

Increase in the Use of 4th Generation HIV-1/2 Immunoassays in the HIV Diagnostic Testing Algorithm over Time: New York State's Experience

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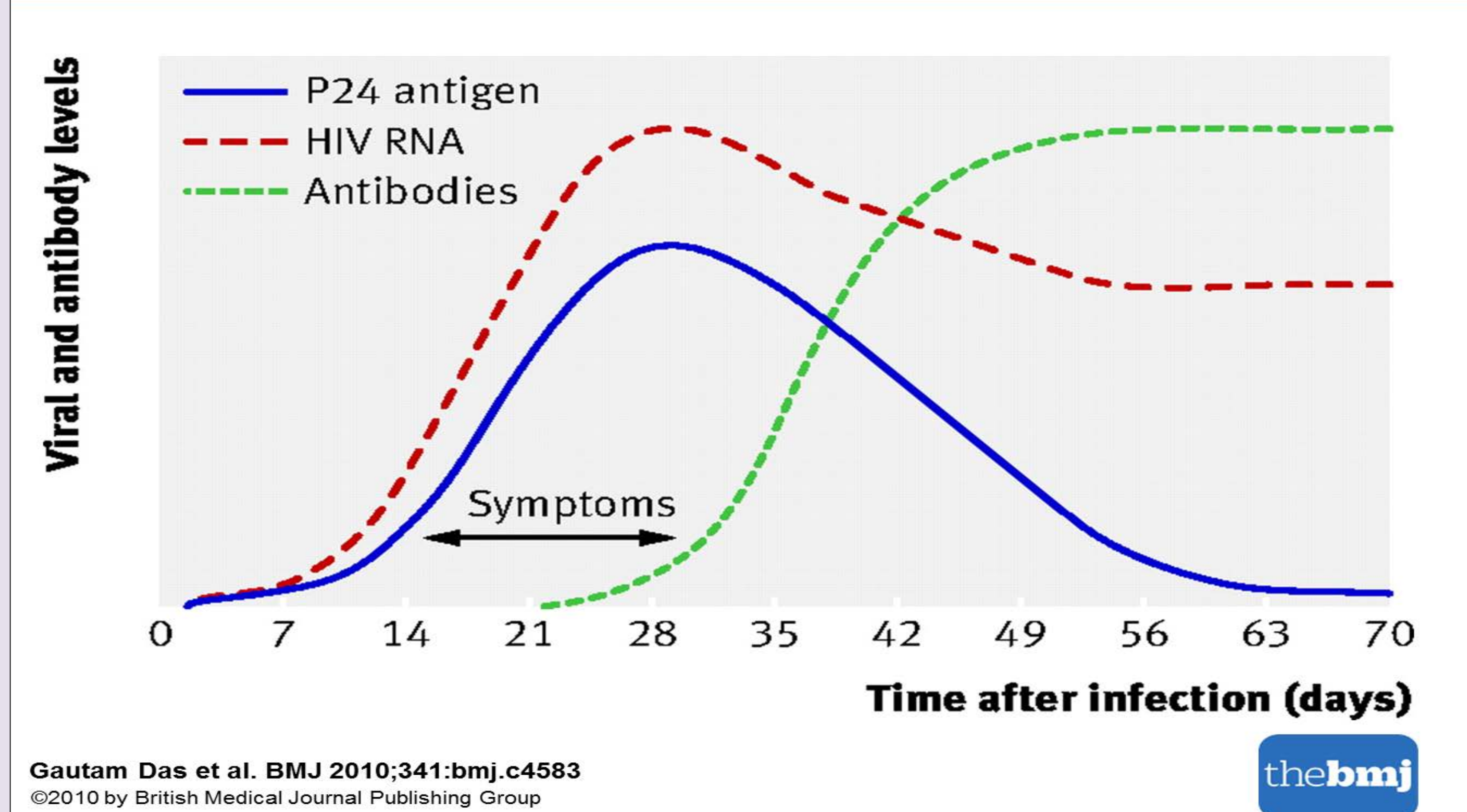
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BACKGROUND

