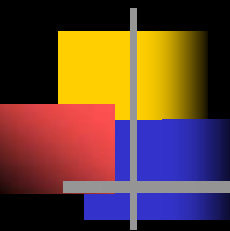


Can a second rapid HIV test discriminate false positives as effectively as a Western Blot? The NJ Experience

Evan M. Cadoff, MD

Robert Wood Johnson Medical School

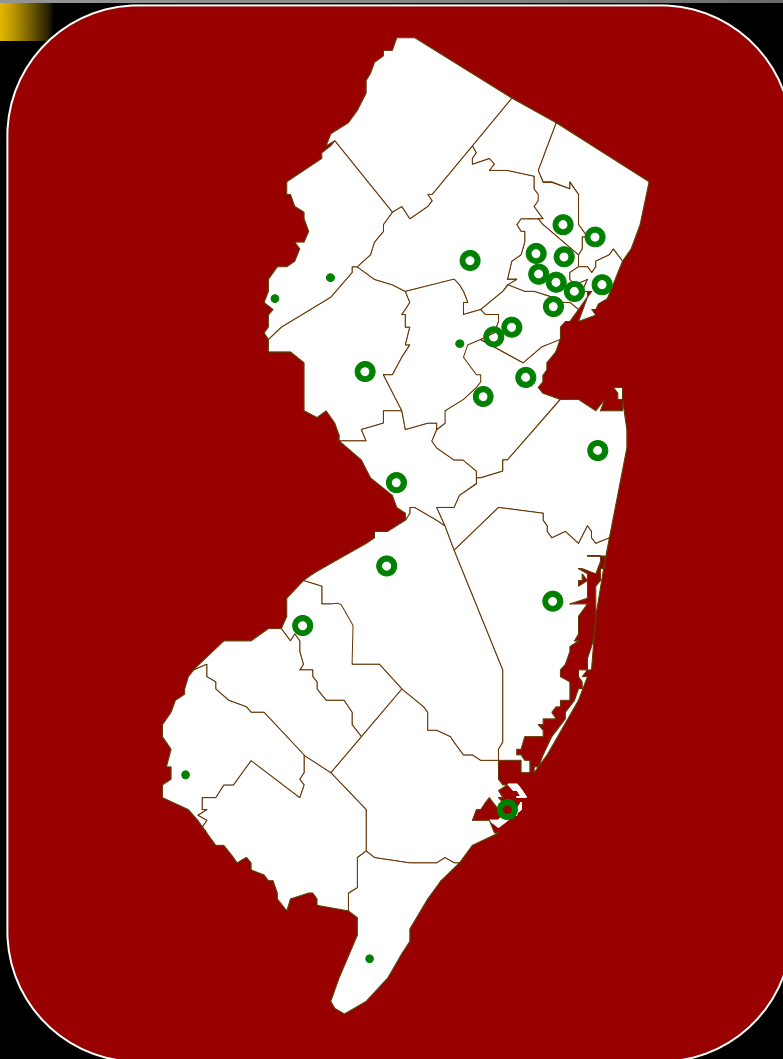
New Brunswick, NJ



Can a second rapid HIV test
confirm preliminary positives
as effectively as a Western Blot?
The NJ Experience

Evan M. Cadoff, MD
Robert Wood Johnson Medical School
New Brunswick, NJ

New Jersey CTS sites



- 23 primary sites

Conventional testing:

- Blood/oral specimens sent to NJ-DHSS lab
- 65% receive post-test counseling
- 35% do not return for results
- Rapid testing needed

