Specificity and Workflow of the BioPlex HIV Ag-Ab Assay in Routine HIV Screening at a Public Health Laboratory

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Introduction

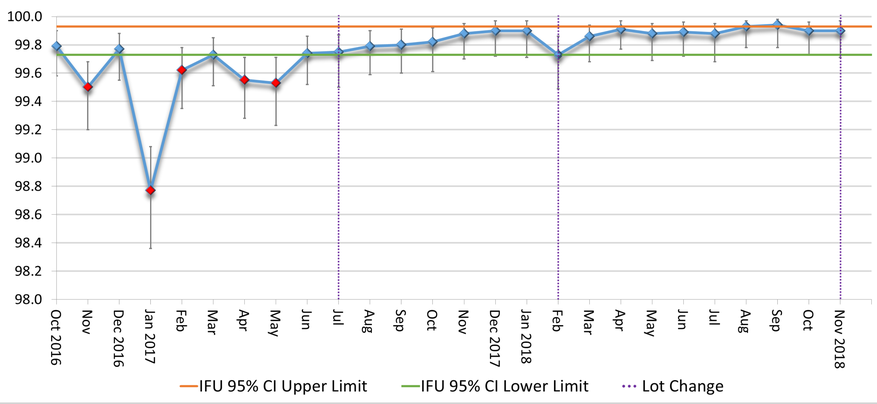
The Texas Department of State Health Services (DSHS) utilizes the BioPlex 2200 HIV Ag/Ab immunoassay (BioPlex assay) for initial screening for HIV infection. The assay can detect and differentiate between HIV-1 p24 Antigen, HIV-1 Antibody (M and O groups) and HIV-2 Antibody, allowing for screening of acute HIV infection before seroconversion. We illustrate the specificity of the BioPlex assay for routine HIV screening in a diagnostic laboratory setting and our observations. We also illustrate the testing turn-around-times (TAT) for the HIV algorithm.

Materials and Methods

94,434 serum samples (fresh and frozen) submitted to the Texas Department of State Health Services Laboratory for routine HIV screening were analyzed between October 2016 and November 2018 by the BioPlex assay, Geenius HIV-1/HIV-2 differentiation assay (Geenius), and when required, HIV Nucleic Acid Testing (NAT) performed at the Dallas County Health and Human Services laboratory. The specificity of the BioPlex assay, month-to-month, was compared to the manufacturer's stated specificity (BioPlex assay IFU, July 2016) and checked for significant deviation using Fisher's exact test (p-value ≥ 0.05). Specimen collection date, date of receipt, and date of when results were released were retrospectively analyzed. Geenius and HIV NAT results for suspected acute HIV cases (HIV p24 Ag+/HIV-1 Ab-/HIV-2 Ab-) were evaluated.

Results

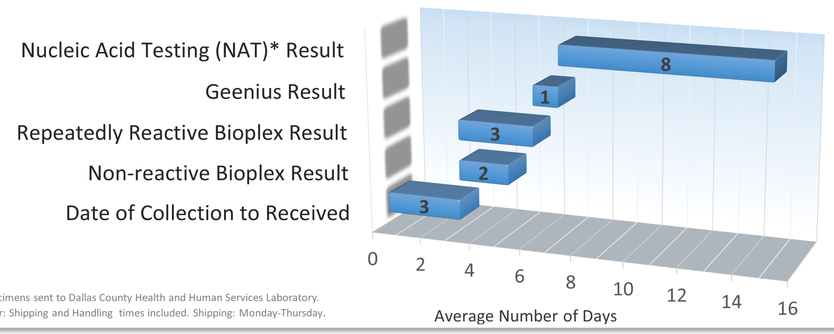
Figure 1. Specificity of the BioPlex 2200 HIV Ag/Ab Multiplex Assay



The overall specificity of the BioPlex assay was 99.76%, lower than the manufacturer's reported specificity of 99.86%, but within the stated confidence intervals.

During the November 2016 to May 2017 timeframe, there was an increase in false positives (HIV Ag+, NAT-). Conversations with manufacturer led to an investigation into the reagent lot.

