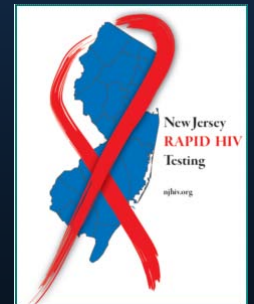


Implementation of "Rapid-Rapid" in New Jersey: Our First 25,000

Eugene Martin, Ph.D.
UMDNJ - Robert Wood Johnson Medical School

CDC/APHL DIAGNOSTICS MEETING
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March 24-6, 2010



Goals for Today

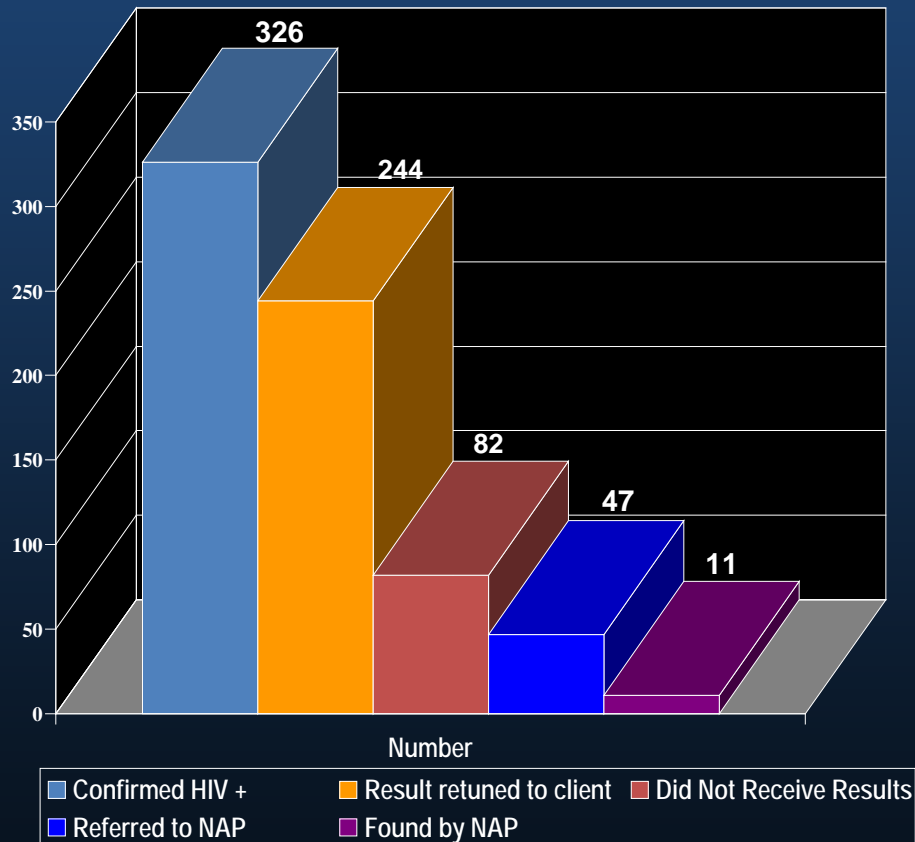
1. How we got here.
2. Issues in selecting a Rapid Testing Algorithm (RTA).
3. Why New Jersey isn't your typical HIV epidemic.
4. Validation studies: – “Does an RTA work?”
5. Implementation – NJ Rapid-Rapid -The first 25,000
6. Bottom line → Are we testing more? Are we getting more folks into treatment?
7. NJ's To Do List

Western blot – “The Gold Standard”

- Getting old...
 - Complex test - prone to QA issues.
 - Cost issues
 - Supply and Manufacturing issues
 - Indeterminate HIV-1 **Western Blots**:
 - Need for additional **testing**
 - Differences in Western blot performance
- and delays in rendering a final interpretation
- Sometimes we focus too much on the issue of specificity and not enough on the consequences of delay.

Why Rapid Verification?

Disposition of Confirmed HIV + Clients



NJ Statewide Data - 2004

– Problem

- Preliminary Positive clients fail to return for results (21.8%)
- NAP succeeds ONLY 20% of the time in locating these clients

– Solution

- Confirmatory testing on-site, same day

How Often Do We Lose Clients When We Fail to Complete a Multi-Step Assessment

- New Jersey: 25 – 30% fail to return for a second testing-related visit.
- Los Angeles: 35-40% fail to return

Assumptions

- Its difficult for some clients to work up the courage
→ if there is any delay it is an excuse for procrastination
- Identifying an infected individual and linking them to care immediately → increases the likelihood for treatment
- Consistently Identifying truly infected individuals improves overall program credibility with providers.
- Our goal: Test and Link to Care in a single visit

RTA strategy

- Testing strategy - recognize that disordered lives relate poorly to scheduled encounters.
- Efficient screening and immediate connection to healthcare are more likely to be successful than requiring individuals to keep appointments at some point in the future.
- OUR GOAL:
“Screen today → If necessary, connect with a healthcare provider today”

RTA: Design issues

- How is your program organized?
 - Centrally organized or independent labs?
- How much
 - Confidence do you have in each lab's ability to handle multiple assays?
 - Experience do your laboratories have in sorting out 'discordant results'?
- Support
 - What will happen if there is a problem?

