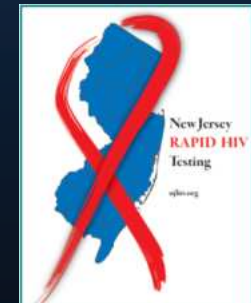


# A New Paradigm for HIV Testing in the United States

Eugene Martin, Ph.D.  
Professor of Pathology & Laboratory Medicine  
UMDNJ - Robert Wood Johnson Medical School

25<sup>th</sup> World Congress  
SVU - Czechoslovak Society of Arts & Sciences  
Tuesday, June 29, 2010



# Today

- The evolving HIV epidemic in the US & NJ
- The traditional HIV testing paradigm
- "Rapid" HIV Testing
- "Rapid-Rapid" Testing
- What is coming and why!

# US HIV Infections

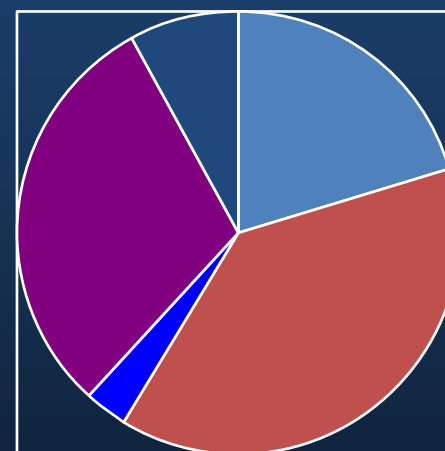
- The face of the HIV epidemic in the US is changing!
- Minorities, particularly blacks, represent more than half of all new HIV/AIDS cases in the US
- Of the 1.1 million Americans with HIV/AIDS more than 500,000 are black and more than half of AIDS-related deaths in the US occur amongst African Americans.
- **And... 20 percent of African Americans in the US with HIV do not know they are infected!**

# New Jersey's HIV Epidemic

- The face of the NJ HIV epidemic differs 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
    - 1st in the proportion of women with AIDS among its cumulative reported AIDS cases.
    - 34,915 persons living with HIV or AIDS (12/31/08)

# NJ HIV cases among IVDU

- Historically, 41% of HIV cases in New Jersey are among IVDU
- Today 8-10% of cases are associated with IVDU
- Increasingly, heterosexual transmission is occurring.



# HIV and Drug Use

- Drug users are a high-risk population for HIV infection/transmission
  - **NOT ONLY** through actual “use” → studies have shown a decrease in prevalence and incidence after successful implementation of syringe needle exchange programs
  - **BUT MOSTLY** through high-risk sexual activities (rates of STDs have not decreased)

# Questions?

- What strategies will get more people to learn their HIV status.
- How can get more infected individuals into care
- How did we stop the cycle of transmission.

# The traditional HIV testing paradigm

1983 -2003

- 1985 – FDA Approval granted Abbott HIV-1 Assay
  - Collect blood
  - Send it to a lab
  - Enzyme Immunoassay – 3 hrs +
    - Singlet. If positive → repeat in duplicate
    - If one or more of the duplicates repeat
    - → Perform a Western blot (wblot) assay
    - If key bands are present on wblot → HIV +

TODAY

- Perform a rapid HIV test (20 minutes)
- If positive → collect specimen → send it to a lab
- Perform a wblot
- Perform an EIA

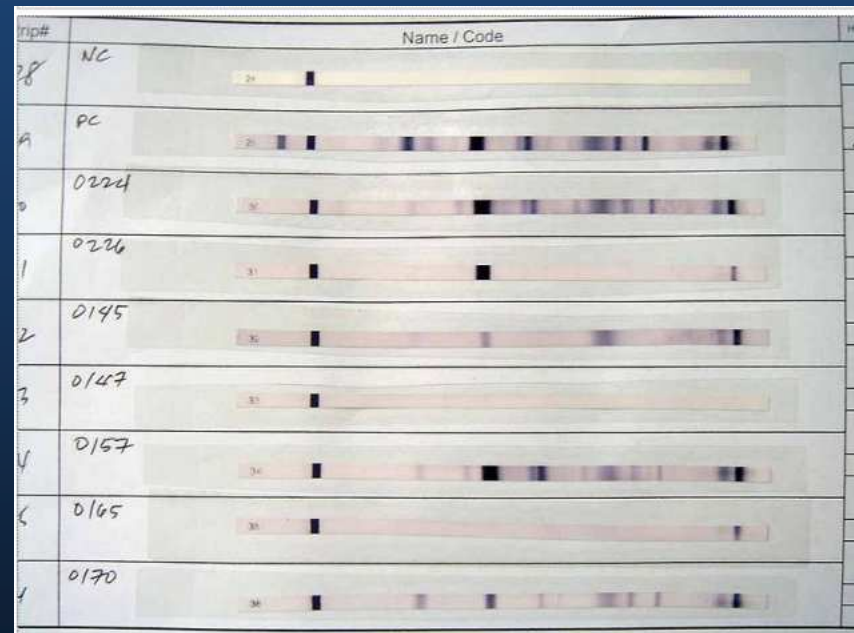
What do they have in common?

– Waiting for results!



# An HIV Western blot

- High complexity, labor intensive assay that CONFIRMS an HIV infection.
- Introduced in the mid-80's to improve the **specificity** of the HIV testing process
- Not very sensitive and potentially problematic but it does improve the performance of the testing algorithm. **Less likely to have falsely positive results.**



# The traditional approach

- ...the use of repeatedly reactive enzyme immunoassay, followed by confirmatory Western blot remains the standard method for diagnosing HIV-1 infection.
- **With confirmatory Western blot, the chance of a false-positive identification in a low-prevalence setting is about 1 in 250 000 (95% CI, 1 in 173 000 to 1 in 379 000).**

# The trouble is

- Not how you test; it's who you test and how good a patient they are!
- The traditional assay works great with a compliant patient in a compliant setting
- Not necessarily in a public health environment
- MORE on this shortly.