- New York State (NYS) Public Health Law requires laboratories conducting HIV-related testing for NYS clinicians and/or residents to electronically report any laboratory test, tests or series of tests approved for the diagnosis of HIV or for the periodic monitoring of HIV infection.
- Laboratories report using the Electronic Clinical Laboratory Reporting System (ECLRS), a single secure platform for all laboratory reporting to the State.
- The NYS Department of Health (NYSDOH) Bureau of HIV/AIDS Epidemiology (BHAIE) enrolls labs conducting testing into ECLRS reporting.
- In June 2014 the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories recommended a diagnostic testing algorithm (algorithm) for HIV infection that offers several advantages over the traditional enzyme immunoassay (EIA)-Western blot strategy, including earlier and more accurate detection of HIV infections, the ability to differentiate between HIV-1 and HIV-2 infections, and lower costs.
- The preferred first test (Step 1) is an HIV-1/2 antigen (Ag) antibody (Ab) combo immunoassay (Ag/Ab combo or 4th generation), though the HIV-1/2 immunoassay (3rd generation) that detects Ab but not Ag has been considered acceptable.
- As Ag is detectable earlier in HIV infection than Ab (Figure 1), the HIV-1/2 Ag/AB Combo tests are preferred over the less sensitive Ab only HIV-1/2 immunoassays.
- Laboratories have been urged to replace less-sensitive HIV-1/2 immunoassays with a recommended Ag/Ab combo immunoassay test to detect infection earlier and to reduce the number of false negative test results.

FIGURE 1: Approximate Time Course of Viral and Ab Changes During Primary HIV Infection



OBJECTIVE

- The objective of this study was to use routinely submitted electronic laboratory results submitted to NYSDOH ECLRS to assess implementation of the recommended Ag/Ab combo immunoassay compared to the acceptable HIV-1/2 immunoassay.

METHODS

- As of August 2015, 46 laboratories were certified to electronically report algorithm Step 1 immunoassay results to NYSDOH via ECLRS.
- 22,088 Step 1 results with specimen collection dates between January 1, 2014 and August 31, 2015 were received from these laboratories.
- Laboratory test results included Logical Observation Identifiers Names and Code (LOINC) to identify test type and testing methodology (i.e. 3rd or 4th generation).
- HIV Ag/Ab combo results were reported with LOINC 56888-1 and HIV-1/2 immunoassay results were reported with LOINCs 31201-7, 48345-3 and 57975-5.
- Reports were unduplicated and monthly rates were compared by testing methodology.
- The Mantel-Haenszel test for trend was applied to determine change over time

RESULTS

FIGURE 2: Frequency of Reported HIV-1/2 Ag/Ab Combo Immunoassay and HIV-1/2 Immunoassay Test Results by Month of Specimen Collection, 2014-2015

