Validating the BioPlex 2200 Automated Enzyme Immunoassay (EIA) for Detection of HIV

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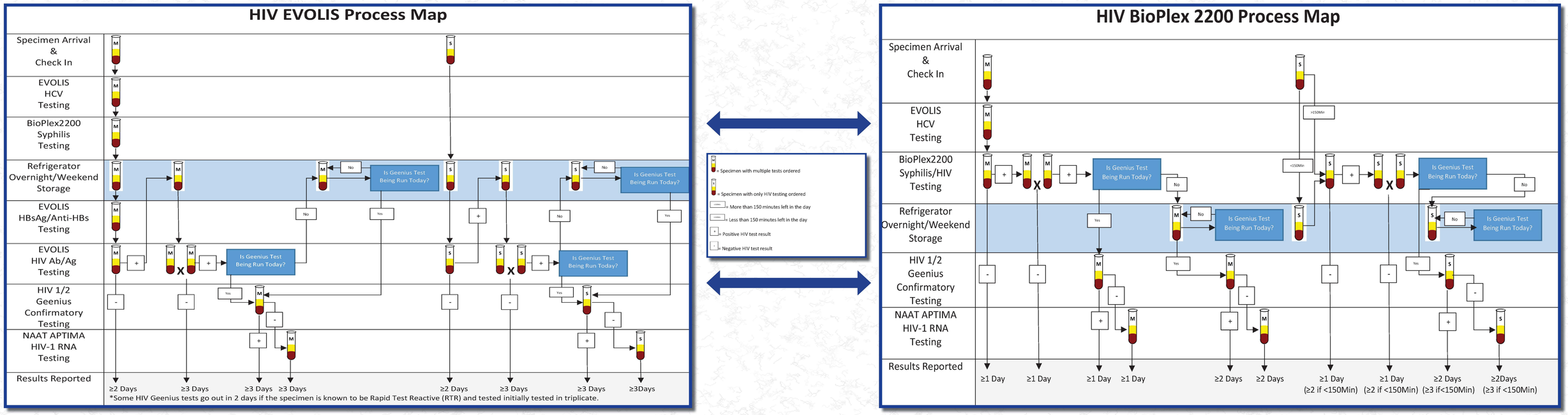
Introduction

The BioPlex 2200 is a self-contained multiplex-flow instrument capable of improving efficiencies in routine specimen testing by reducing instrument maintenance, test preparation time, sample handling, and eliminating batches through random-access testing. The BioPlex 2200 is also beneficial in that it can run multiple tests concurrently on a single sample, which can reduce unnecessary handoffs and reduce the possibility of contamination occurring. For HIV detection, the BioPlex 2200 differentiates between HIV-1 (groups M and O) and HIV-2 antibodies, plus HIV-1 p24 antigen. A validation was performed to ensure that the BioPlex 2200 was a suitable substitute for the EVOLIS EIA instrument previously used for testing and the new method was assessed for improvement in HIV test turnaround time (TAT) for the approximate 9,000 HIV EIA specimens tested each year.

Methods

To be considered a valid replacement for the HIV Ag/Ab Combo Test on the EVOLIS, the BioPlex 2200 needed to exceed 90% in test precision, reproducibility, and accuracy. To determine accuracy, 225 specimens (144 non-reactive and 81 reactive) previously run on the BioRad EVOLIS were run on the BioPlex 2200. A BioRad training representative ran an HIV-1 Ab and HIV-2 Ab QC 20 times and an HIV-1 p24 antigen diluted QC 12 times to determine test Intra-Assay precision/reproducibility. A BioPlex 2200 to BioPlex 2200 correlation test was also run with HIV-1 Ab, HIV-1 Ag, and HIV-2 Ab samples. Four months after beginning HIV testing on the BioPlex 2200, a process map was created to see how workflow had changed within the laboratory and to see whether improvements to TATs were being made (**Figure 1**). To quantify the changes in TATs, the data from each instrument was aggregated in STARLIMS (our laboratory LIMS) for a three-month period of HIV testing. The timeframes were set at one year apart to best replicate patient populations and reduce discrepancies in TATs due to holidays. Additionally, data was collected for reactive specimens that went on for supplemental testing with the BioRad Geenius Assay.