# Rapid Diagnostic HIV Assays

- In the US the first **reliable** rapid test was approved in June, 2004.
- **ADVANTAGES:**
  - No transportation expense or delay
  - Minimal equipment requirements
  - Whole blood, finger-stick or oral specimens
  - Easy to interpret
  - No additional laboratory personnel expense.
  - Negative results can be reported immediately
- **DISADVANTAGES:**
  - Detects antibodies, not the virus
  - Western Blot Confirmation **MUST BE** performed
  - **PRELIMINARY POSITIVE** on 1<sup>st</sup> Visit or **NEGATIVE**

# Oraquick Advanced -Specimen Types



Fingerstick



Wholeblood

## RAPID HIV ASSAY-

- Performed and interpreted at the site of care/counseling
- Varying formats:
  - Whole blood
  - Fingerstick
  - Oral
- From 20-40 minutes



Oral Mucosal Transudate

# HIV Rapid Test Formats



Clearview StatPak



Clearview HIV1/2 Complete

CLIA-waived Complexity



Trinity Uni-Gold



Oraquick Rapid

# FDA-Approved Rapid HIV Tests

FDA Approved	Manufacturer	Product	Method	Sensitivity %	Specificity %	HIV2	Waived formats
November, 2002	Orasure Technologies Inc., Bethlehem, PA	Oraquick Rapid HIV1/2	LF	99.6	100	Yes	OF WB
December, 2003	Trinity Biotech plc, Bray, Ireland <a href="http://www.unigoldhiv.com">www.unigoldhiv.com</a>	UniGold Recombinant HIV1	LF	100	100	No	WB
May, 2006	Inverness Medical Professional Diagnostics <a href="http://www.invernessmedical.com">www.invernessmedical.com</a>	Clearview HIV1/2 StatPak	LF	99.7	99.9	Yes	WB
May, 2006	Inverness Medical Professional Diagnostics <a href="http://www.invernessmedical.com">www.invernessmedical.com</a>	Clearview HIV1/2 Complete	LF	99.7	99.9	Yes	WB

- *A sensitivity – i.e. the ability to call a true positive, positive*

# FDA-Approved Rapid HIV Tests

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May, 2006	Invemess Medical Professional Diagnostics <a href="http://www.invemessmedical.com">www.invemessmedical.com</a>	Clearview HIV1/2 StatPak	LF	99.7	99.9	Yes	WB
May, 2006	Invemess Medical Professional Diagnostics <a href="http://www.invemessmedical.com">www.invemessmedical.com</a>	Clearview HIV1/2 Complete	LF	99.7	99.9	Yes	WB

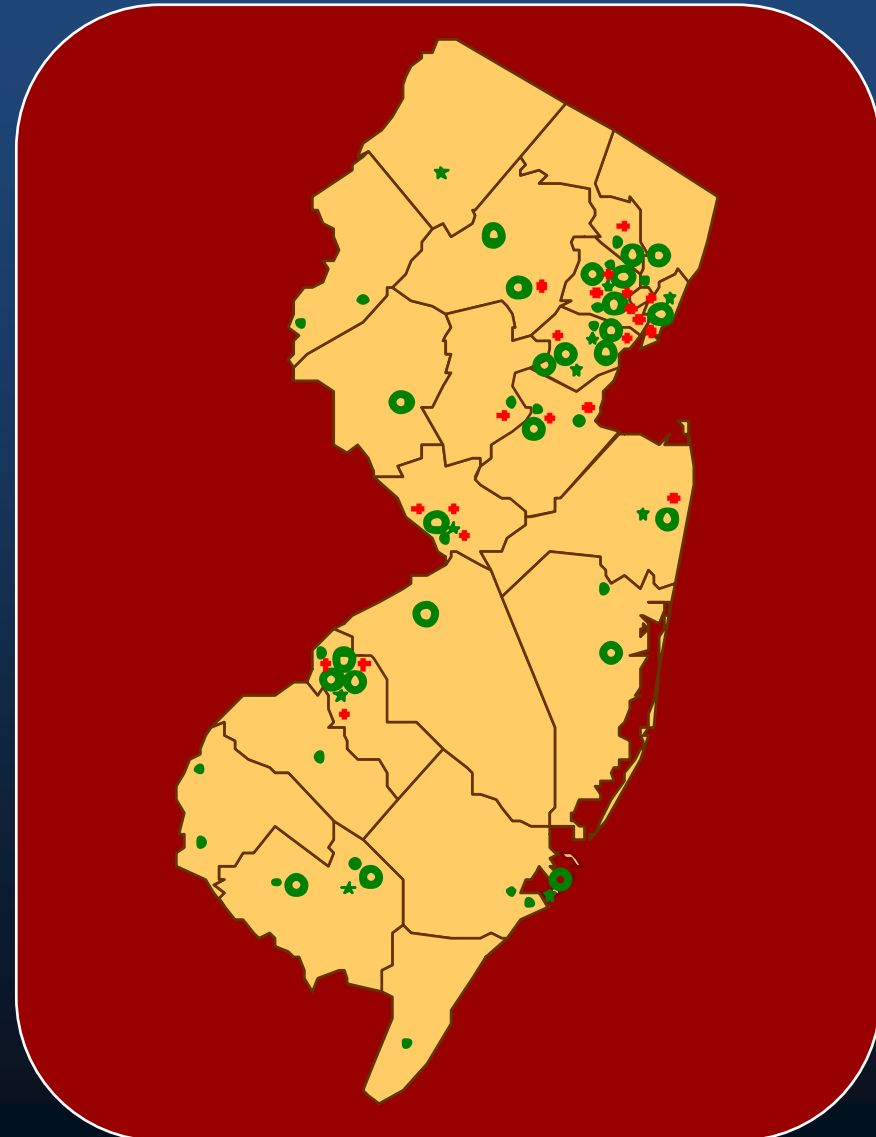
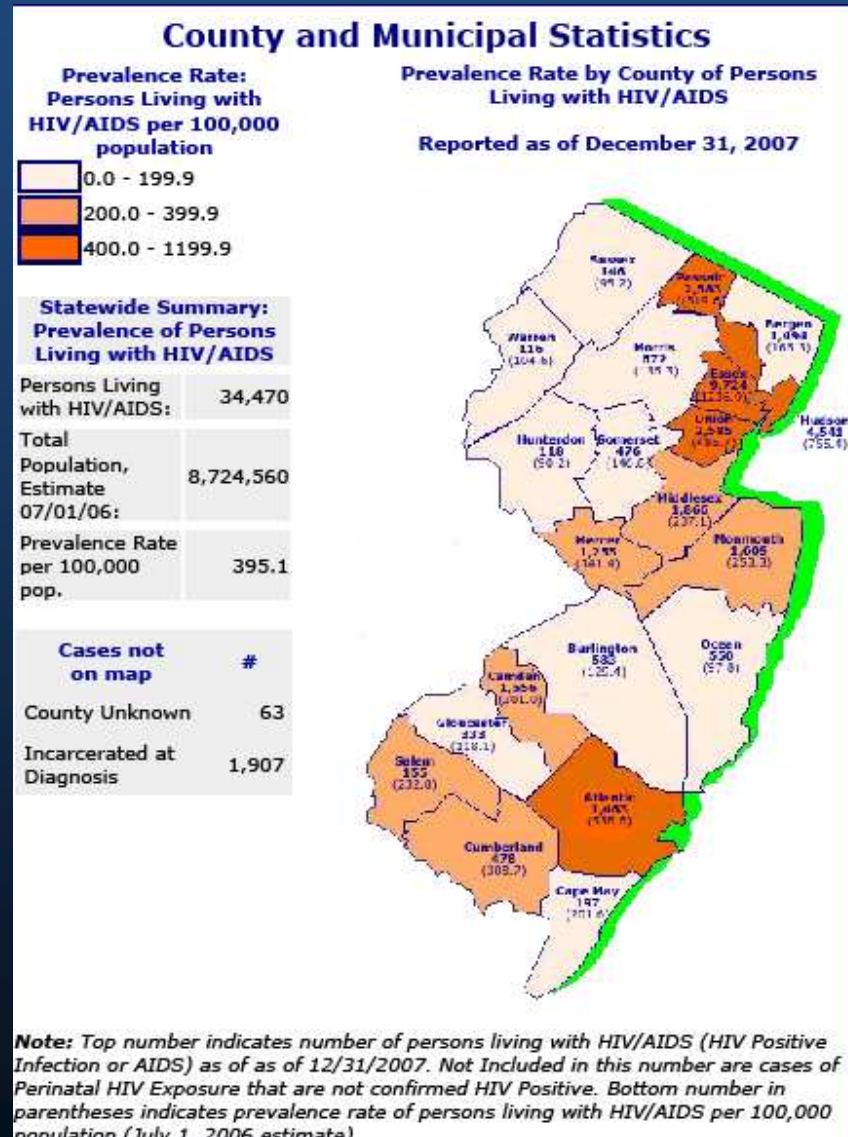
**SPECIFICITY – i.e. the ability to call a true negative, negative**