Three Test RTA vs. Two Test RTA

- **Definitive** (3 Test RTA)

- Does program credibility hang on 'getting it completely right'?
- A 3 test RTA will allow you to resolve more discordant events; BUT
- **Downside:** QC costs and potential operator errors for seldom used tests

- **Efficient** (2 Test RTA)

- If we identify 98% of infected clients in a single visit, and successfully connect them to healthcare → way ahead.
- Less to remember, less to forget in a two-test algorithm
- **Downside:** A very small number will not be resolvable at the time of initial testing.
- **Key:** What happens to the problem cases – NJ is centralized → laboratorian/physician interaction early.

New Jersey's HIV Epidemic

- The face of the NJ HIV epidemic is a bit different from urban centers like San Francisco and New York City
 - Although NJ is a high prevalence state, the face of HIV is made up increasingly of **women and minorities**.
 - The NJ epidemic is characterized by urban pockets of **infection, drug abuse and poverty**
 - Historically,
 - 5th in the US in cumulative reported AIDS cases
 - 3rd in the US in cumulative reported pediatric AIDS cases
 - 34,915 persons living with HIV or AIDS (12/31/08)

Unique Characteristics

- **Area:**
 - New York State: 54,475 square miles
 - **New Jersey: 7,836 sq. mi**
 - Los Angeles: 469.1 sq mi
 - San Francisco: 47 sq. miles
- **Population:**
 - New York State ~ 19.49 million
 - Greater LA (2007) ~17.78 million
 - **New Jersey ~ 8.69 million**
 - San Francisco ~ 4.18 million
- **Scale:** Drive End to End in NJ 3 hrs. (W→E 1 $\frac{1}{2}$ hours)
- A mixture of urban/suburban and rural communities
 - North - urban
 - South - rural
- Many different venues perform rapid testing

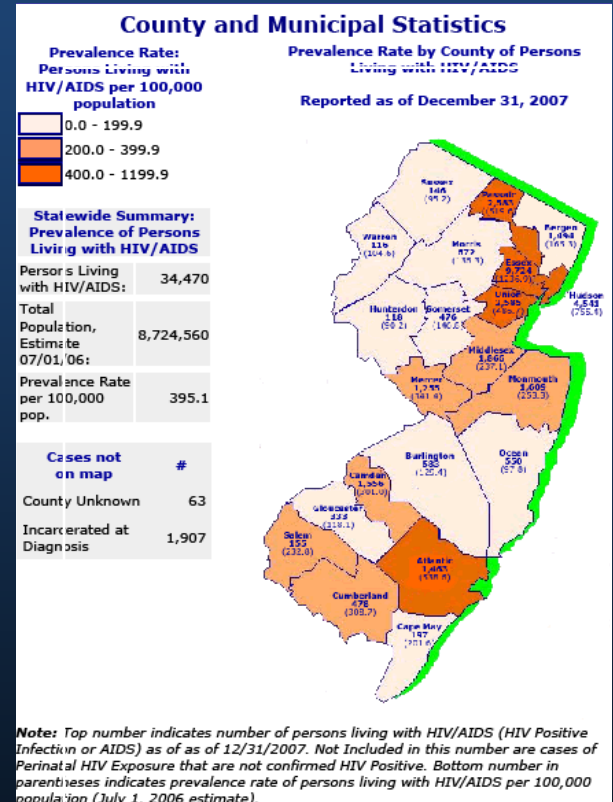
New Jersey's Rapid Testing is Widely Available

NJ Rapid HIV Testing Program

- 39 licensed primary facilities
- 34 satellite licenses
- Western Blot confirmation at state lab (PHEL) in Trenton

Over 90 CTS testing sites:

- Hospitals/EDs
- FQHCs
- CBOs
- Health departments
- Mobile vans
- Prisons

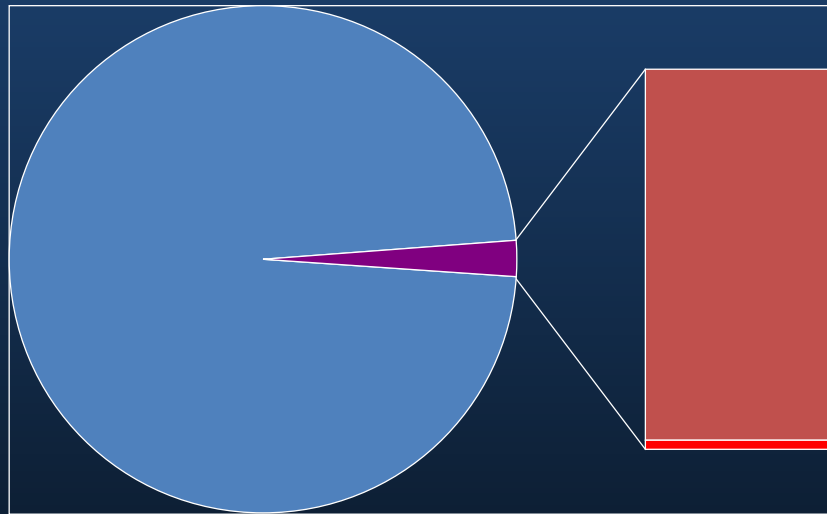


Validation Studies – 2004-8

- Goal – To satisfy ourselves that a second, independent rapid HIV test could reliably identify false positive HIV tests
 - 2004 – Using residual serum confirmed all Western blot positive sera obtained in the previous year and available at the Public Health Labs
 - 2005-8:
 - Using residual sera and plasma samples to confirm that a second independent rapid HIV test could reliably identify false positive HIV tests

Rapid confirmation trial

July 1, 2004 through April 19, 2005



■ Negative ■ WB Pos ■ Discordant

- 15,923 OraQuick tests statewide
- 363 prelim positive samples to state lab for confirmatory testing
 - 355 Western Blot positive
 - 8 Western Blot negative
- A second rapid test – Unigold identified all 8 false positive rapids and agreed with all 355 HIV + diagnoses

Practical issues in our RTA Selection

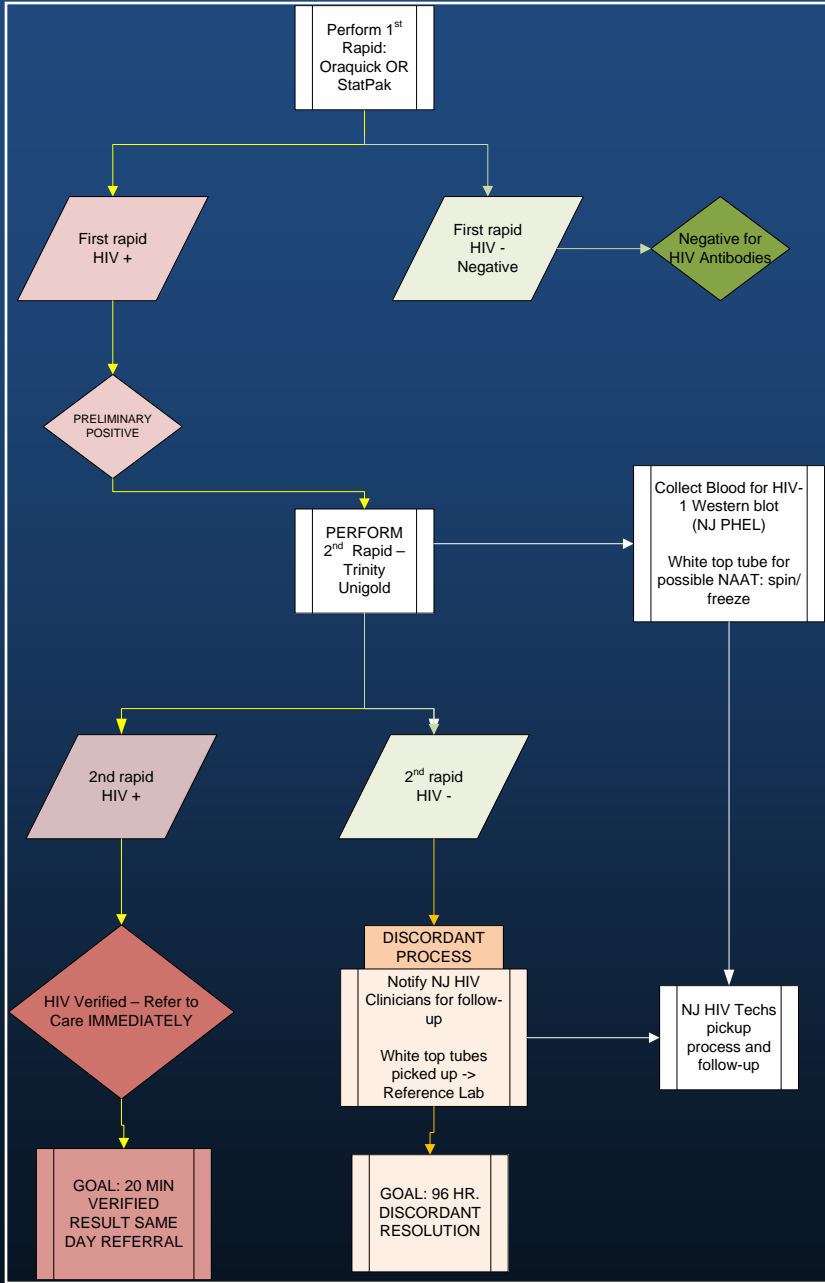
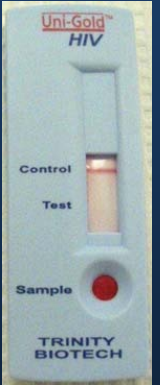
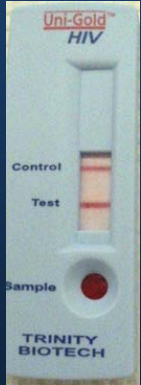
1. Oraquick (Oral or Fingerstick) were both in use in NJ from 2004 on.
2. StatPak was introduced in NJ at a significant number of sites 2008