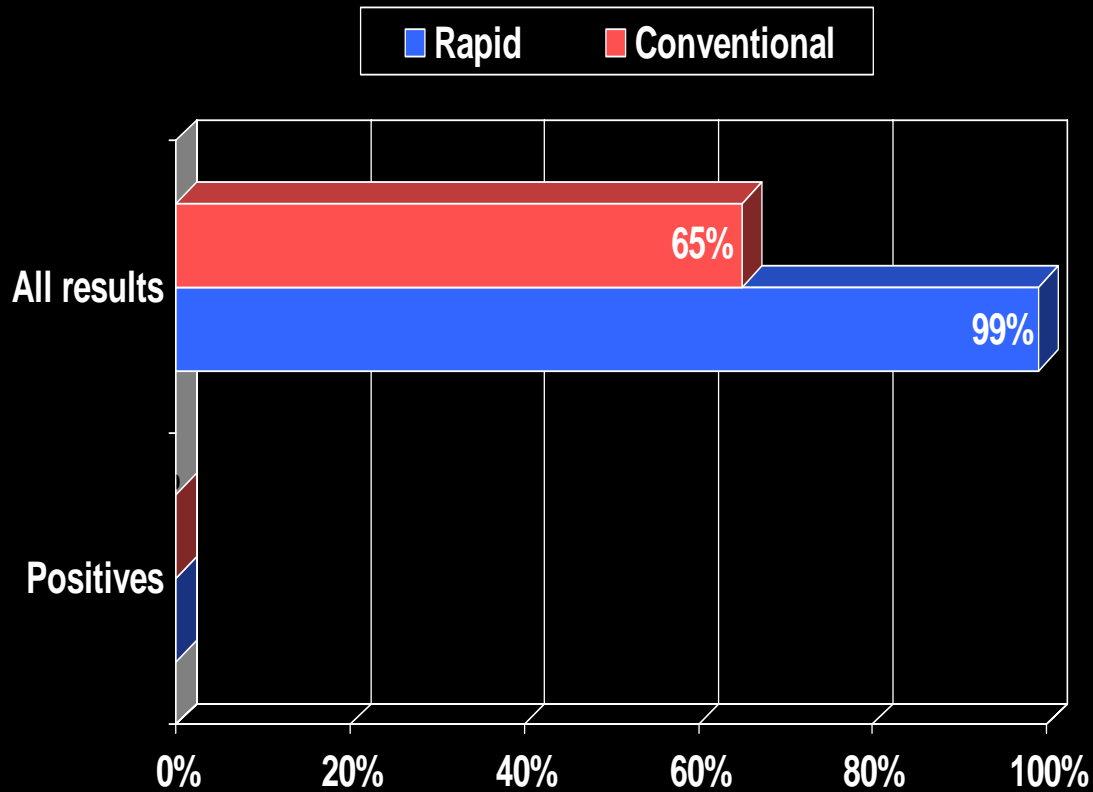
New Jersey rapid testing

OraQuick started Nov 1, 2003:

- 23 primary licensed sites
- 32 satellite sites
- Western Blot confirmation at state lab
- Over 70 CTS activities, including:
 - Hospitals/EDs
 - FQHCs
 - CBOs
 - STD clinics
 - Health departments
 - Mobile vans
 - One-time community events