# Public Health HIV Screening

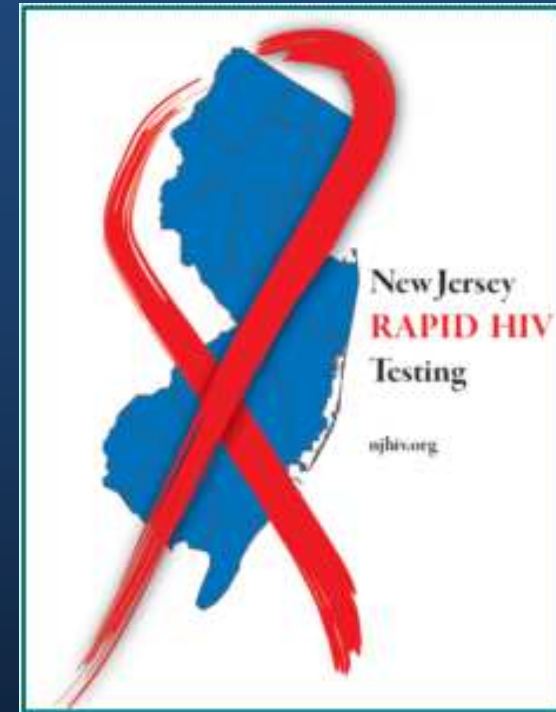
- So - we have **several excellent rapid HIV tests**
- But a laboratory test is really only as good as the **quality assurance** associated with it; and
- The processes that link the client/patient into the healthcare system **efficiently** when it is needed.

# Rapid Testing is Widely Available in NJ



# Centralized Approach to Rapid HIV Testing

- laboratory oversight
- uniform procedures, policies
- quality assurance
- proficiency testing
- training
- certification
- support with testing discordants
- logistics
- licensing
- inventory
- testing data for rapid HIV program
- monitoring, site visits, compliance and competency reports
- 2 MD, 1 PhD, 1 manager, 6 techs



# 2010 – Pushing the Envelope!

1. Rapid Testing Algorithms (RTA) – “Rapid-Rapid” – The first 25,000!
2. “Pooled Screening” -Testing for very early infection in antibody negative blood – Newark ER’s
3. The impending licensure of 4th generation POC tests – our role



# LIMITATIONS OF RAPID TESTING

- The Rapid HIV Test Measures
  - **Antibodies** to HIV
- It **DOES NOT Measure?**
  - **HIV virus/RNA or DNA**
- How Sensitive Is It?
  - At least as sensitive as more complex EIA technology used in hospitals and laboratories
  - In some cases it is more sensitive than the Western blot, the 'Gold Standard' for validation.

# Western blot – “The Gold Standard”

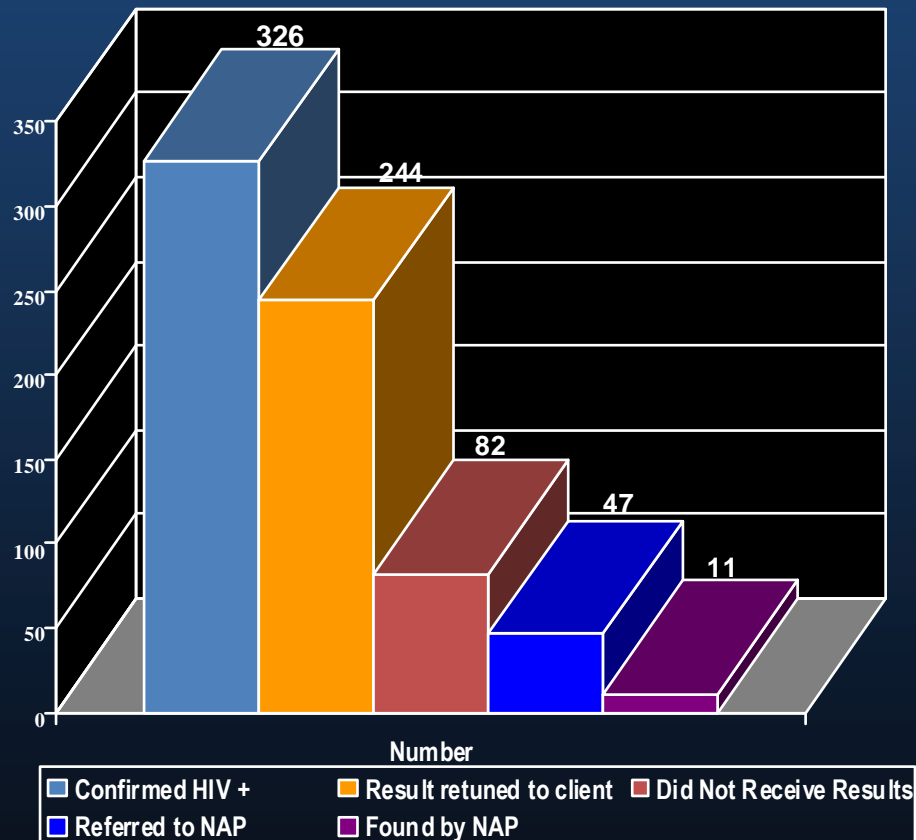
- Every HIV Positive currently requires a confirmation
  - Getting old...
    - Complex test - prone to QA issues.
    - Cost issues
    - Supply and Manufacturing issues
    - Indeterminate HIV-1 **Western Blots**:
      - Need for additional **testing**
      - Differences in Western blot performance
  - ..... 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.