(**Figure 1**) Process maps showing changes in workflow between EVOLIS and BioPlex 2200 specimens tested for HIV with improved efficiencies for the BioPlex 2200.

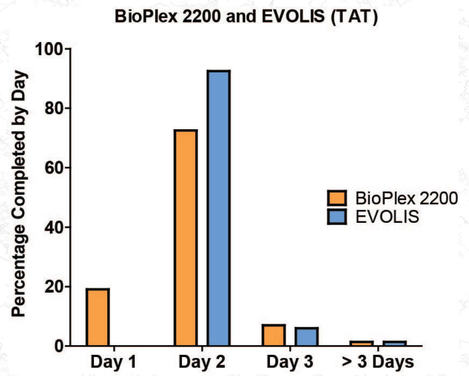
Results and Discussion

The BioPlex 2200 was found to be a suitable replacement with a positive agreement of 92.0% and a negative agreement of 100% with the EVOLIS assay, leading to a total agreement of 96.9% (**Table 1**). Additionally, the 7 specimens that were non-reactive on the BioPlex 2200 but reactive on the EVOLIS tested non-reactive by the laboratory's supplemental assay (Geenius or Multispot) and tested HIV-1 NAAT negative by APTIMA HIV-1 RNA Assay. The Specimen that tested HIV-1 Ag reactive on the BioPlex 2200 but non-reactive on the EVOLIS was redrawn and tested HIV-1 NAAT negative. The Intra Assay Precision and BioPlex 2200 to BioPlex 2200 tests were in complete agreement.

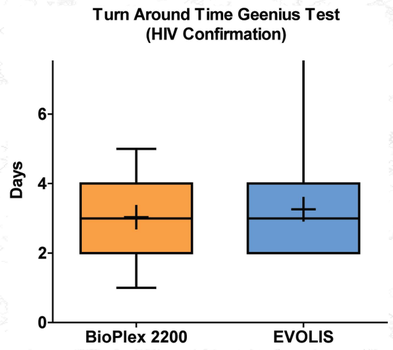
The process maps for the BioPlex 2200 HIV testing (**Figure 1**) showed increased opportunities to report specimens out in a shorter time than the EVOLIS with less handoffs to the refrigerator and the ability to combine HIV and syphilis testing for Multi-Test Specimens. By combining HIV and syphilis testing, HIV testing was moved up in the workflow order, eliminating any delays to and from Hepatitis B testing for Multi-Test Specimens, which competed for time in the mornings. Single-Test Specimens which typically arrive later in the day, were also able to be tested in some instances. This ability comes from the random-access testing capability of the BioPlex 2200 that allows specimens to be run as they arrive as opposed to waiting to combine them into batches. The increase in efficiencies is apparent, with 19% of BioPlex 2200 tested specimens being reported out the same day as arrival (**Figure 2**). Same day reporting did not previously occur with EVOLIS testing. Geenius testing is only performed twice a week so a large reduction in TAT for confirmatory testing is constrained by the testing schedule. However, there was a small 7% reduction in TAT for specimens that go on for Geenius testing (**Figure 3**).

Statistical Summary of Previous Positives and Negatives			
	EVOLIS Negative Reference	EVOLIS Positive Reference	Total
BioPlex 2200 Negative Test	137	7	144
BioPlex 2200 Positive Test	1	80	81
Total	138	87	225
Positive Agreement=92.0% Negative Agreement=99.3% Total Agreement=96.9%			

(**Table 1**) 2x2 Table showing Evolis and BioPlex 2200 sensitivity and specificity.



(**Figure 2**) Graph showing HIV turnaround times (TAT) with BioPlex 2200 providing the ability to report specimens within one day.



(**Figure 3**) Graph showing turnaround times (TAT) for HIV specimens tested with Geenius Supplemental Assay with tighter spread of TAT and one day release potentials for specimens initially tested on the BioPlex 2200.

Conclusion

- The BioPlex 2200 is a suitable replacement for the EVOLIS for HIV testing.
- The BioPlex 2200 can improve Turn Around Time for routine testing specimens.