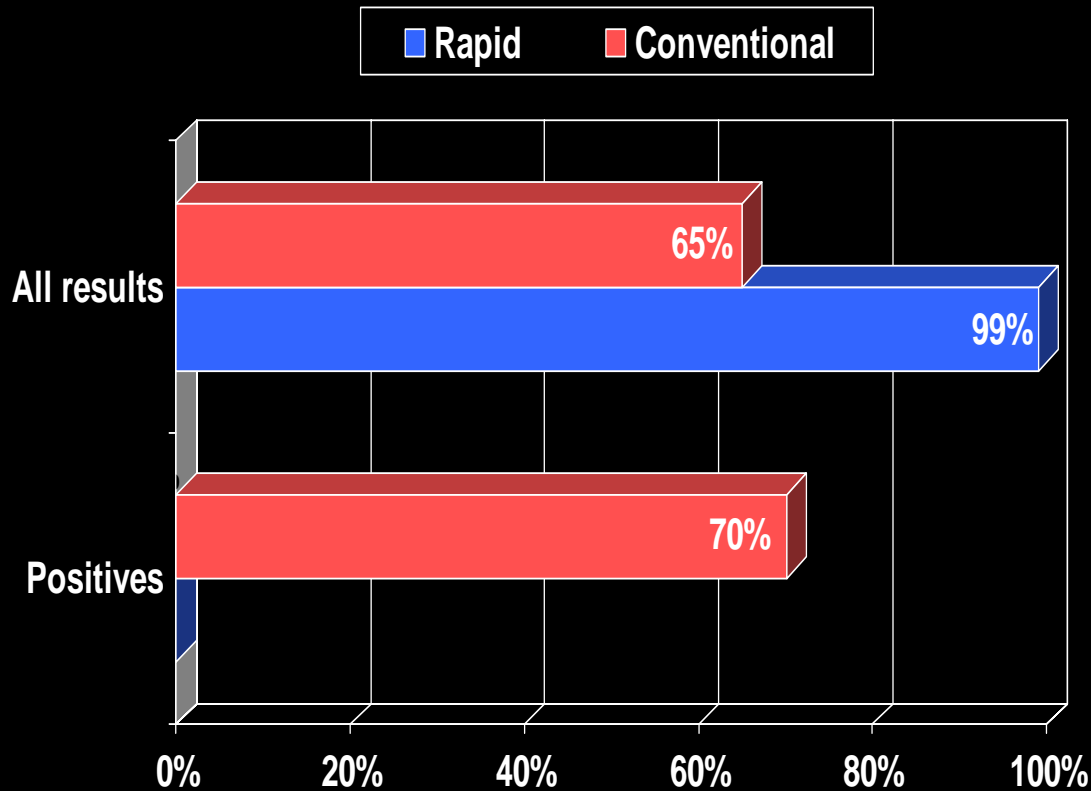


Clients receiving post-test counseling



Marked improvement with introduction of rapid testing

Clients receiving post-test counseling

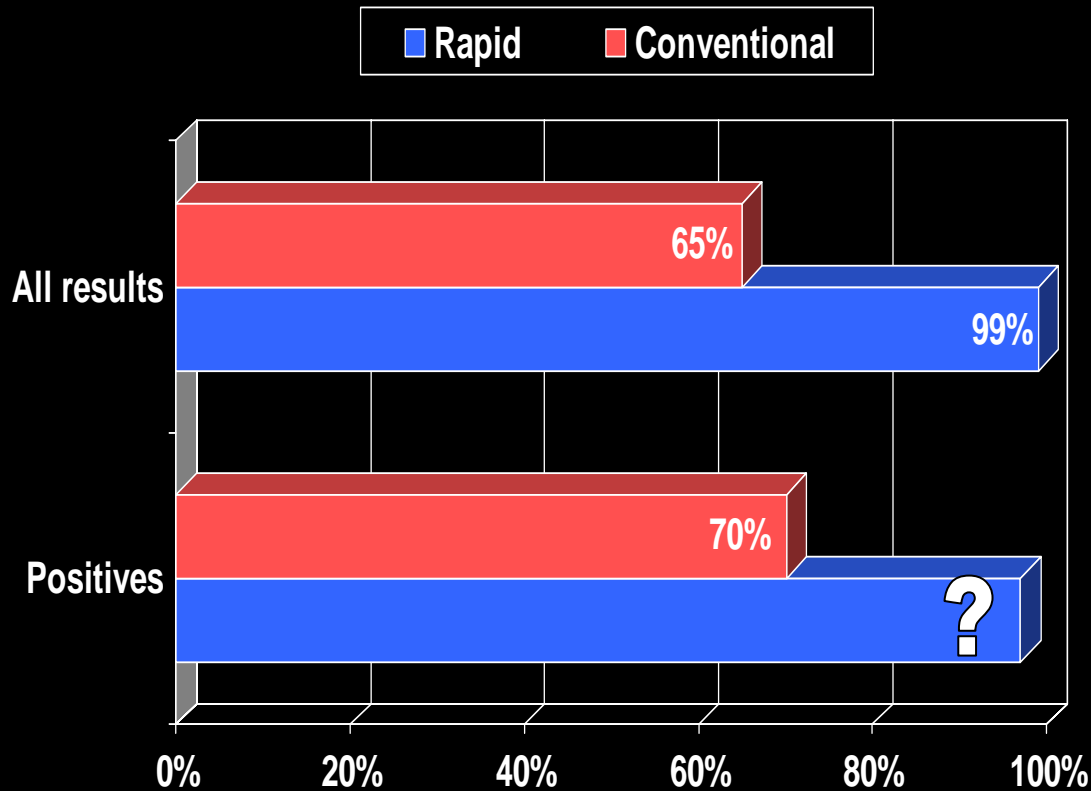


Marked improvement with introduction of rapid testing

Preliminary positives:

- 7.1% refused blood draw for confirmation
- 25.8% of those drawn did not return for results
- 70.1% of confirmed positives got their results and post-test counseling

Clients receiving post-test counseling



Marked improvement with introduction of rapid testing

Preliminary positives:

- 7.1% refused blood draw for confirmation
- 25.8% of those drawn did not return for results
- 70.1% of confirmed positives got their results and post-test counseling

Can rapid confirmation extend our success to preliminary positives?



Questions for rapid confirmation

- Will a finger stick be more acceptable for confirmation
- Can rapid immunoassays perform as well as the 'gold standard' Western Blot?

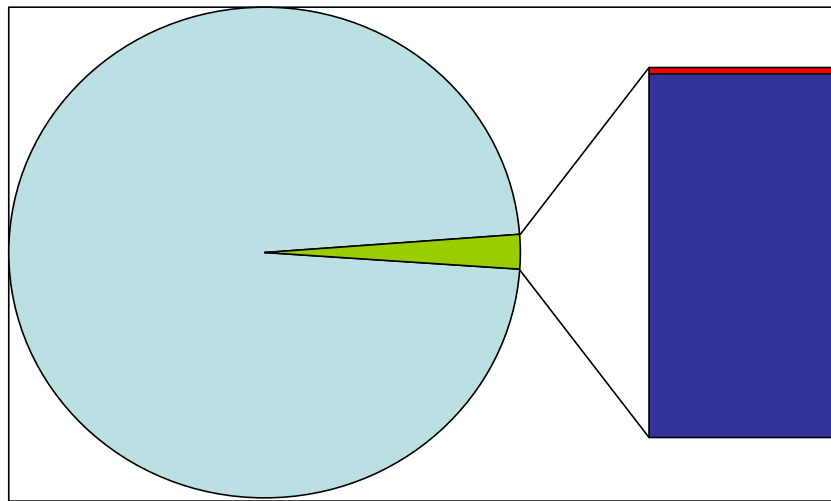


BBI Seroconversion Panel Results:

