

Results of a Pilot Point-of-Care (POC) HIV Testing Program Using INSTI HIV in an Urban Sexual Health Clinic in Canada

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OBJECTIVE

To evaluate the efficacy of point-of-care (POC) testing in a sexual health clinic catering to at risk clients.

METHODS

Clients attending Hassle Free Clinic for voluntary anonymous HIV testing received pre- and post-test counseling and were offered a choice of POC or routine (venipuncture) lab based testing. POC testing was done using the Health Canada approved INSTI (bioLytical Laboratories, Richmond, BC, Canada) POC assay. The assay employs recombinant HIV1 (gp41) and HIV2 (gp36) proteins, has an IgG control and stated sensitivity and specificity of 99.6%. All reactive or indeterminate results were confirmed by routine laboratory testing.

RESULTS

In the one-year period beginning May 15 2006, 4751 clients received HIV testing: 88.8% of men (2993) and 86.5% of women (1187) choose POC testing. Of 4180 POC tests done, 4108 were non-reactive; 62 were reactive and 10 were considered "indeterminate". Of the 62 clients who tested reactive, 4 had been previously diagnosed as HIV positive and confirmatory testing was not performed, and 1 refused confirmatory testing. Of the 57 reactive tests that had specimens forwarded for confirmatory lab testing, 56 were confirmed as HIV antibody positive; one was HIV antibody negative. Of the 10 clients whose POC result was "indeterminate", 1 was found to be an HIV seroconverter with weakly reactive HIV antibody that increased over time, and 9 were confirmed HIV antibody negative. Overall specificity for INSTI during the pilot was 99.7% [95%CI 99.5 - 99.9%] and positive predictive value was 82.4%.

CONCLUSIONS

Based on the performance of the INSTI assay during the pilot phase of the program, the Ontario Ministry of Health and Long-Term Care is scaling up the HIV POC testing program to include more than 50 additional sites across the province. Program implementation includes training, competency assessment, and the implementation of an extensive quality assurance program.