Evaluation of HIV Point of Care Testing Results Compared to Lab-Based Third and Fourth Generation Assays in a Public Health Setting

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ABSTRACT

Background:
Standard laboratory-based HIV testing by public health systems is often performed in designated laboratories and requires that a serum or plasma sample be sent to a public health laboratory. If the initial laboratory testing is reactive, then the sample is retested in duplicate and confirmatory testing is performed. Patients must often wait several days for results to become available because of the length of time required by testing personnel to perform and confirm testing in its entirety.

Rapid point-of-care (POC) HIV tests are excellent options in situations where patient follow-up may be difficult, allowing for clinicians or health workers to provide patient test results in a matter of minutes as opposed to waiting several days and requiring that the patient return to the clinic to obtain results and consultation with a healthcare provider. However, confirmatory HIV testing at an approved HIV testing laboratory is still required for all reactive POC results.

With the advent of 4th generation laboratory-based HIV screening capabilities, which are able to detect both HIV p24 antigen and HIV antibodies simultaneously, POC rapid tests may no longer be the preferred screening method in many situations, *especially* in cases with recent exposure risk.

Objective:
The objective of this study was to evaluate both 3rd and 4th generation lab-based screening and confirmatory testing results against POC reactive samples in an effort to elucidate costs and benefits of each assays performance characteristics in a low-prevalence state.

Results:
Of the 31 samples flagged as POC reactive, 29 confirmed positive. Of the two specimens determined to be negative, one sample had reactive result interpretations on all three screening assays (BioRad 3rd gen., BioRad and 4th gen., and Abbott 4th gen.), but was negative on both confirmatory assays (BioRad Western Blot, BioRad Multispot). The other POC reactive sample was interpreted as negative for all three screening assays and both confirmatory assays.

Conclusion:
Among the many benefits associated with rapid testing, HIV POC tests are an accurate and effective means for obtaining HIV results, according to this study's data. However, with the advent of better sensitivity and specificity and earlier detection times currently available in laboratory settings, the use of POC screening may not always be the most appropriate screening choice, especially in areas of low prevalence and/or situations involving recent exposures. Because of more sensitive technology and faster result output (Abbott Architect HIV 4th Generation test and Biorad Multispot Confirmatory test), laboratory turnaround times have greatly improved, thereby reforming the standard for high-quality testing and services to patients and clinicians.

MATERIALS AND METHODS

Between July, 2010 and May, 2012, Unified State Laboratories: Public Health received 3,860 serum/blood specimens for HIV testing. Of the specimens received, 31 samples flagged as POC reactive by the submitting agencies were evaluated on the Biorad HIV 1-2-O 3rd generation assay and subjected to Western Blot testing on the Biorad HIV-1 Western Blot assay according to standard testing algorithms. Sample aliquots were stored at -20 and retrospectively evaluated on two separate 4th generation screening assays including BioRad 4th generation HIV Ag/Ab and Abbott Architect HIV Ag/Ab combo as well as the BioRad Multispot platform (part of new CDC recommended 4th generation testing algorithm for public health laboratories).

ACKNOWLEDGEMENTS

Michelle Mendenhall & Kelly Holmes, Immunology/Virology Department, Unified State Labs: Public Health

RESULTS

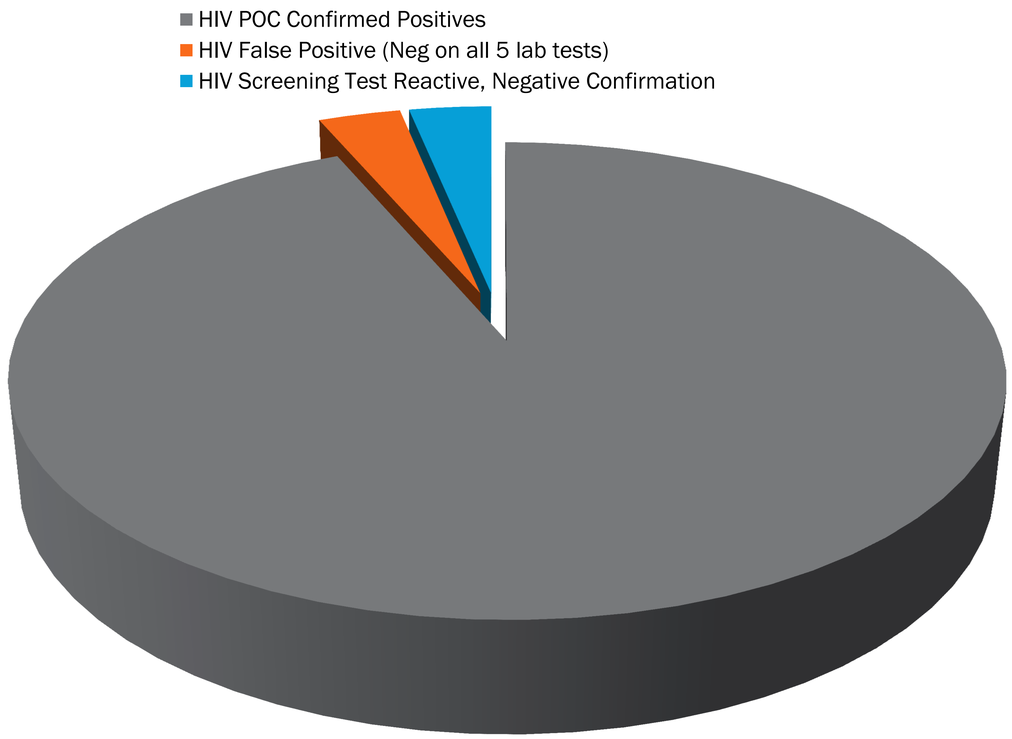

Figure 1: HIV POC Positive Samples. Of 31 rapid test positive (POC) samples submitted, 29 (Grey) were concordant with all 5 laboratory assays. 2 of the 31 samples were ultimately determined to be negative.

DISCUSSION

Early identification of HIV disease not only improves sensitivity but also allows potential reductions in disease transmission. According to James W Galbraith Jr, MD, approximately 21% of individuals with HIV infection are unaware of their status, and these persons account for more than 50% of new transmissions of the disease , which makes early detection crucial. Dr. Galbraith states that "the risk of contagion from individuals with acute early infection is reported to be greater than that from patients with chronic infection because of elevated viral load. Identification of these highly contagious individuals via p24 antigen detection during the acute phase of infection affords the opportunity of reducing the viral load with antiretroviral medications, as well as initiating behavioral modification." He also notes that early antigen recognition with fourth-generation assays reduces the window period for detection by approximately 5 days, potentially allowing earlier diagnosis of acute HIV disease [1]. Additional advantages to this combination assay include reductions in laboratory costs, time, and personnel required to run equivalent assays separately.

REFERENCES

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