➔ **INITIAL SCREENING:** EITHER OraQuick (FS or O) or StatPak

➔ **VERIFICATION:** Trinity Unigold

1. Two test process to minimize:
 - Issues of training
 - Issues of competency assessment
 - Issues of required QC
 - A discordant situation in the second step immediately brings the specimen and the client to the attention of clinicians for definitive follow-up
 - Healthcare linkage are achieved on the basis of two tests taking less than ½ hr.
2. Since UniGold was not labeled for HIV-2 detection, we opted to initially screen by Oraquick or StatPak and verify by UniGold. If it turned out that there was a problem due to HIV-2 detection, it would have triggered central support.

NJ RAPID TESTING ALGORITHM



Rapid-Rapid Implementation

– DEPLOYMENT PLAN:

- December, 2008: 3 pilot sites began the 'roll-out'
- Higher prevalence first, lower prevalence later
- Policies, Procedures, Counseling Messages and Forms were completed for the entire system available before training
 - Available on the 'web': <http://www.njhiv1.org>
- Side-step the issue of confirmation

– EXPECTATIONS:

- Doesn't eliminate Western blot confirmation, BUT allow immediate linkage to care reliably without a western blot!
- Less than 1 in 100 would later be removed from care because of a failure to confirm

– UNKNOWNNS: What will be the real world performance of a rapid test in a confirmatory setting?

- Does reducing the delay really improve the linkage to care?
- False Pos frequency? Would there be False Neg's

Status of Rapid-Rapid in New Jersey

February, 2010

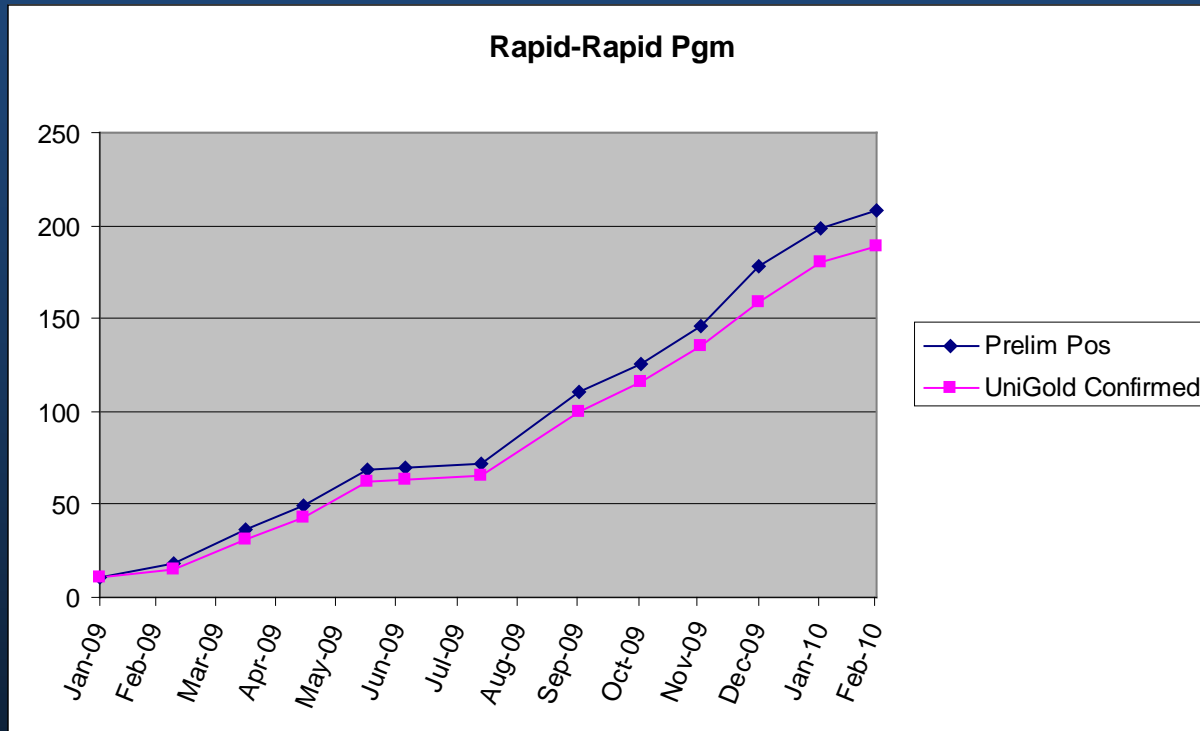
Issues

- Number of Rapid-Rapid Sites
- Distribution of sites throughout the state
- Training
- Real-world performance of the 'second rapid'
- Costs of the 'second rapid'
- Does it increase the linkage to care?

