

## **Sensitivity of OraQuick and Early Generation Enzyme Immunoassay (EIA) within a Pooled HIV Nucleic Acid Amplification Testing (HIV NAAT) Program**

<i>Abstract Category:</i>	Laboratory-based Strategies Using Combinations of Screening Assays and Rapid Tests
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### **OBJECTIVE**

To describe sensitivity of different HIV antibody tests within an HIV NAAT program.

### **METHODS**

In September 2003, Public Health - Seattle & King County (PHSKC) implemented pooled HIV NAAT for antibody-negative men who have sex with men (MSM). We offered confidential or anonymous HIV testing using rapid HIV antibody testing with OraQuick (OraSure Technologies, Inc) or a 1st or 2nd generation EIA (Vironostika HIV-1 Microelisa System, bioMerieux; or Genetic Systems rLAV EIA, Bio-Rad Laboratories). OraQuick used finger-stick blood samples or oral fluids, depending on the testing site. Since November 2005, when we identified one individual with early HIV infection who was OraQuick-negative but antibody-positive by the 1st generation EIA, we have screened all OraQuick-negative MSM with the 1st or 2nd generation EIA prior to pooling to reduce costs associated with NAAT and to decrease the time between testing and receipt of results.

### **RESULTS**

Since September 2003, 268 (2.2%) of 12020 specimens were HIV antibody-positive, and 28 (0.2%) of 11752 antibody-negative specimens were HIV NAAT-positive. One HIV-infected individual tested HIV-negative by EIA and NAAT four days after an exposure to an acutely-infected partner. Since November 2005, we have identified 9 HIV-infected MSM with discordant antibody test results (OraQuick-negative and 1st or 2nd generation EIA-reactive). Western Blot assays were positive for 8 of the 9 MSM, and the ninth was indeterminate due to a faint anti-gp120 band; all 9 were notable for the lack of anti-gp41 (the glycoprotein in OraQuick). Among rapid testers, OraQuick was 82% sensitive (detecting 113 of 138 HIV-infected MSM), OraQuick plus EIA was 88% sensitive (122/138), and pooled HIV NAAT had 100% sensitivity. Stored sera were OraQuick-reactive from each of the 5 cases with discordant results that could be re-tested but none of 10 acutely-infected MSM initially screened by EIA.

### **CONCLUSIONS**

OraQuick may be less sensitive than EIAs during early HIV infection, and individuals identified by OraQuick as antibody-negative/NAAT-positive may actually have early and not acute HIV infection. It may be relatively more important to use NAAT in populations with frequent HIV testing and high rates of HIV acquisition, especially when rapid HIV antibody testing is employed.