

# Implementation of Alere™ Determine HIV-1/2 Ag/Ab Combo

## in New York State CLIA Waived Point of Care Testing Sites

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### Background

With the launch of the National HIV/AIDS Strategy (2010) and under the Center for Disease Control and Prevention (2012) funding guidance for High Impact Prevention (HIP), HIV testing services and activities in NYS are targeted for high risk individuals unaware of their status, with the goal to reduce new HIV infections. HIV testing is the entry point for prevention and treatment and there is a public health need to identify new (acute) HIV infection when individuals are most infectious. To prevent further transmission, HIV testing technologies used in strategies targeting high risk individuals must emphasize sensitivity in performance. With the Food and Drug Administration (FDA) approval (January 2015) of the CLIA waived Determine Combo HIV 1/2/Ag/Ab® rapid test (Determine Combo), the potential to reach HIP goals of identifying early (new) and acute HIV infection was considered.

Rapid HIV tests are proven effective tools used in HIV prevention strategies to reach high risk individuals in non-clinical and alternate venues because they are simple, easy to use and test results are available within a matter of minutes. There are several different CLIA Waived devices available for use by HIV prevention programs. Approved rapid HIV test technologies have high sensitivity for established HIV infection, but they may have limited sensitivity for the diagnosis of early HIV infection. With the development and approval of a CLIA waived rapid test capable of detecting both HIV p24 antigen and/or HIV antibodies during the early phase of HIV infection, the potential is now available for HIP programs to detect early HIV infection in high risk populations they reach. Based on this evolution in test technology, guidance was issued to funded HIV testing programs encouraging them to use the most sensitive technology available and appropriate for their outreach settings in the beginning of 2015. In follow-up of the correspondence, New York State was able to identify five sites who implemented the Determine Combo.

### Objectives

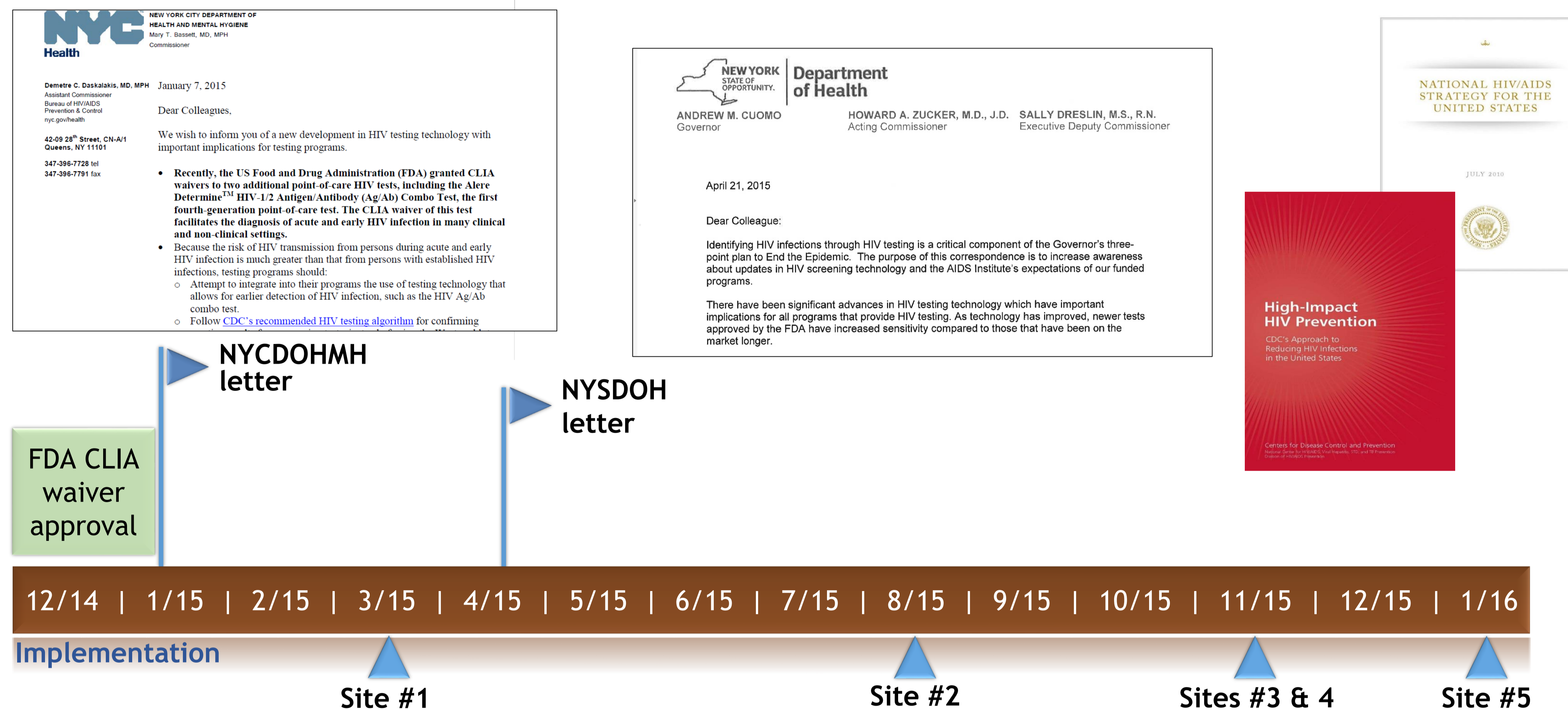
- Assess uptake of Determine Combo following FDA Approval CLIA-Waiver.
- Monitor ability of the Determine Combo to identify early/acute HIV infection in sites targeting high risk population.