Timeline Rapid-Rapid Testing

2009-2010

2010

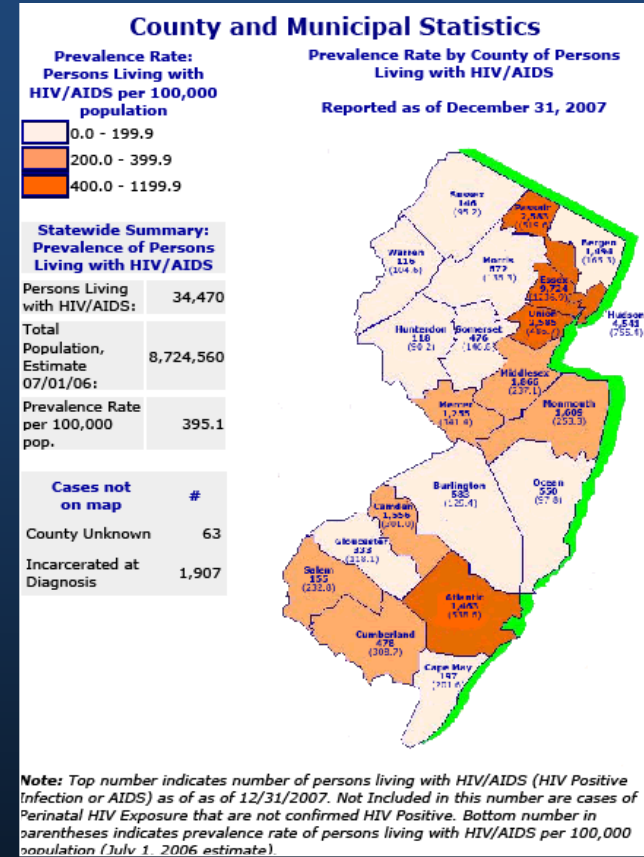
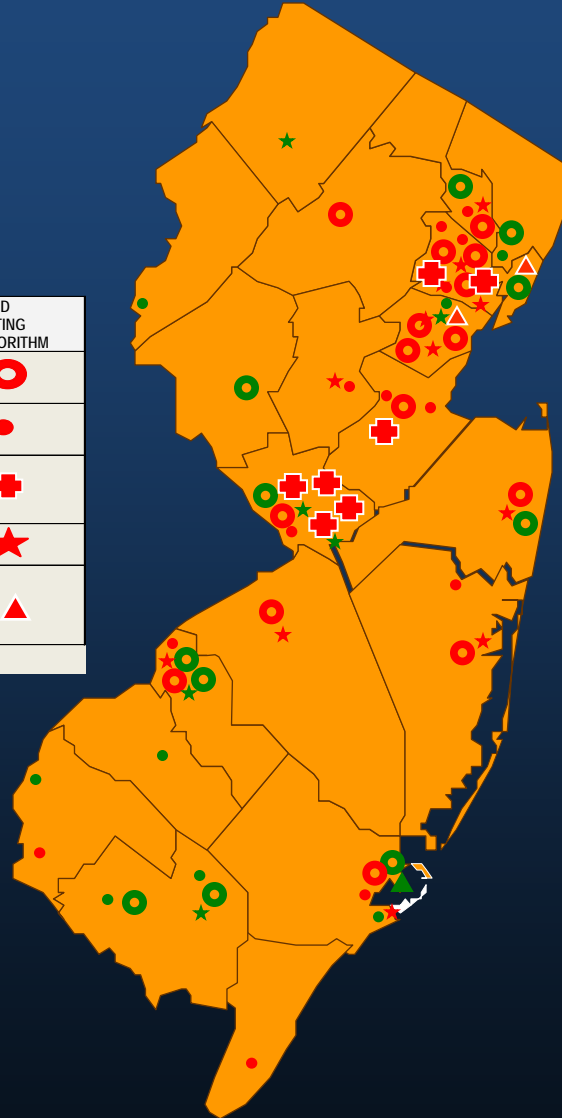


Various Venues for Rapid-Rapid Program

- 21 Primary Sites Operational in NJ
 - 42 Satellite Sites
 - FQHC's: 4
 - Hospital ER's: 7
 - CBO's: 16
 - Mobile Van Initiatives: 15
- >140 individuals Trained

