

New York State Experience in Implementing Alere™ Determine HIV-1/2 Ag/Ab Combo in STD Clinics

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Background

Since 2007, the New York State Department of Health (NYSDOH) Expanded HIV Testing (EHT) Initiative has supported routine HIV screening strategies in clinical settings to identify individuals with HIV infection who are unaware of their status and to reduce HIV transmission through linkage to care and access to treatment. These efforts have been carried out in accordance with recommendations put forth by the National HIV/AIDS Strategy (NHAS) and Center for Disease Control and Prevention guidelines and recommendations. The integration of HIV screening in Sexually Transmitted Disease (STD) clinic services has been a key component of the EHT initiative. HIV and STDs share common risk factors and modes of transmission, making clients of STD clinics high risk for acquiring HIV. Given frequent and ongoing risk among STD clients, the relationship between STDs and the spread of HIV infection, as well as a recent rise in syphilis in NYS, there is potential for increased rates of new HIV infection. For these reasons, STD clinics were deemed logical sites to implement new test technology and monitor the impact on the identification of acute and new HIV infection.

Objectives

The aim was to evaluate the experience in implementing the Alere™ Determine Combo HIV 1/2/Ag/Ab (Determine Combo) moderately complex test in STD clinics and to assess test performance.

Project

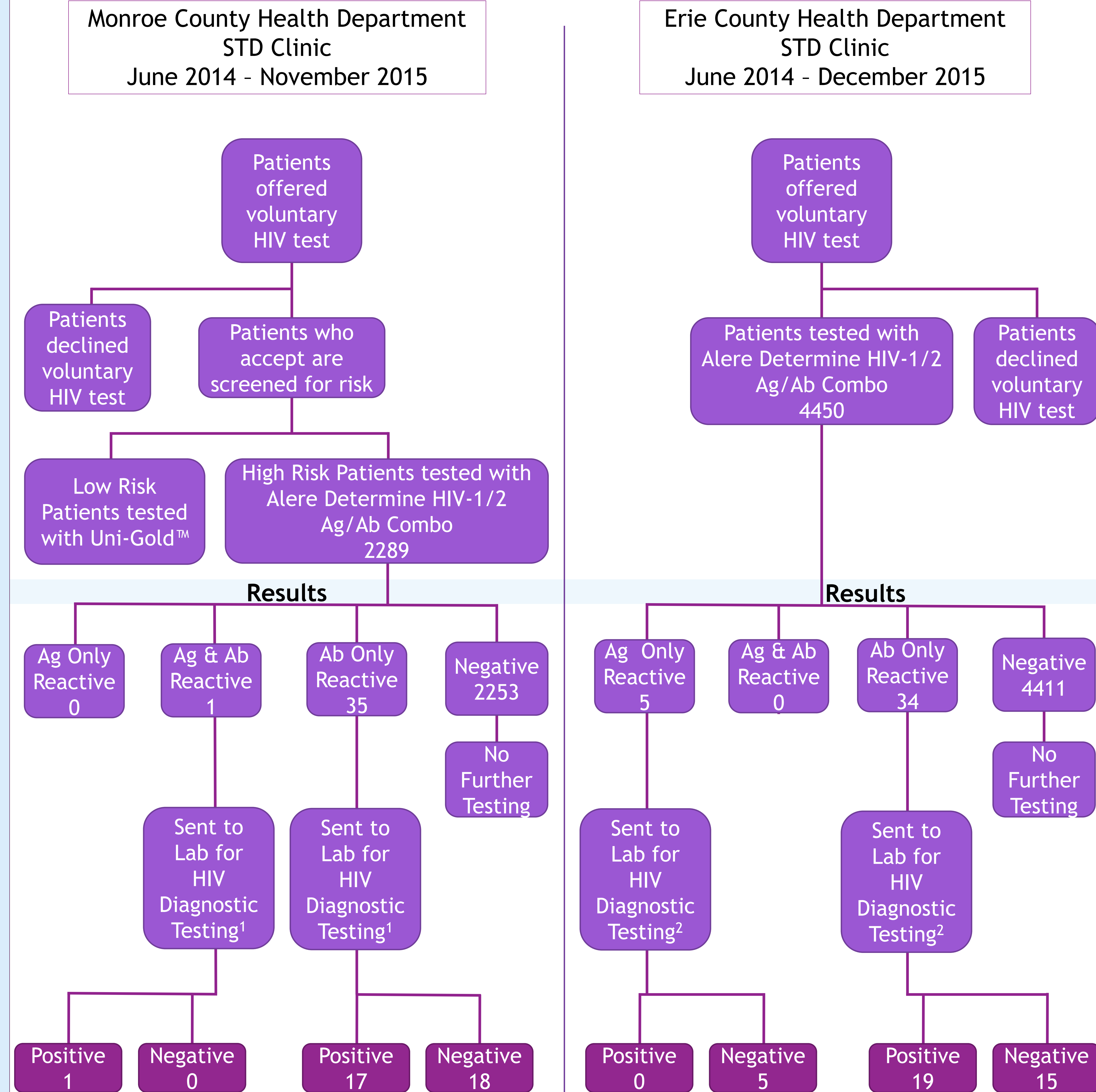
NYSDOH partnered with two high volume County STD clinics located in Western New York. Collaboration activities included:

- Provision of HIV rapid test kits and controls
- Provision of technical assistance and information to STD public health programs in keeping pace with changes in test technologies and diagnostic algorithms
- Monitoring testing outcomes, linkage to care and partner services through data collection

STD clinic protocol

- Laboratory update to existing permit category under NYS Clinical Laboratory Evaluation Program.
- Laboratory developed quality assurance protocols following manufacturer's instructions and conducted validation study of test.
- Laboratory established reference laboratory services for diagnostic testing of rapid reactive specimens.
- Clinic staff offered voluntary HIV screening, risk assessment, prevention counseling and specimen collection as part of routine STD services.
- STD clinic laboratory staff performed the Determine Combo as a moderately complex test using venous whole blood specimens
- Results were available by completion of service and delivered by clinic staff.