Figure 2. Average Turn-Around-Time for HIV Submissions



*NAT specimens sent to Dallas County Health and Human Services Laboratory.
Disclaimer: Shipping and Handling times included. Shipping: Monday-Thursday.

Average turn around time (TAT) for HIV submissions to results ranged from 5 to 15 days.

Figure 3. HIV Ag/Ab results for specimens screened by the BioPlex 2200 HIV Ag/Ab Multiplex Assay

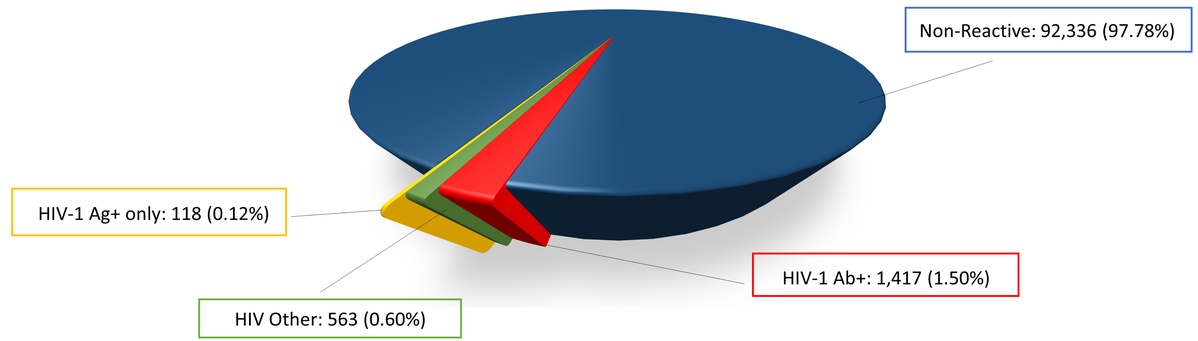
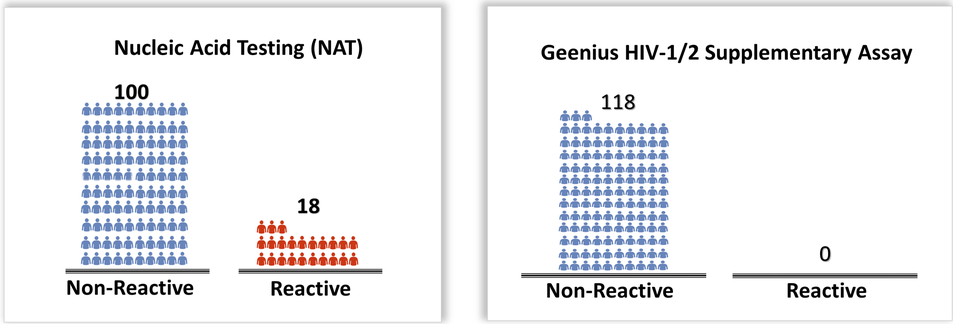


Figure 4. Geenius HIV-1/2 Supplementary Assay and NAT results for HIV-1 p24 Ag+ only specimens.



One hundred-eighteen specimens submitted for routine HIV screening were repeatedly reactive only for HIV-1 p24 Ag by the BioPlex assay. As only 18 of these confirmed positive for HIV by NAT, the positive predictive value for those specimens with suspected acute HIV was 15.25%. All 118 tested non-reactive by the Geenius assay.

Conclusion

- The overall specificity of BioPlex 2200 HIV Ag-Ab immunoassay is very high (99.76%) and performance appears to have stabilized over time.
- Based on the results in our population, among those testing positive for HIV p24 Ag but negative for HIV-1 and -2 antibodies (HIV-1 Ag+ only), only 15.25% appear to have acute infection.
- With a TAT of 15 days, an in-house NAT would be preferable to reducing time to identification of HIV cases.
- Geenius HIV-1/2 Supplementary Assay may not be necessary in confirming HIV infection for HIV-1 p24 Ag+ only specimens. The extra test could cause a delay in identifying and reporting cases.

Acknowledgement

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