**INTRODUCTION**

Following CLIA-waiver in December, 2014, NJ began statewide roll-out of the 4th generation rapid HIV test: Determine Combo. This rapid test provided results in 30 minutes and included a viral load result. NJ subsequently expanded the rapid test program to the New Jersey Health Care Network (NJHCN) to facilitate the earlier detection of HIV infections.

**THE ISSUES**

- It’s not just a question of how sensitive a test is... it’s also a question of how often we test clients, how effectively we link those who are infected into care, and how well we retain clients in care and treatment.
- In use since 2011, the NJ rapid testing algorithm (NJ - RTA), utilizes orthogonal testing i.e., independent verification of an initial antibody result by a second, but different HIV rapid test to confirm initial HIV screening results.
- FDA approval of a 4th generation test (DC) that detects both HIV-1/2 antibodies and the HIV-1 p24 antigen offers the potential of earlier detection that could improve screening performance, but complicates the issue of confirmation and linkage because it relies upon p24 Ag detection as an indication of recent infection.

**PLANNING FOR LINKAGE**

In each of the twenty-one New Jersey counties including both Ryan White (RW) Part A Transitional Grant Areas (TGAs), RW Part A Eligible Metropolitan Areas (EMAs) and Part B Planning regions collaborative groups were established. Additionally, collaboration was expanded to include Federally Qualified Health Care centers (FQHCs) and community clinics.

**The NJ Health Care Network**

- An HIV Specialty Care Clinic or Hospital was designated as the clinical caresite. Because sites share a common set of testing policies and procedures, screening could be tailored to experience, frequency of positive results and ability to provide on-site linkage into a care environment.
- To address agencies that only rarely experience a single rapid positive test or procedures, screening could be tailored to experience, frequency of positive results and ability to provide on-site linkage into a care environment.

**WHY USE A RAPID TEST ALGORITHM?**

The use of the (RTA) was pioneered in New Jersey alongside mandatory HIV-1 Western blot confirmation. We were among the first jurisdictions to employ a two-test RTA and to identify the potential value in shorting linkage delays.

**THE DEVIL IS IN THE DETAILS!**

The promise of a Point-of-Care device that would allow rapid screening facilities to identify acutely infected individuals and potentially bring them into care was attractive:

- Optimists thought this might happen as early as 2012!
- In 2010, two of our licensed clinical sites participated in the original FDA submission serving as ‘low prevalence’ sites providing data for the initial submission
- In addition to these sites, 17 more sites were added to the second phase in 2011.
- Other states and partners were being added in support of our clinical implementation.
- This initial contact allowed our medical technologists and scientists to gain experience with the product as the company envisioned it and to begin to think about potential implementation issues and training requirements.

**FDA Approval 2013**

- FDA Approval (CLIA Moderate Complexity) – August 13, 2013
- The absence of waiver limited our ability to employ the 4th generation rapid HIV test as a screening test in the majority of our screening locations – most sites are CLIA waived, but NJ CLIS licensed locations.
- In the fall of 2013, we plotted the product in one of our CLIA moderate complexity sites in Newark. NJCRI and followed use of the product for the next several months as an initial screening device in the NJ Rapid Test Algorithm
- Performance on standard, required Quality Control (QC) Issues: No significant increase in QC failures
- Performance Issues: Increase in “Discordant Results”, but not enornous

**Waiting for Godot – CLIA WAIVER**

- For a variety of reasons, FDA CLIA Waived (CLIA Waived) did not occur until December 9, 2014
- The decision to seek CLIA Waiver after initial product results revealed a significant delay and changes in the product that was eventually entered distribution
- Many of the required changes resulted in significant changes to the rapid testing policies and procedures
- Nevertheless, we began to transition in January, 2015.

**Conclusions**

1. NJ has established a statewide, collaborative linkage program designed to provide HIV screening at multiple venues, with credible verification of screen positives and linkage into care within 2 business days.
2. We have adapted an existing two test RTA for use with a 4th generation screening assay
3. We have transitioned throughout NJ rapid HIV screening from a 2nd generation screening device to a newly FDA waivered, 4th generation screening device
4. We have analyzed discordant results from positive HIV screening using both devices and conclude that the p24Ag marker is responsible for a significant number of false positive referrals without substantial gain in number of infections being diagnosed
5. The six additional infections associated with a falsely negative Unigold represent enhanced sensitivity of the Determine Combo device in detecting HIV-12 antibodies
6. Although the total of 41 falsely positive results remains within the manufacturer’s product claimed, it is problematic for many sites.

**References**