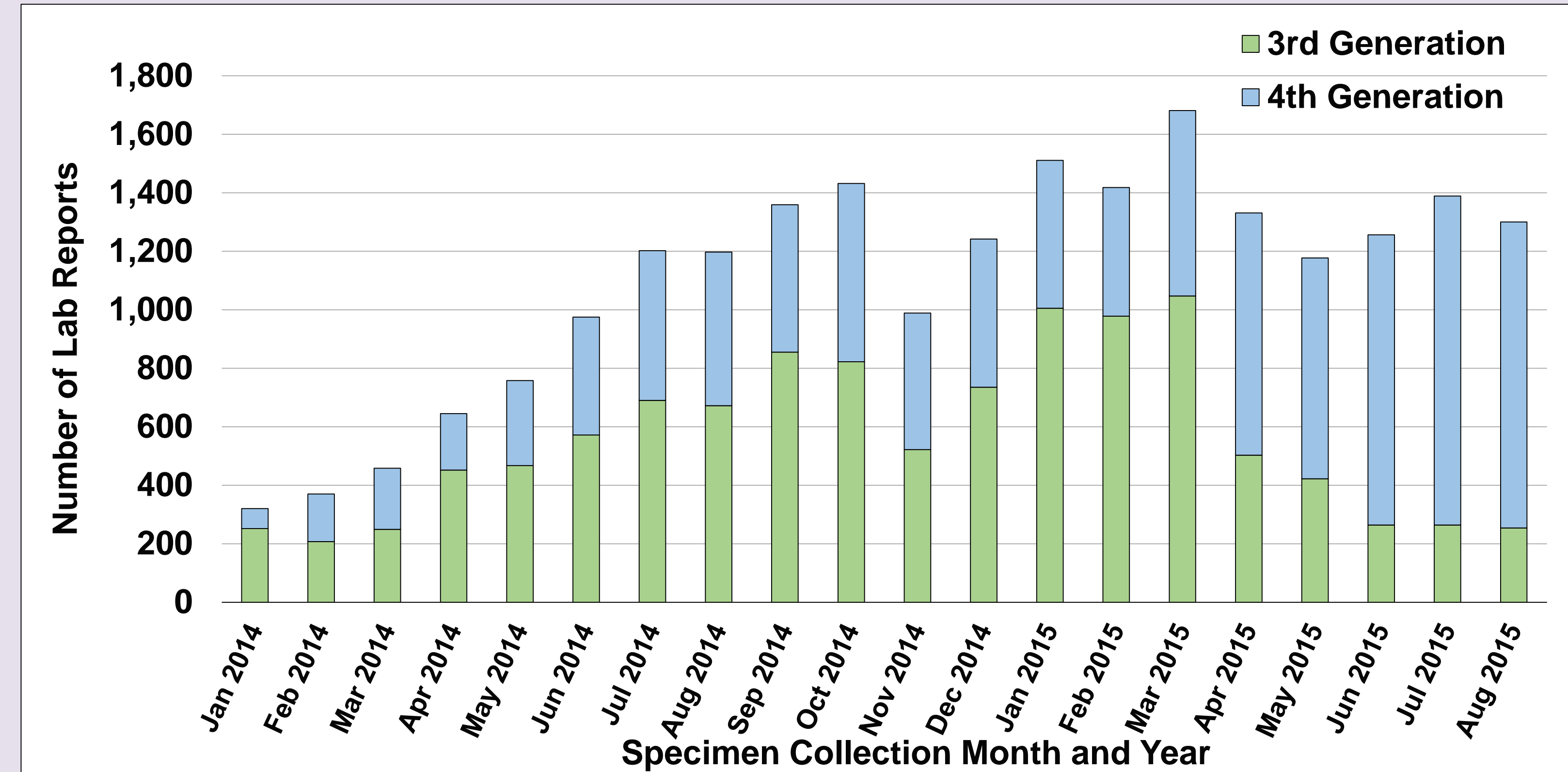


FIGURE 3: Trends in Rates of Reported HIV-1/2 Ag/Ab Combo Immunoassay and HIV-1/2 Immunoassay Test Results, January 2014-August 2015