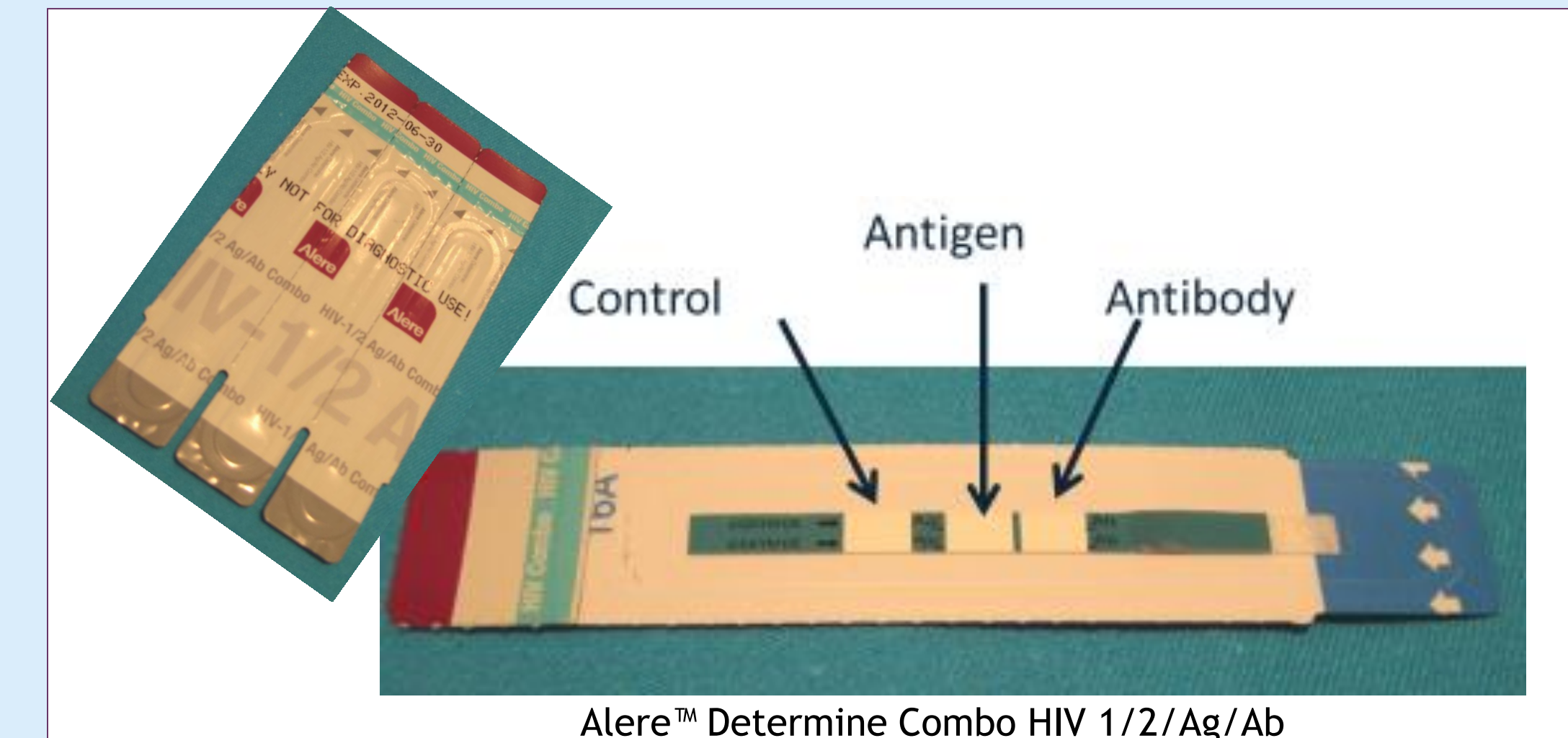
Results



1. New York State Wadsworth Center Blood Borne Viruses Laboratory (WC-BVL) performed HIV Diagnostic Testing. WC-BVL performed all three steps of the HIV Diagnostic Algorithm.
2. The STD clinics main laboratory performed the first two steps of the HIV diagnostic algorithm. Referred to WC-BVL to perform the third step of the HIV diagnostic algorithm.

Summary of Results

38 of the 75 (51%) Determine Combo reactive results were false positives.
1 of the 1 (100%) Ag & Ab Determine Combo reactive results was confirmed positive.
5 of the 5 (100%) Ag only Determine Combo reactive results were false positives.



Conclusion

- During this time period, implementation of Determine Combo in STD clinics did not demonstrate ability to detect individuals with new/early HIV infection.
- The use of rapid HIV tests, particularly in STD clinics serving high risk populations, benefits public health goals by providing same day results. However, laboratory diagnostic tests may better identify early HIV infection to aid in prevention efforts.
- More studies are needed to evaluate the Determine Combo performance and ability to detect acute/early HIV infection.

Considerations

- Clinic and lab staff differed in expectations and attitudes toward test device performance.
- The increased number of false positives compared to past experience using other devices impacted staff attitudes toward the advantages of HIV rapid test use for STD clients.
- There is an increased need for staff training and technical assistance during implementation of new test processes.
- Review of HIV test result messages, protocols for linkage to care based on a single rapid reactive test is needed.
- Promote consideration of clients risk assessment/history in test result interpretation and provide retesting messages for high risk patients.

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