### Project

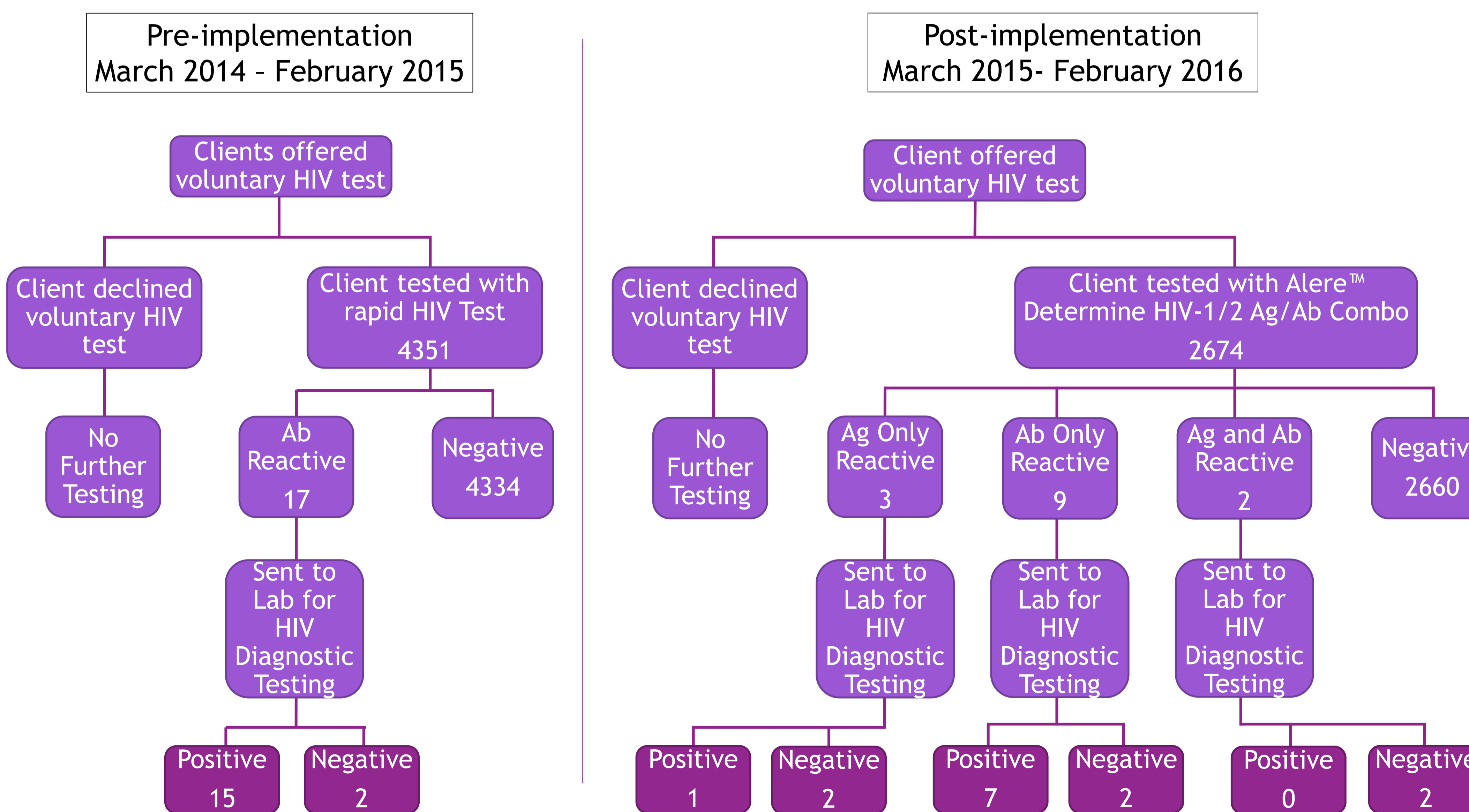
**Project:**  
Driven by HIP, NYS investigated the utilization and implementation of new HIV test technology available to CLIA waived sites to attain public health goals to identify and reduce HIV infection.

Assess the ability of Determine Combo to detect early/acute HIV infection in targeted testing programs under HIP.