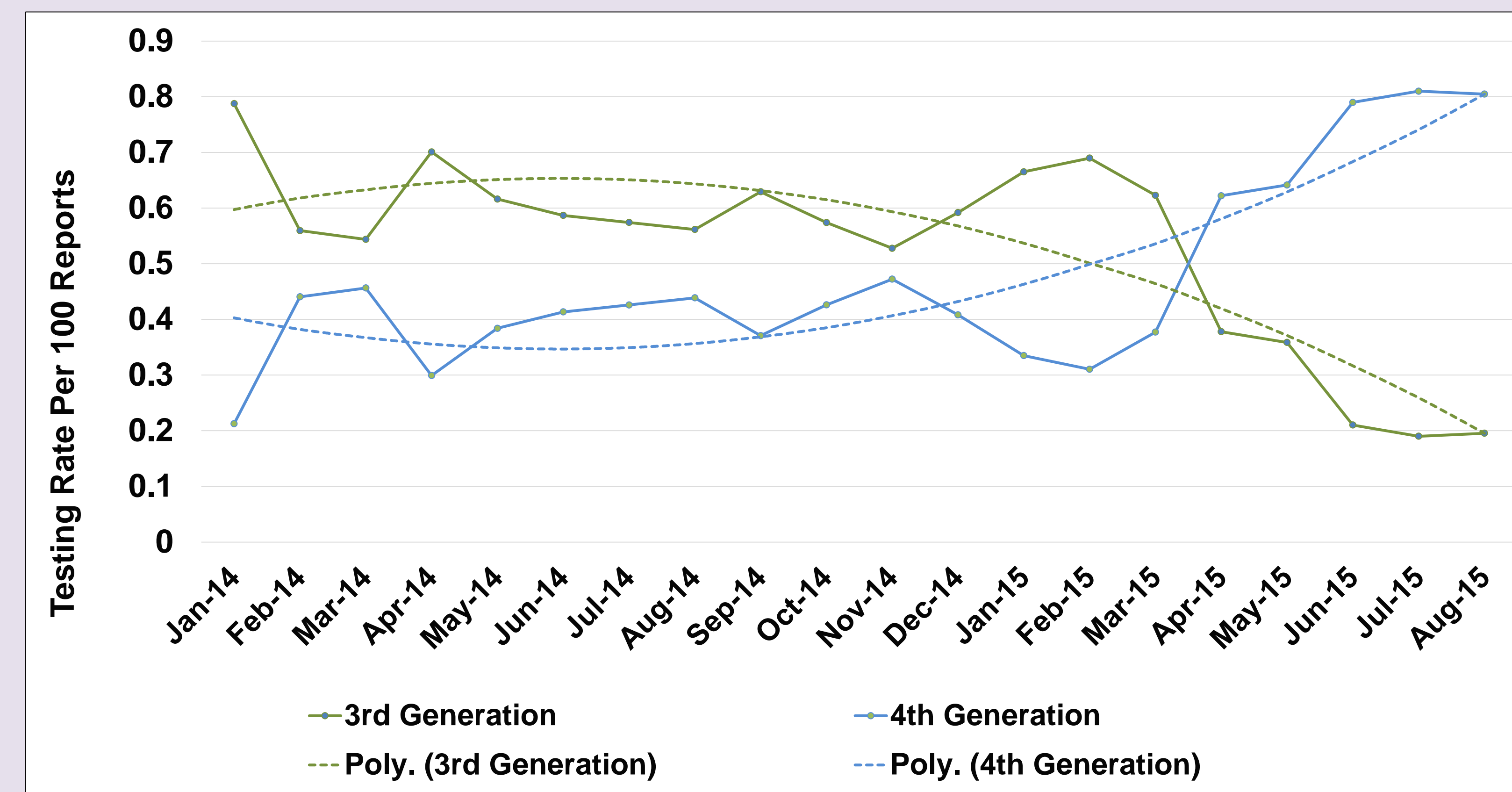


FIGURE 4: Percent of HIV-1/2 Ag/Ab Combo Immunoassay and HIV-1/2 Immunoassay Test Results by Laboratory Type, January 2014-August 2015

