



# Performance of the Abbott ARCHITECT HIV Ag/Ab Combo Assay in a Low Incidence Population

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## Abstract

**Background:** In March 2015, the Massachusetts State Public Health Laboratory (MA SPHL) implemented the automated Abbott Architect i2000 system for HIV Ag/Ab combo (CMIA), to handle increasing HIV testing volume and to test all submissions for HCV antibody. The performance characteristics for 12,998 specimens, through August 2015, are reported.

**Methods:** Serum specimens were collected and shipped to the laboratory within 72 hours for testing using the CDC recommended algorithm of screening with a 4th generation antigen/antibody combination immunoassay and testing repeatedly reactive specimens with the BioRad MultiSpot HIV-1/HIV-2 antibody differentiation immunoassay (ADI). If results were discordant, an HIV-1 RNA NAT was performed.

**Results:** Over six months, MA SPHL reported results for 12,998 specimens. Of those, 126 (0.97%) were reactive by both CMIA and ADI. Twenty-nine (0.22%) were CMIA reactive, ADI negative or indeterminate, and NAT negative. Two discordant specimens were NAT positive. The signal-to-cut off (s/c) value of the true positives ranged from 5.45 to 977.13 with a mean of 500.24. The s/c value of the combo immunoassay false positives ranged from 1.01 to 42.15 with a mean of 5.08. The s/c of true positives varied on repeat testing by 10%, while s/c varied by 22% for the false positives. There were 12,841 true negative tests. The positive predictive value (PVP) was 81.5% and the negative predictive value (PVN) was 100%. During the same time period in 2014, 7,240 specimens were tested with BioRad HIV antigen/antibody combo EIA. Of those, 103 (1.4%) were reactive by both EIA and ADI. Seven (0.01%) were BioRad combo reactive and ADI negative and NAT negative. There were 7,129 true negative tests. The PVP was 93.64%. The EIA NPV was 100%.

**Conclusions:** By changing to the Abbott Architect automated platform, the laboratory gained efficiencies e.g. handling increased specimen volume and decreasing TAT and allowing for simultaneous testing for HCV antibody; however, the increased percentage of false positives required additional testing. With the CMIA, significant variance at low s/c values was observed, supporting the need for supplemental testing.

## Introduction

The Massachusetts Department of Public Health, State Public Health Laboratory has automated HIV testing utilizing the Architect i2000SR HIV antigen-antibody combo assay (List 2P36; Abbott Diagnostics, Abbott Park, IL). The HIV Combo is a chemiluminescent magnetic microparticle-based immunoassay. We compared the performance characteristics of the Architect to the manual BioRad HIV antigen/antibody combo EIA which the lab had used since 2012. The benefits of the Architect are that it is a completely automated testing platform and It has been demonstrated to be a highly sensitivity assay which assures that truly infected individuals will not escape detection. While the Architect is highly sensitive, it does have a lower specificity. The assay is designed to detect HIV type 1(HIV-1; groups M,O, and N) and HIV-2. The performance of the Architect was evaluated on 12,998 specimens from individuals attending Massachusetts Department of Public Health sponsored collection sites.

## Methods:

- All testing was performed according to the package insert. Specimens with a signal-to cut-off (S/CO) ratios of 1.0 or greater are considered reactive.
- All reactive specimens were repeated in duplicate and the average of the three s/co calculated. The s/co most distant from the mean was then divided by the mean to determine the variation.
- The results of the Architect were compared to the results of the BioRad during the same time period of the previous year, i.e., March 13, 2015 to July 24, 2015 (Architect) compared to March 13, 2014 to July 24, 2014 (BioRad).