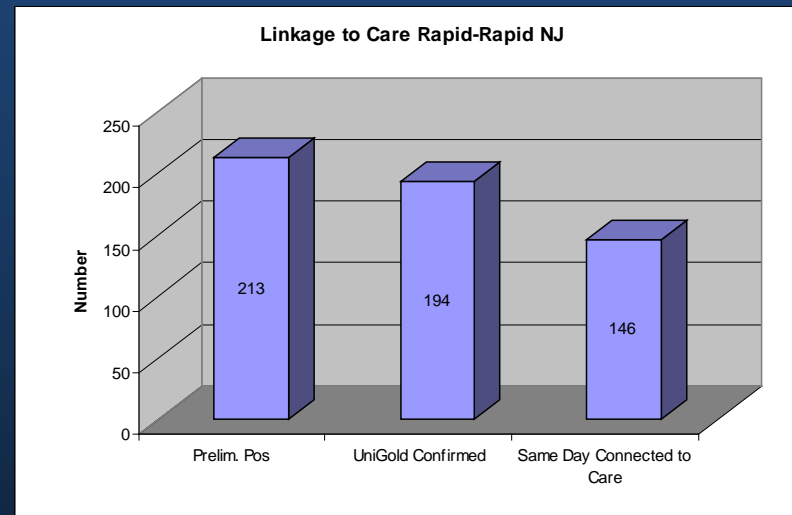
Diversity of sites using an RTA

LEGEND	TRADITIONAL	RAPID TESTING ALGORITHM
RAPID TESTING PRIMARY SITE		
COMMUNITY BASED ORG. (CBO)		
MEDICAL CTR. ER		
MOBILE VAN		
PRISONS		



Outcomes

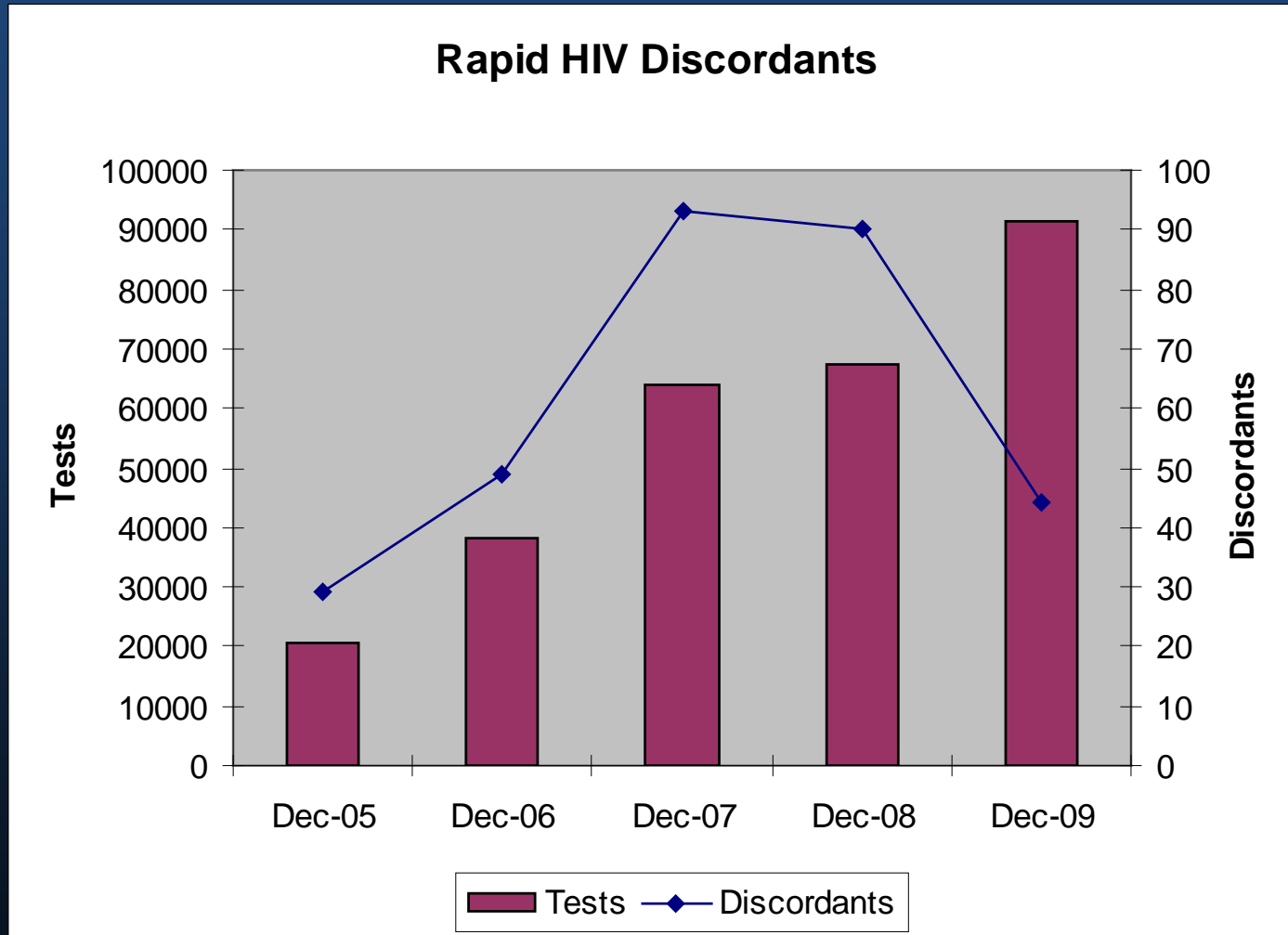
2/28/2010	Prelim. Pos.	213
	Unigold Verified	194
	Same-Day Connect to Care	146
	Verified & Linked Same Day	75%