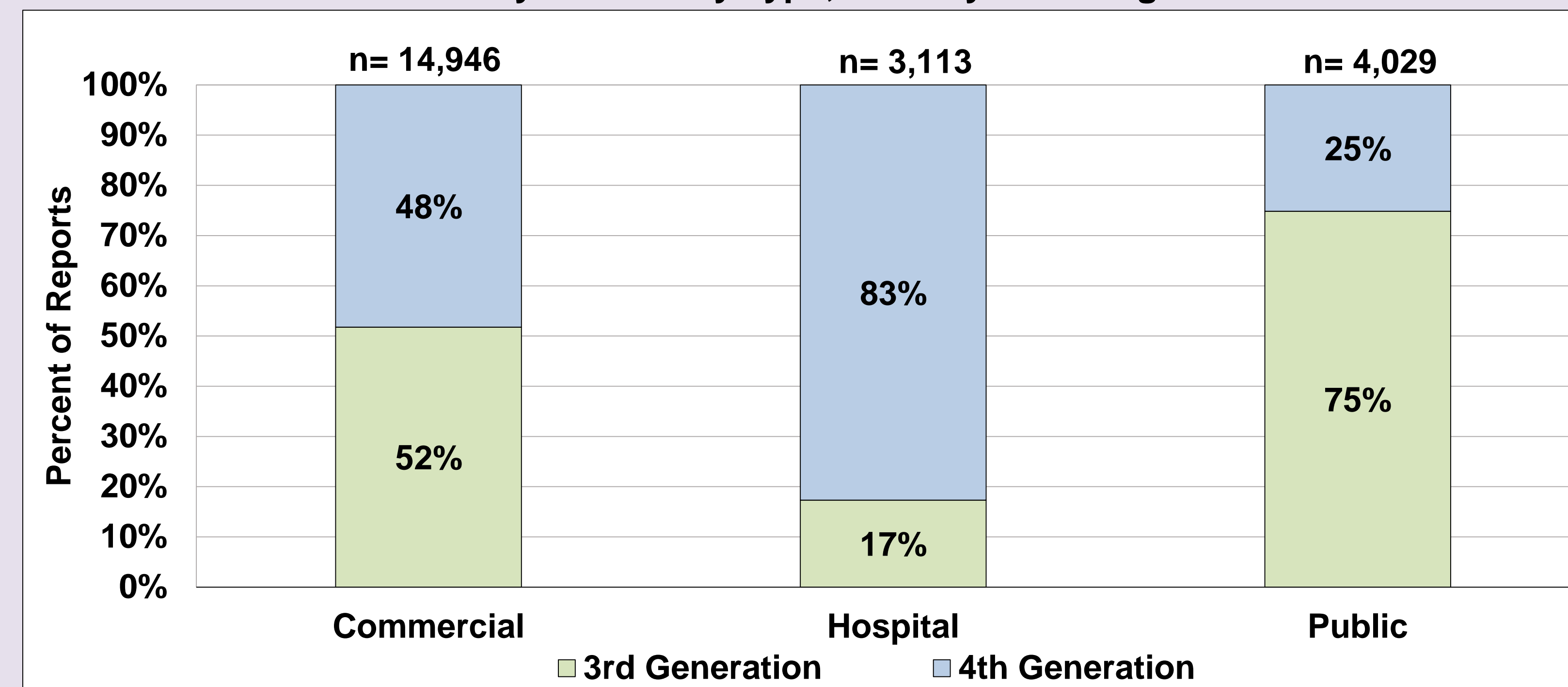
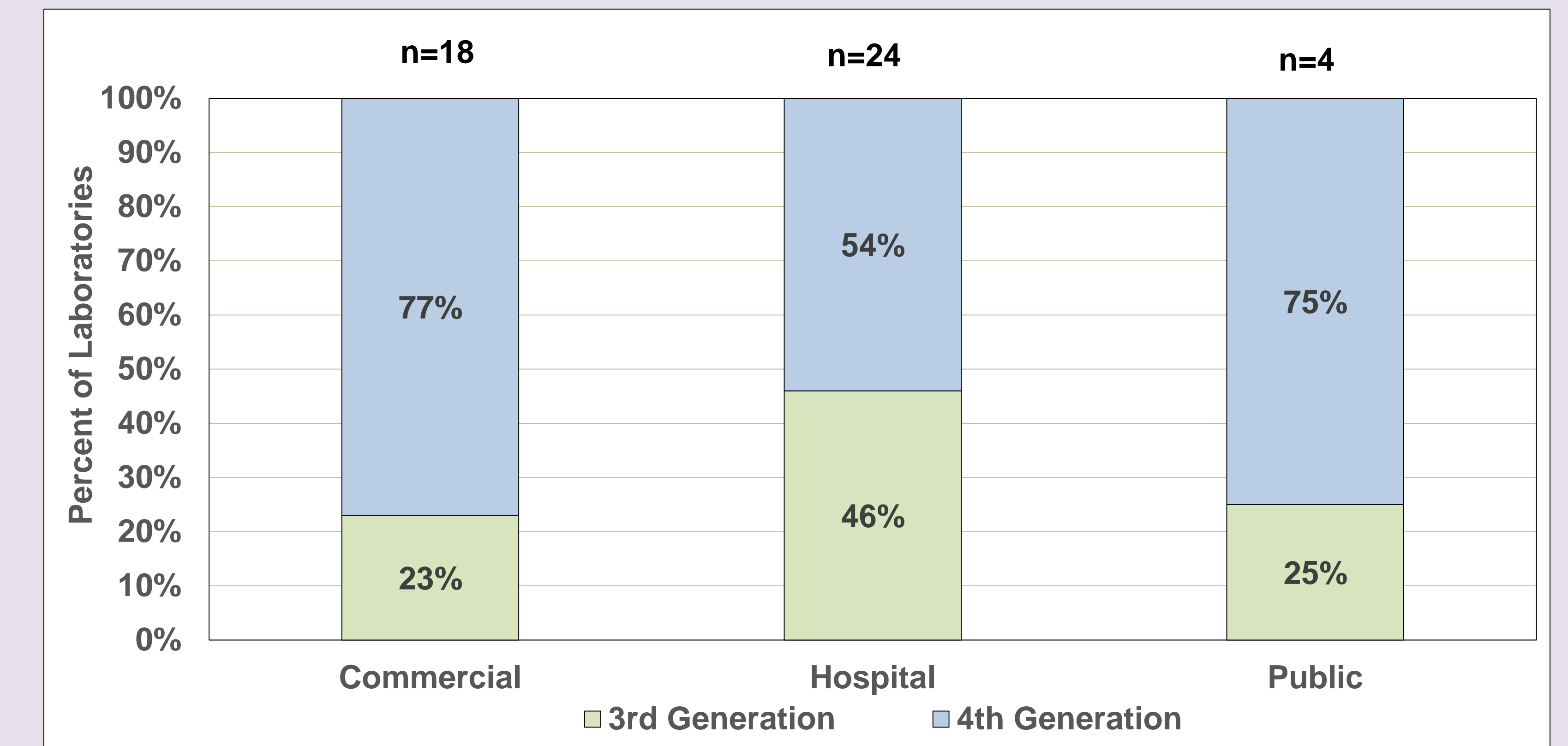