# Problem - confirmatory process

- People refuse confirmatory tests
  - 7.1% of positives could not be confirmed because **specimens not collected**
- Many don't return to get their final results
  - New Jersey: 25 – 30% fail to return for a second testing-related visit.
  - Los Angeles: 35-40% fail to return
  - Other urban environments – similar story sometimes even worse
- **Bottom line:**
  - **ONLY ~ 70 % actually get their confirmed + result!!**
- Impact → Linkage to Care is -→
  - Delayed – Sometimes for years!

# *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



# Why? What can we do?

- 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.
- Goal: Test and Link to Care in a single visit

# Is Rapid-Rapid Testing the solution?

- Widespread use of rapid HIV devices worldwide ~ fifteen years
  - Resource-poor
  - High prevalence environments
- What was not tested was low prevalence environments
- Los Angeles/San Francisco CDC pilot studies “rapid-rapid” – RTA 2008-9
- New Jersey implementation – December 2009

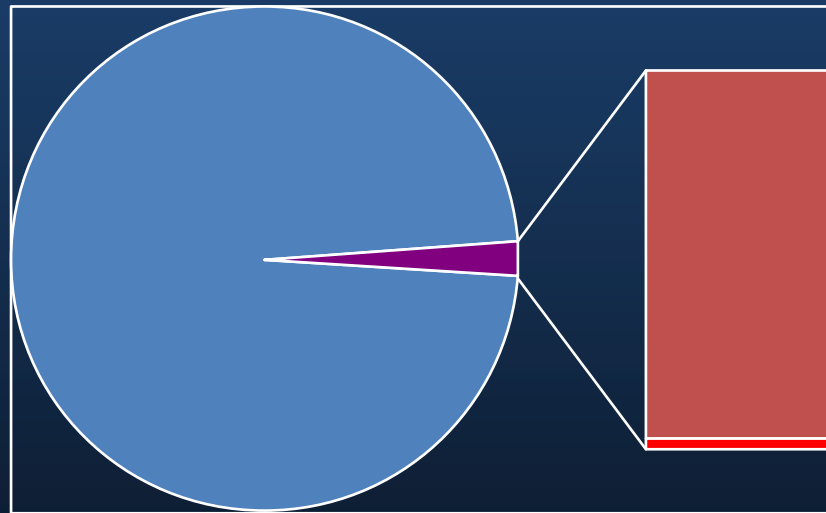
# Two Test Rapid Testing Algorithm

- **Efficient** (2 Test RTA)

- **Concept:** 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 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.

