



# Reducing the Delay: Can a Rapid HIV Test Discriminate False Positives as Effectively as a Western Blot – the NJ Experience



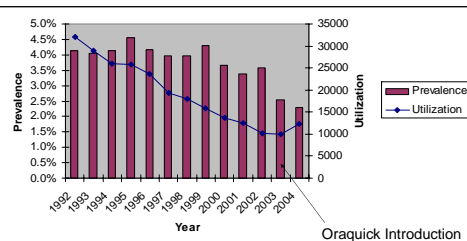
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## Issues/Background

- Concerns about the significance of false-positive results in low-prevalence populations led the US Public Health Service to utilize a sequential, two-test algorithm (EIA followed by a Western Blot) to confirm initially reactive rapid HIV results.
- Confirmation of preliminary positives by Western Blot is time-consuming, complex and labor intensive. Clients often wait 48-96 hours before receiving a confirmed result, experience enormous anxiety and many fail to return for follow-up.
- Among HIV EIA screen positive blood donors 4.8% have false positive Western Blots.<sup>1</sup>
- Prior to rapid testing approximately 35% of all patients visiting NJ Counseling and Testing Sites (CTS) for HIV testing failed to receive their results, because they failed to return for a follow-up visit.

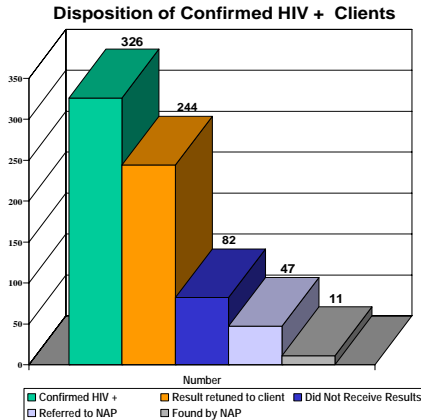
Currently, more than 97 % of tested clients receive negative results at their initial visit, but 35% of clients who need to return for HIV confirmation *still fail* to return and may not be referred for treatment.

## HIV Testing in New Jersey



<sup>1</sup> Kleinman S, Busch MP, Hall L, et al. False-positive HIV-1 test results in a low-risk screening setting of voluntary blood donation. *JAMA*. 1998;280:1080-1085.

## THE PROBLEM – The Second Visit



## RETURN FOR RESULTS:

Of 326 Western Blot Confirmed Positive HIV results, 82 (25.2%) failed to return and were not initially notified of their HIV status. Forty seven were referred to the Notification Assistance Program (NAP). Eleven (23.4%) of those referred to the NAP were eventually located after varying periods of delay. Seventy-one (71) HIV + clients were never contacted regarding their final HIV status.

## PROPOSED SOLUTION:

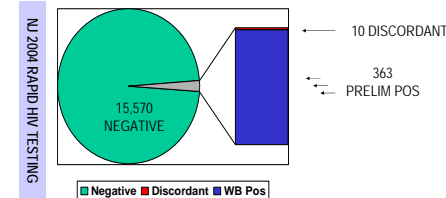
**CONFIRM A RAPID HIV RESULT WITH A SECONDARY RAPID HIV TEST AT THE TIME OF THE INITIAL SCREENING**

## THE ISSUES:

- Will it detect False Positives as successfully as the Western Blot?
- Will it confirm True Positives as effectively as the Western Blot?

## Methods:

- Retrospective study using all residual specimens sent to NJ Public Health and Environmental Labs for HIV confirmatory testing.



TOTAL TESTS	HIV PRELIM POSITIVE	WESTERN BLOT – Discordants
7/1/04 – 4/19/05	363 (2.3 %)	10 (3.4% of Prelim Pos. – 0.07% Overall)
15,923		

- Utilizing the Western Blot serum samples available on 8 of 10 discordants, alternative rapid HIV tests were performed: (BioRad Multispot®, MedMira Reveal®, and Trinity Uni-Gold™) to see whether a second, rapid HIV could effectively identify a discordant specimen.
- Residual specimens from 363 Western Blot confirmatory specimens were retrospectively tested with alternative rapid HIV tests: (BioRad Multispot®, MedMira Reveal®, and Trinity Uni-Gold™) to see whether a second, rapid HIV could confirm a preliminary positive HIV specimen.

## Results

- IDENTIFICATION OF FALSE POSITIVES
  - OraQuick® testing was reproducible in 7 of 8 available serum discordant specimens .
  - Two of three alternative rapid tests (Uni-Gold® and Reveal®) successfully identified all 8 available discordant specimens as non-reactive.
  - The Multispot® assay correctly identified 7 of 8 samples as negative with one specimen demonstrating operator-dependent results.

## Results

	Confirmatory test results	
	8 Western Blot negative (False Positive OraQuick)	355 Western Blot positive (True Positive OraQuick)
OraSure OraQuick	7 positive 1 negative	355 positive
Trinity Uni-Gold	8 negative	355 positive
BioRad Multispot	7 negative 1 positive	354 positive 1 QNS
MedMira Reveal	8 negative	340 positive 15 sample interference
Follow-up of >2 months	4/6 negative Western Blot 4/6 negative viral load	



## CONCLUSION:

- A rapid, alternative confirmatory algorithm has been used to retrospectively confirm all Oraquick® HIV positive tests in New Jersey over a ten month period.
- A **waived algorithm** based upon initial Oraquick® HIV screening and confirmatory testing by Trinity Unigold™ Recombigen confirmed all Western Blot positive specimens while excluding all false positives identified by the initial Oraquick® screen.
- A rapid testing strategy that provides a complete answer in a single visit would allow Counseling and Testing personnel to more effectively guide HIV + patients into treatment, while avoiding the nearly 25% of HIV + clients who are lost to follow-up.