## Data:

System	Performance Summary	S/C Range	S/C Mean	S/C Variability
<b>Architect</b> Tested = 12998 Reactive = 126 (0.97%) Acute Phase = 2 Non-Reactive = 12,841	True Positive = 111 (0.85%)	S/C = 5.45-977.13	500.24	10%
	False positive = 29	S/C = 1.0-42.15	5.08	22%
	True Negative = 12,841	S/C = <1.0		
	PVP = 81.5%			

System	Performance Summary
<b>BioRad</b>	True Positive = 96
Tested 7,240	False Positive = 7
Reactive 103 (1.4%)	True Negative = 7,129
Acute Phase = 0	PVP = 93.64%
Non-Reactive = 7,137	

## Discussion

- Massachusetts is considered a low incidence state with only 629 new cases reported in 2014. Cases have continued to decline since 2005 when 897 cases were diagnosed.
- The automation allowed the lab to increase from 7,240 specimens between March 13, 2014 to July 24, 2015 to 12,998 tests in the same time period in 2015, an 80% increase in test volume, with the same number of FTE's in the lab section.
- The S/C variability compared to the mean was much greater at the low end of the spectrum than the high end.
- PVN was determined to be 100%, since surveillance indicates do that no patient was reported to be positive for HIV to DPH post test performance and report.

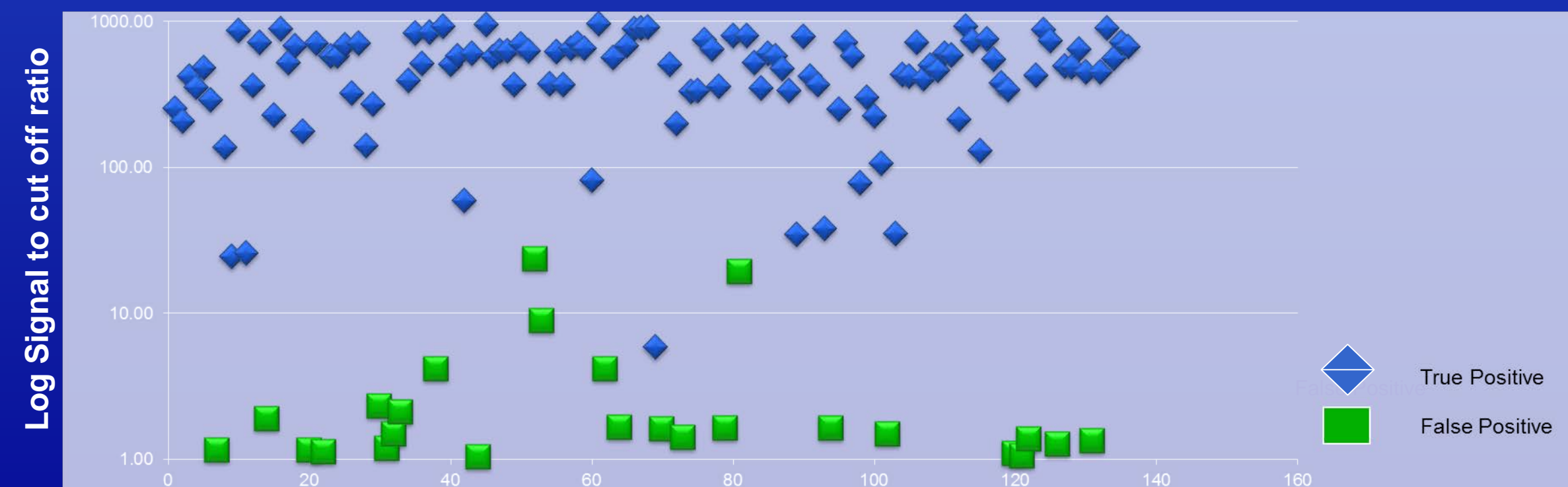


## Conclusions

- The Architect offers significant value in that it is a throughput random access instrument.
- There is additional supplemental testing needed because of an increase false positives.
- At the low end of the S/C there is greater variation upon repeat testing.

## Further Information

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Architect Test Results Chronologically March 13 to July 24, 2015