# Validation of the Concept

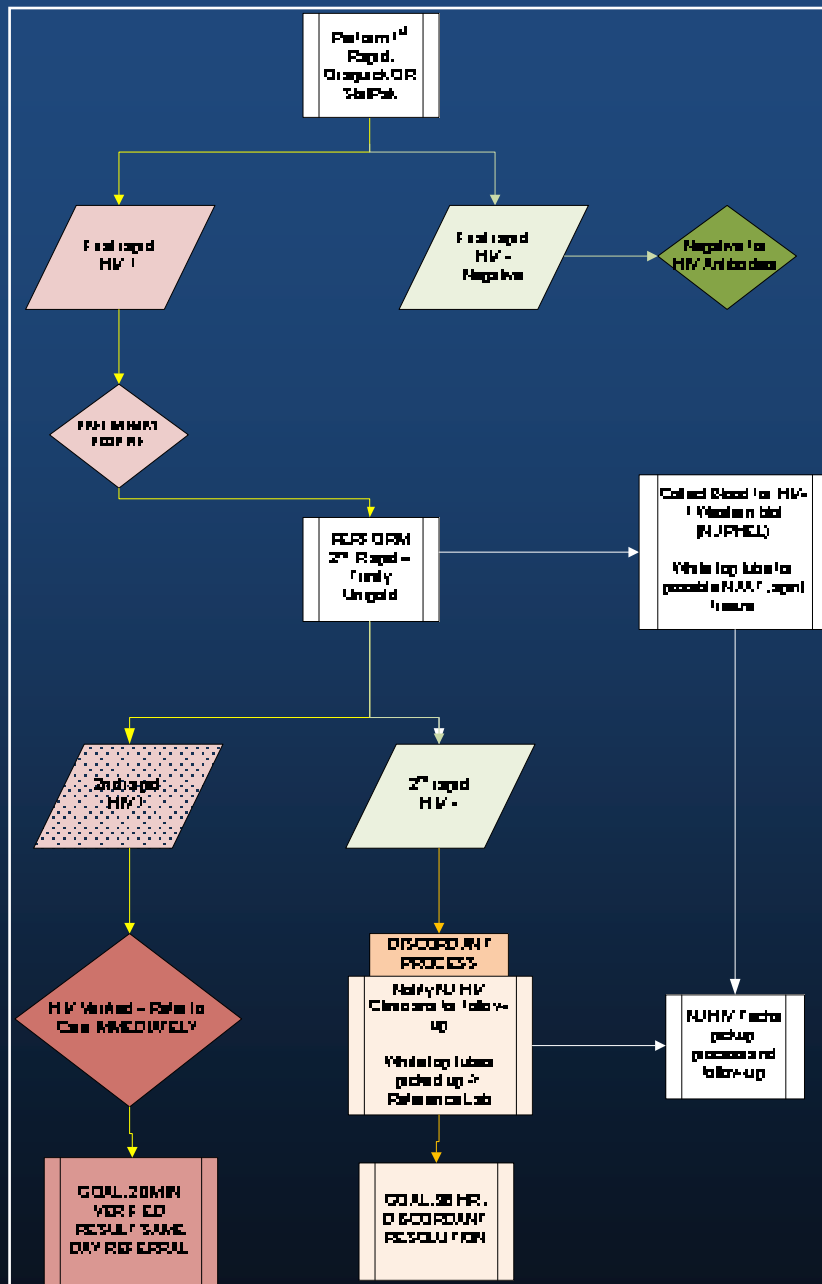
July 1, 2004 through April 19, 2005



■ 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

# 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

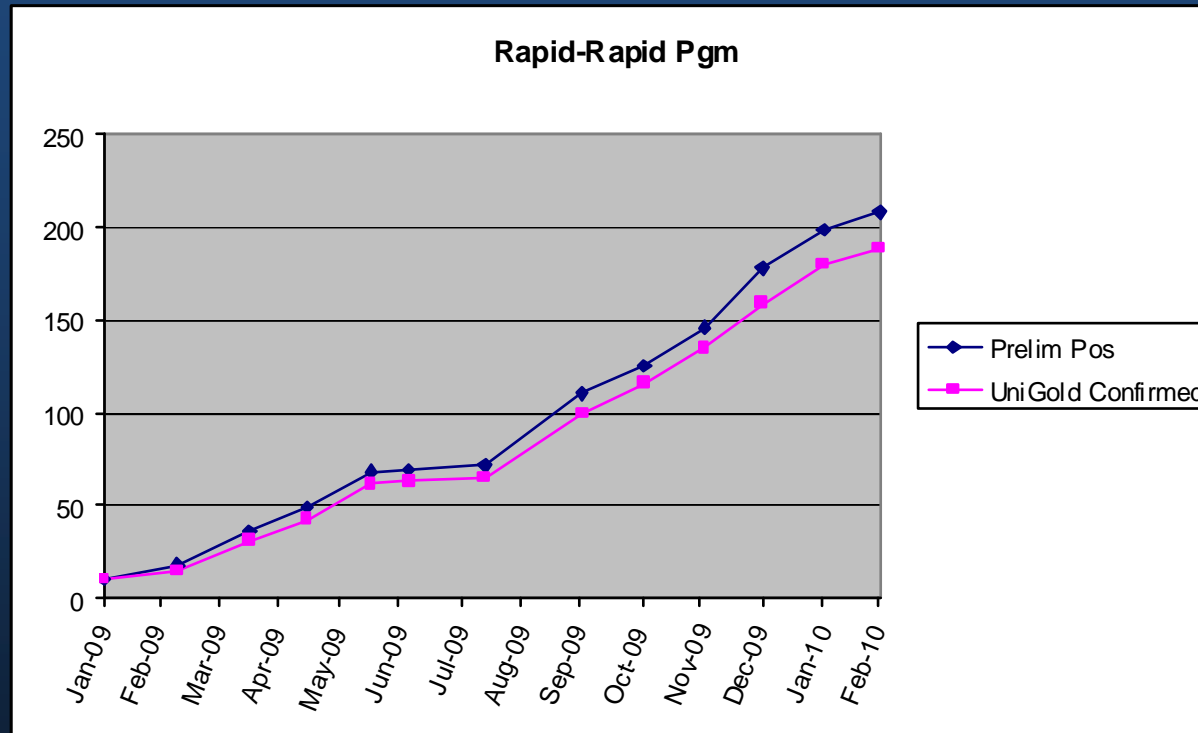
## – UNKNOWN: What will be the real world performance of a rapid test in a confirmatory setting?

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

# 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?

# Implementation of Rapid-Rapid



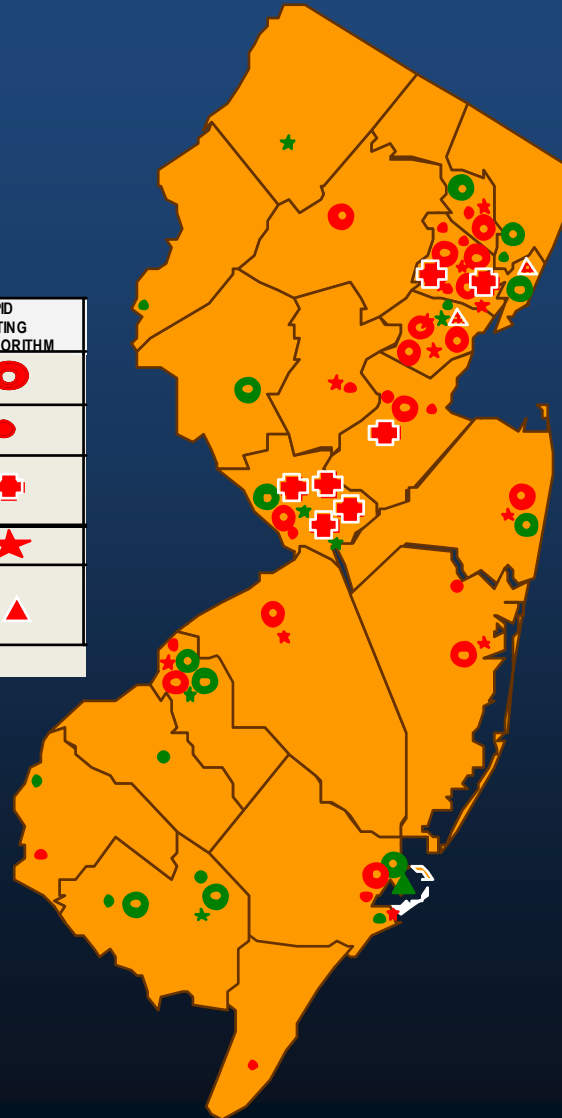


## *Various Venues for Rapid-Rapid Program*

- 22 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

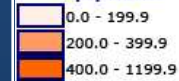
# Diversity of sites using an RTA

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



## County and Municipal Statistics

Prevalence Rate:  
Persons Living with  
HIV/AIDS per 100,000  
population

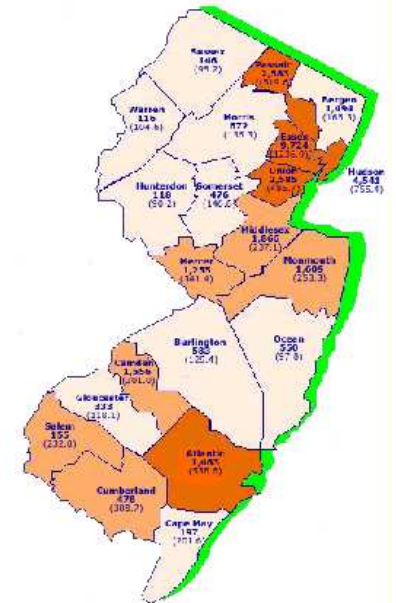


Statewide Summary:  
Prevalence of Persons  
Living with HIV/AIDS

Persons Living with HIV/AIDS:	34,470
Total Population, Estimate 07/01/06:	8,724,560
Prevalence Rate per 100,000 pop.	395.1

