

## Quality Assurance Monitoring, the Lynchpin of Rapid HIV Screening in 10 Publicly Funded New York City Sexually Transmitted Disease Clinics, NYC, January, 2004

<i>Abstract Category:</i>	Point of Care Algorithms Using Combinations of Rapid Tests
<i>Primary Author:</i>	Alexis Kowalski
<i>Affiliation:</i>	Bureau of Sexually Transmitted Disease Control, New York City Department of Health & Mental Hygiene
<i>Co-Authors:</i>	Mavinkurve, M, Paneth-Pollak, R, Borrelli, J, Rubin, S, Blank, S

### PROJECT

Sexually transmitted disease (STD) clinics are important venues for diagnosing HIV. The New York City (NYC) Department of Health and Mental Hygiene's 10 STD clinics offer free and confidential HIV testing at all visits; ~500 HIV cases are diagnosed annually. In January 2004, the Bureau of STD Control (BSTDC) implemented rapid HIV-1/2 testing (OraQuick (OQ) Advance HIV-1/2). As used at BSTDC STD clinics, OQ provides either a final negative result or a preliminary positive (PP) result (confirmed via Western Blot (WB) testing at the NYC Public Health Laboratory). Upon rolling out the new test technology rapid test quality assurance (QA) procedures were developed and monitored.

### ISSUES

A monthly average of ~5 false-positives (FP)/3900 tests was observed as the false-positive (PP-OQs; WB negative) baseline. However, in November 2005, BSTDC received reports from staff of FP clusters, raising concerns among staff and patients of the quality of BSTDC's oral-rapid testing services.

### RESULTS

QA data gathered over the next two months revealed a decline in OQ test specificity. During this time period there were 35 FPs/3,753 tests (test specificity 99.07%; below the lower limit of FDA and manufacturer's specificity level of 99.8 (95% CI: 99.6%-99.9%)). BSTDC implemented immediate repeat testing using whole-blood (fingerstick) on all PP-OQs, and immediate counseling messages were adjusted based on the second test result. The manufacturer, CDC and FDA were notified, and began investigations. The BSTDC also undertook investigations to identify the cause of the FP clusters, and to maintain the credibility of rapid oral-fluid test results. Investigations showed no correlation between FPs and kit lots, storage temperatures, or test processing. By 2005, the number of FPs returned to acceptable levels (81/47,204 rapid tests; test specificity 99.82%).

### LESSONS LEARNED

Aggressive QA and good communication enabled BSTDC to preserve the capacity to offer rapid oral-fluid testing. BSTDC continues repeat testing via rapid whole-blood (fingerstick) on all PP-OQs.