FIGURE 5: Percent of Laboratories HIV-1/2 Ag/Ab Combo Immunoassay and HIV-1/2 Immunoassay Testing by Laboratory Type in August 2015



- In January 2014, 15% (7/46) of laboratories reporting algorithm Step 1 results used the recommended HIV Ag/Ab combo immunoassay, representing 21% of all algorithm Step 1 results reported to the NYSDOH (Figure 2).
- In March 2015, the HIV-1/2 Ag/Ab combo immunoassay test became the dominant method employed by laboratories reporting algorithm Step 1 results to NYSDOH (Figure 3).
- Based on the frequency of submitted Step 1 results January 2014-August 2015, the transition from use of the less sensitive HIV-1/2 immunoassay to the recommended HIV-1/2 Ag/Ab combo immunoassay test was highly significant ($p < 0.0001$) (Figure 3).
- By August 2015, 65% (30/46) laboratories were using the HIV-1/2 Ag/Ab combo immunoassay methodology and 80% of the results were from the recommended HIV-1/2 Ag/Ab combo immunoassay test (Figure 5).
- Over 75% of commercial and public laboratories have moved to HIV-1/2 Ag/Ab combo immunoassay testing as of August 2015. Nearly half of reporting hospital laboratories continue to use the less sensitive HIV-1/2 immunoassay (Figure 5).

CONCLUSIONS

- After nearly two years, the majority of laboratories reporting algorithm Step 1 results to the NYSDOH have transitioned to the recommended HIV Ag/Ab combo immunoassay.
- Though substantial uptake of the preferred more sensitive test has occurred, several labs are not using the preferred testing methodology. Notably hospital laboratories lag behind public and commercial labs in adopting the HIV-1/2 Ag/Ab combo immunoassay.
- Most commercial and public laboratories have moved to 4th generation testing.
- The greatest volume of reporting of HIV-1/2 Ag/Ab combo immunoassay test results is by commercial laboratories.
- Education efforts should be made to encourage hospital laboratories to transition to the use of the HIV-1/2 Ag/Ab combo immunoassay test for Step 1 of the diagnostic testing algorithm.
- Laboratories are changing to recommended HIV testing methodologies. However, contractual and financial responsibilities may have precluded immediate adoption.
- Health departments should consider monitoring the adoption of the recommended test to improve early detection of HIV infection.

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