Cases not on map	#
County Unknown	63
Incarcerated at Diagnosis	1,907

Prevalence Rate by County of Persons  
Living with HIV/AIDS  
Reported as of December 31, 2007



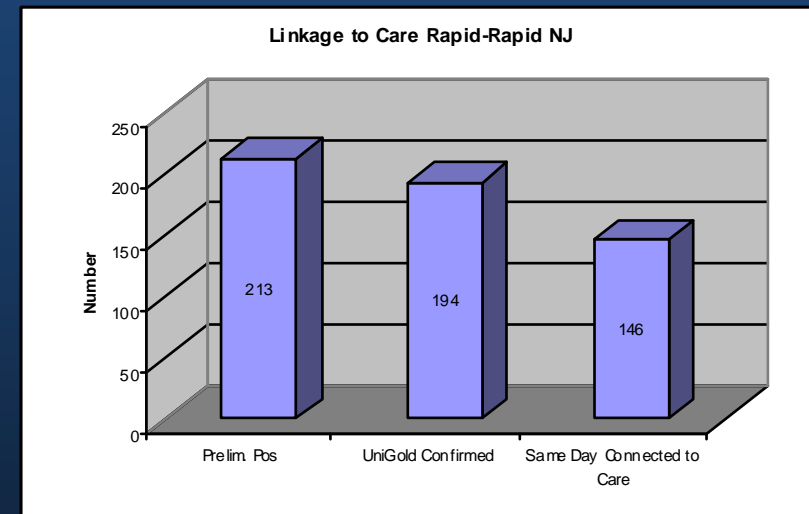
*Note: Top number indicates number of persons living with HIV/AIDS (HIV Positive Infection or AIDS) as of as of 12/31/2007. Not Included in this number are cases of Perinatal HIV Exposure that are not confirmed HIV Positive. Bottom number in parentheses indicates prevalence rate of persons living with HIV/AIDS per 100,000 population (July 1, 2006 estimate)*