Discordant Results

NJ Rapid Testing Program

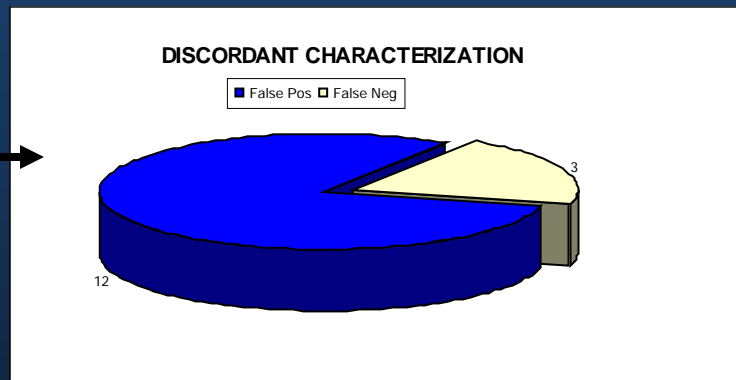
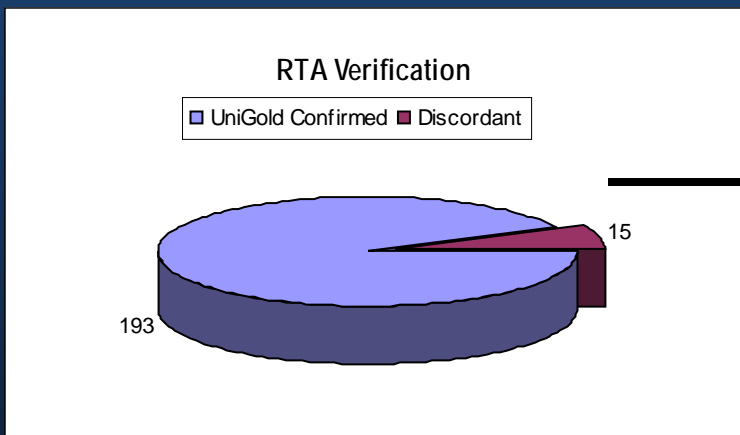
Rapid AND Rapid-Rapid



Rapid-Rapid Summary

Rapid Test 1	Tests	<i>PCT</i>	
StatPak	19,830	77.4%	
Oraquick Oral	3,005	11.7%	
Oraquick Finger Stick	2,778	10.8%	RTA Total Tested:
Rapid Test 2			25,623
Unigold	213		

Discordant Issues



RTA PROGRAM	SPECIFICITY
Overall	99.94%

Rapid-Rapid Summary

February, 2010

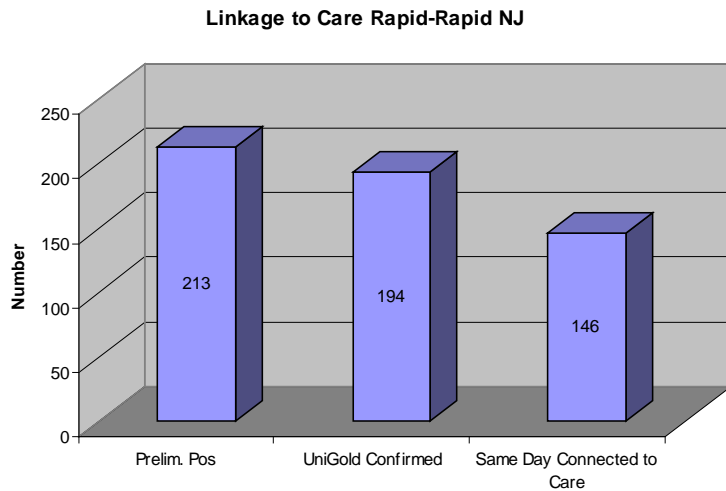
WB Results	1st Rapid Positive	2nd Rapid Positive	2nd Rapid Negative	Notes: <i>Percentages calculated excluding those who refused WB</i>
Total WB results	197	186	11	
Pct WB POS	95.4%	99.5%	27.3%	
Pct WB Ind	0.0%	0.0%	9.1%	
Pct WB Neg	4.1%	0.5%	80.0%	
Pct Refused WB	7.0%			