Member #	Days since first bleed	EIA	Western blot	Viral load	Rapid test
PRB959-01	0	0.1	No bands	2×10^5	Negative
PRB959-02	7	0.1	No bands	$>8 \times 10^5$	Negative
PRB959-03	9	0.2	No bands	$>8 \times 10^5$	Negative
PRB959-04	14	1.8	p24, gp160	8×10^5	Positive
PRB959-05	19	7.3	p24, gp160	5×10^5	Positive
PRB959-06	21	7.6	p24, gp160	3×10^5	Positive
PRB959-07	26	7.8	p24, gp160	$>8 \times 10^5$	Positive

Rapid confirmation trial

July 1, 2004 through April 19, 2005



■ Negative ■ Discordant ■ WB Pos

- 15,923 OraQuick tests statewide
- 363 preliminary positive samples to state lab for confirmatory testing
 - 355 Western Blot positive
 - 8 Western Blot negative



Rapid confirmation trial

- All 8 Western Blot negative clients:
 - Included in CDC Post-marketing surveillance study (PMS-2)
 - 6/6 negative on follow-up at least 8 weeks later, both antibody and nucleic acid testing
 - 4/7 reacted with non-viral components of OraQuick device

All 8 were false positive OraQuick tests

Rapid confirmation trial

Samples re-tested with:

- Trinity Uni-Gold
- BioRad Multispot
- OraSure OraQuick
- MedMira Reveal



Confirmatory test results

	8 Western Blot negative (False Positive OraQuick)	355 Western Blot positive (True Positive OraQuick)
OraSure OraQuick	8 positive	355 positive
Trinity Uni-Gold		
BioRad Multispot		
MedMira Reveal		
Followup of >2 months	6/6 negative Western Blot 6/6 negative viral load	

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BioRad Multispot	7 negative 1 positive	354 positive 1 QNS
MedMira Reveal		
Followup of >2 months	6/6 negative Western Blot 6/6 negative viral load	

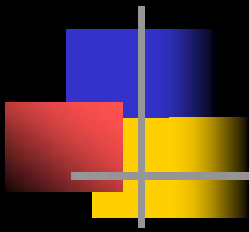
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BioRad Multispot	7 negative 1 positive	354 positive 1 QNS
MedMira Reveal	8 negative	340 positive 15 sample interference
Followup of >2 months	6/6 negative Western Blot 6/6 negative viral load	



Rapid confirmation trial

- **Repeat OraQuick** (CLIA waived for whole blood or oral fluid)
 - All samples reproduced
 - Not approved for serum testing, or stored samples
- **UniGold** (CLIA waived for whole blood, CLIA moderate for serum)
 - All samples matched Western Blot
 - Study used serum, clinics would perform whole blood testing
- **Multispot** (CLIA moderate for serum/plasma)
 - 1 false positive
- **Reveal** (CLIA moderate for serum/plasma)
 - No false positives, or false negatives
 - Several unreadable samples



A second rapid HIV test can confirm
a positive OraQuick result as
reliably as a Western Blot.



Western Blot Confirmation

- Failures to confirm results:
 - No confirmatory sample collected
 - Not all clients return for confirmatory results
- 29.9 got no result—as effective as a false negative result (but follow-up data is not yet complete)

Effective sensitivity of Western Blot confirmation is somewhere above 70.1%



Using OraQuick with Uni-Gold confirmation:

- Matched OraQuick with Western Blot confirmation in 100% of 15,923 clients studied
- Finger stick confirmation may reduce the refuse-to-confirm rate
- Rapid confirmation may virtually eliminate the non-returners
- Effective sensitivity may approach 99-100%
- Counseling, contact elicitation and referral for treatment can be done immediately



Next steps

Prospective evaluation of algorithm of **OraQuick with Uni-Gold** confirmation:

- Real world performance of a rapid test as confirmation
- Effect on post-test counseling rate
- Reduction in time delay in delivering confirmed result to clients using different confirmatory test algorithms
- Expansion to Notification Assistance Program