# Rapid-Rapid Summary

Rapid Test 1	Tests	PCT	
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		

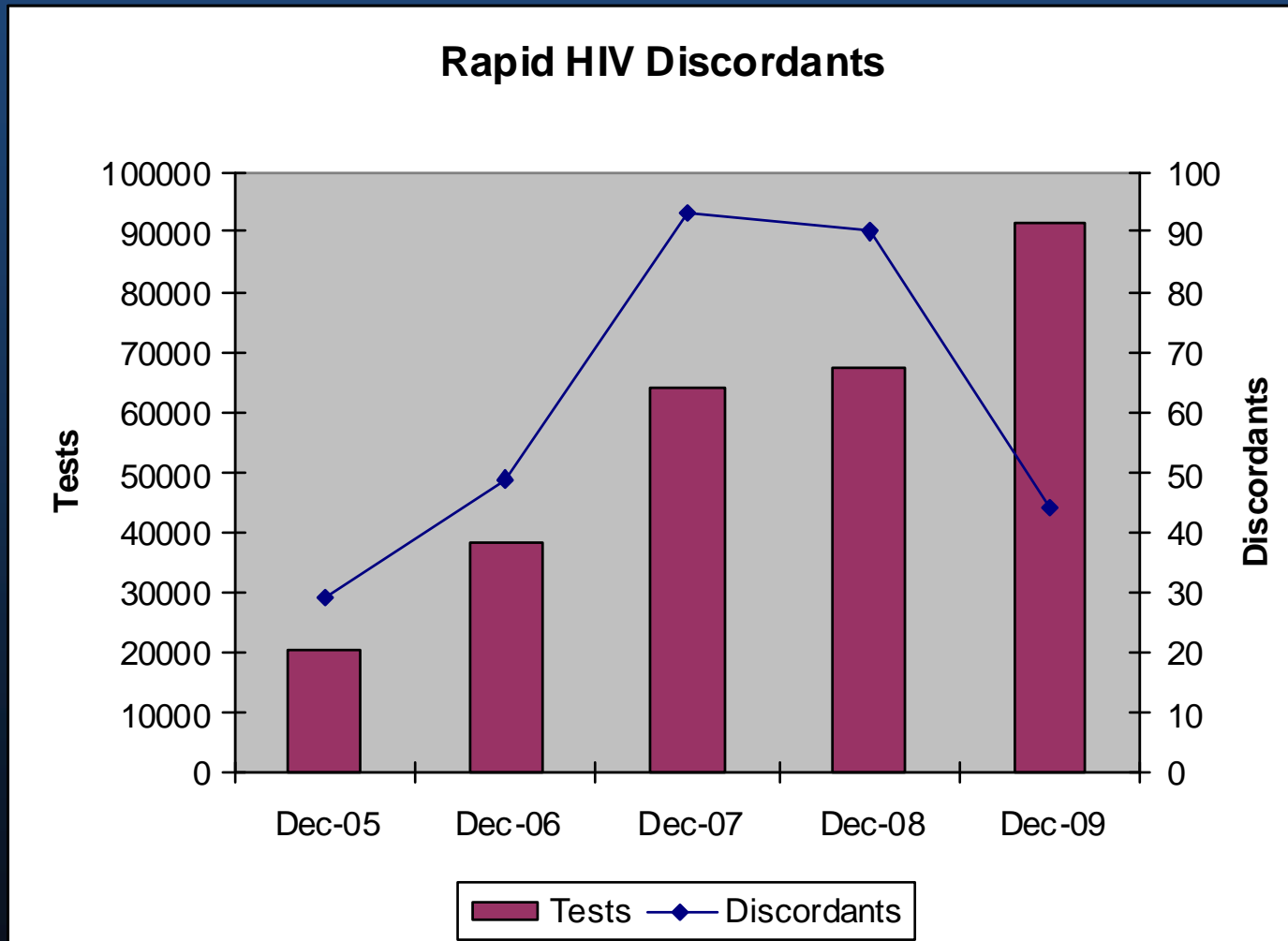
# Outcomes

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

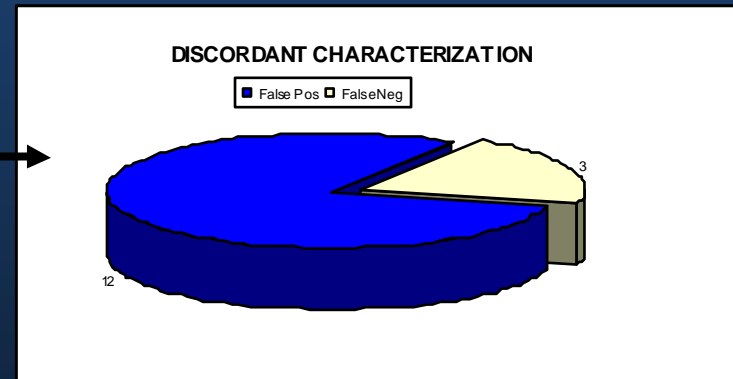
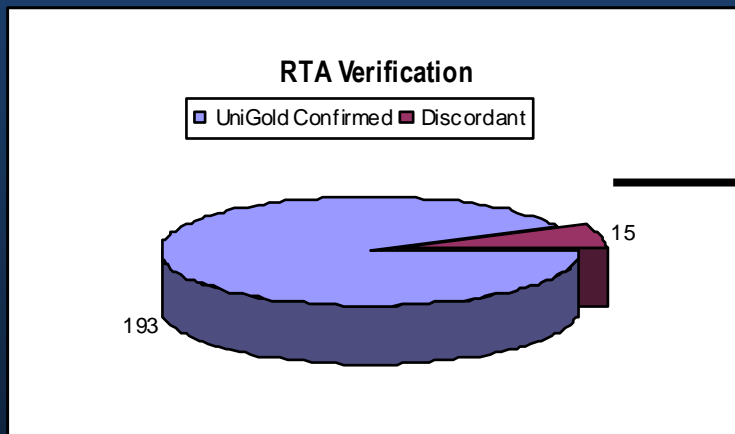


# Discordant Results

# NJ Rapid Testing Program Rapid AND Rapid-Rapid



# 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>
<b>Total WB results</b>	<b>197</b>	<b>186</b>	<b>11</b>	
Pct WB POS	95.4%	99.5%	27.3%	
Pct WB Ind	0.0%	0.0%	<b>9.1%</b>	
Pct WB Neg	<b>4.1%</b>	<b>0.5%</b>	80.0%	
Pct Refused WB	<b>7.0%</b>			



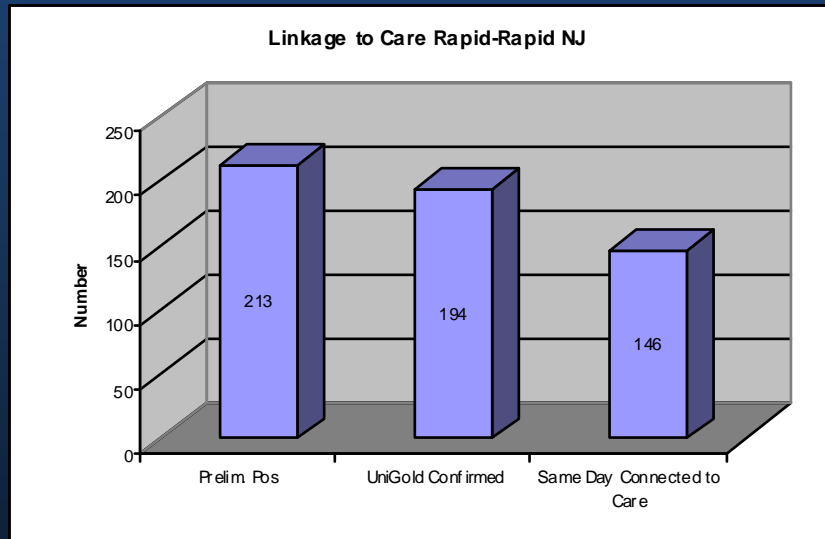
# Linkage to Care

# Linkage to Care

## Rapid Test + W. Blot Algorithm: 2005-2006

- 644 cases - rapid test confirmed by W. Blot
  - 425 (66%) had at least one CD4 count or VL in eHARS database indicating 'in treatment'
  - Based on the date of the 1<sup>st</sup> lab result, 253 of the 425 (60%) got into treatment within 3 mos
  - Of the 172 (41%) who got into treatment after 3 months, the median time to treatment was 524 days (range 93 – 1416 days)
  - > one-third of the 644 cases did not have evidence of a CD4 count or viral load test result
- **Getting results 3.6x more likely to be in RX**

# Who Gets Linked to Care - RTA



- 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
- **15% More then traditional testing!!**

# Linkage to Care with an RTA – Where matters!

- 62 RTA positives identified in the first six months of RTA program: 76.7 % - same day appointments for treatment
  - Academic medical centers (1) and FQHCs (4) identified 33 HIV positive individuals using an RTA
  - 82% received immediate appt
  - **97% were in care at six months, 1 lost to care**
- Health Departments (2) and CBOs identified 29 infections
  - 16 (55%) appts. were made on same day
  - **19 (47%) were in care at 6 months, 10 (34.4%) lost to care**
- Efforts to better connect screened, infected clients to providers is needed in non-traditional healthcare settings

# 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 must return to receive Western blot results fail to do so 25% of the time.
- → ~32%
- 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 rapid tests 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