Rapid-Rapid Summary

	1st Rapid Positive	2nd Rapid Positive	2nd Rapid Negative	Notes
WB POSITIVE	188	185	3	<i>Unigold False Neg</i>
WB Negative	8	1	7	<i>RNA- WB-</i>
WB Indeterm	1	0	1	<i>p17 Only</i>
WB NOT DETERM	15	14	1	
PENDING	1	1	0	
TOTAL RESULTS	213	201	12	

Linkage to Care

Who Gets Linked to Care



- 75% of 'verified' HIV positives receive appts on the same day
- 26% DID NOT receive appts on the same day!!
- Site Specific Issues - Ongoing
- How to improve linkage

HIV Coordinator Survey

- Surveyed: HIV coordinators at rapid-rapid sites in May, 2009 (10 sites) regarding client satisfaction and the effectiveness of linking to care.
- Satisfaction: 60% of clients Positive or Very Positive, 20% lukewarm, 20% didn't understand
- Site Types: Health Depts. (2), FQHC's (4), CBO's (3), Med. School (1)

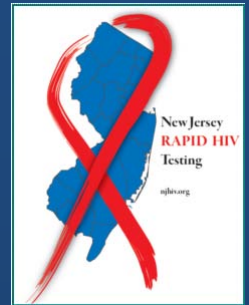
Linkage to Care - Survey

APPT	Site of Rapid-Rapid			
Same Day Appt	FQHC	HD	Med. Sch.	CBO
>90%	4		1	1
>75-90%				
>50<75%	1	2		1
10 <25%				
>10%				

PHYSICIAN	Site of Rapid-Rapid			
Same Day Visit	FQHC	HD	Med. Sch.	CBO
>90%	2			1
>75-90%	1			
>50<75%	1	1		
10 <25%				1
>10%	1	1	1	

- It's not too difficult in NJ to schedule a physician appointment – 6/10 sites could schedule appt 90% of time on same day as RTA positive
- Obtaining an appointment on the same day was more difficult --- only 3/10 sites were able to accomplish this linkage.

SUMMARY OUTCOME



- More than 25,000 rapid HIV performed in the past year
- 21 Licensed facilities in NJ implemented tests as a part of our NJ RTA
- No one has been removed from care once identified as 'HIV verified'
- A small number of discordant results (15) have occurred and been resolved centrally

Facts

- Roughly 7% of clients in NJ refuse Western blot testing altogether.... These have been linked to care on the basis of a second rapid, BUT NOT in its absence.
- Clients who are obliged to return to receive Western blot results fail to do so 25% of the time.
- Partly because of resistance by providers to take on patients prior to a conclusive 'diagnosis' -- Western blot has become a roadblock to entering care.
- If we run two rapid HIV tests from different manufacturers AND they both are positive, 99.5% will confirm WHEN a Western blot is completed.
- If the two rapids disagree:
 - 27.3% of the time the Western blot will be POSITIVE,
 - 9.1% of the time it will be INDETERMINATE
 - 80% of the time it will be completely NEGATIVE
- Using a 'Rapid-Rapid' less than 1:100 will later be pulled out of care. OBVIOUS QUESTION: Why not refer on the basis of a second rapid?

Facts

- The result of the second rapid is a credible verification.
- Clients exposed to the results of the second rapid have little reason to procrastinate about linking to care
- The cost of a second rapid is between \$7-15. The cost of a Western blot is between \$70 - \$250.

A Final Question

- Given the expense, the limited sensitivity, the complexity AND the inability to move the Western blot into the POC environment, do we need to consider the proposition that the Western blot has outlived its usefulness in a screening arena?

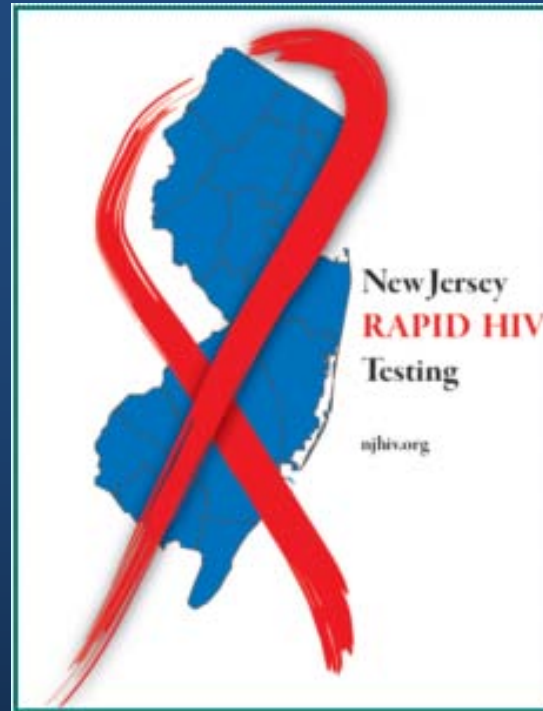


RWJMS

- Evan Cadoff, MD
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