensitivity of 100% (Figure 2). Among the 30 seroconversion panels tested (average time between bleeds = 5.5 days), 3rd generation EIA was slightly more sensitive than OraQuick® for the detection of HIV antibodies, although the differential was small, with an average differential in time to detection of -2.5 days (95% CIs: -1.2 to -3.8 days) (figure 3). All 401 HIV positive plasma specimens were detected by both HIV EIA and the OraQuick® test, for a specificity of 100%. A total of 3,135 oral fluid screening results from 89 public health testing centers in the U.S., were analyzed by re-analysis with western blot. Blister was 99.84% (99.85-99.99%).

**References**