### Timeline

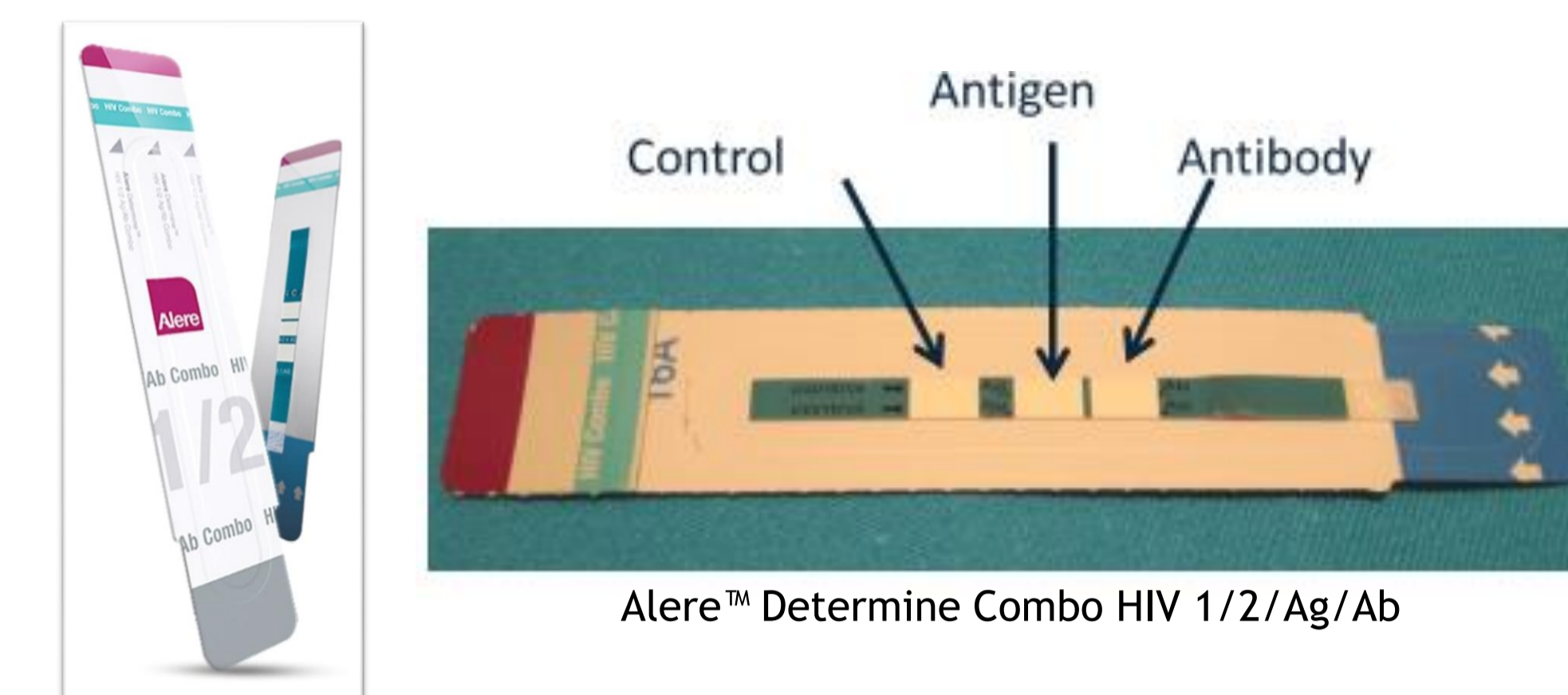


### Results



### Summary of Results

- 2 of the 17 (12%) pre-implementation results were false positives.
- 6 of the 14 (57%) Determine Combo reactive results were false positives.
- 1 of the 3 (33%) Ag only Determine Combo reactive results was confirmed to be an early/new HIV infection.
- 2 of the 3 (67%) Ag only Determine Combo reactive results were false positives.



### Conclusion

Despite the availability of new technology and guidance issued by NYS and NYC Health Departments to CLIA waived sites, few providers have transitioned to using the Determine Combo in their HIV screening programs.

Further data is needed to evaluate the performance and cost-effectiveness of the Determine Combo as a recommended rapid test device for HIP programs.

### Considerations

- Issues identified as reasons for the lagged implementation of Determine Combo include:
- Lack of knowledge of program staff regarding technology advancements.
  - Time and effort to revise laboratory quality assurance protocols.
  - Effort to arrange for staff training, skill building and competency assessments.
  - Regulatory requirements related to NYS CLEP program registration update of devices.
  - Benefits and costs analysis. Determining the benefit of introducing a new test, and the cost associated with the transition.
  - Testing staff concerns regarding the introduction of new technology and the impact on work flow.
  - Development of new messages for preliminary positive test results (Ag/Ab).
  - Arrangements for reference laboratory services to ensure appropriate confirmatory algorithms.

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- Site #2 - Greater Hudson Valley Community Health Center
- Site #3 - Community Health Action of Staten Island
- Site #4 - Asian and Pacific Islander Coalition on HIV/AIDS
- Site #5 - Trillium