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

# The Obvious Questions

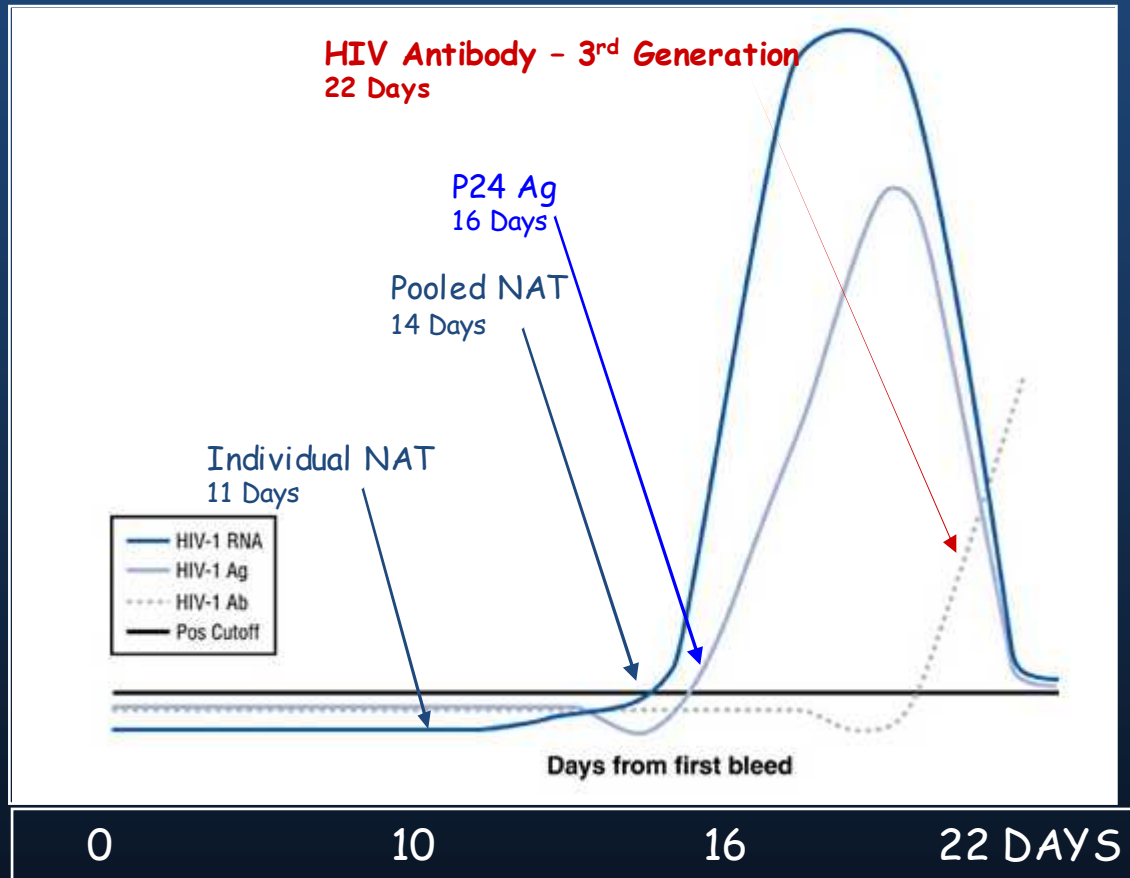
1. Given the expense, the limited sensitivity, the complexity AND the inability to move the Western blot into the POC environment, do we need to consider the proposition that the Western blot has outlived its usefulness in a screening arena?
2. Is testing for the HIV antibody good enough?

# Testing for Early Infection

“NAT Testing of Pooled Negatives”



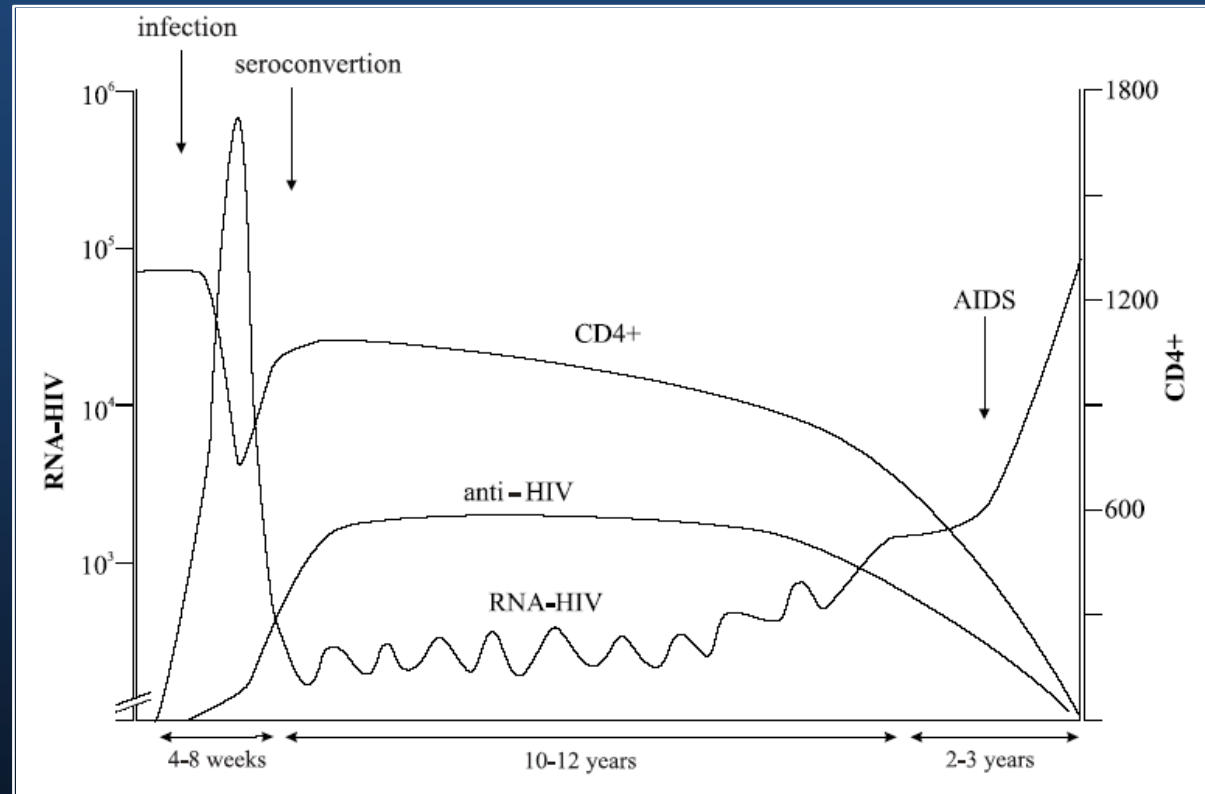
# Viremia During Early HIV Infection



- Ramp-up Viremia Doubling Time = 21.5 hrs
- Peak Viremia 10<sup>6</sup> - 10<sup>8</sup> gEq/mL
- Viral set-point 10<sup>2</sup> - 10<sup>5</sup> gEq/mL
- WINDOW
  - Antibody - 22 Days
  - Antigen - 16 Days
  - Pooled NAT - 14 Days
  - Individual NAT - 11 Days

ANTIBODY WINDOW

# Natural History - HIV Infection



Couthino et al., Bulletin of Mathematical Biology 2001

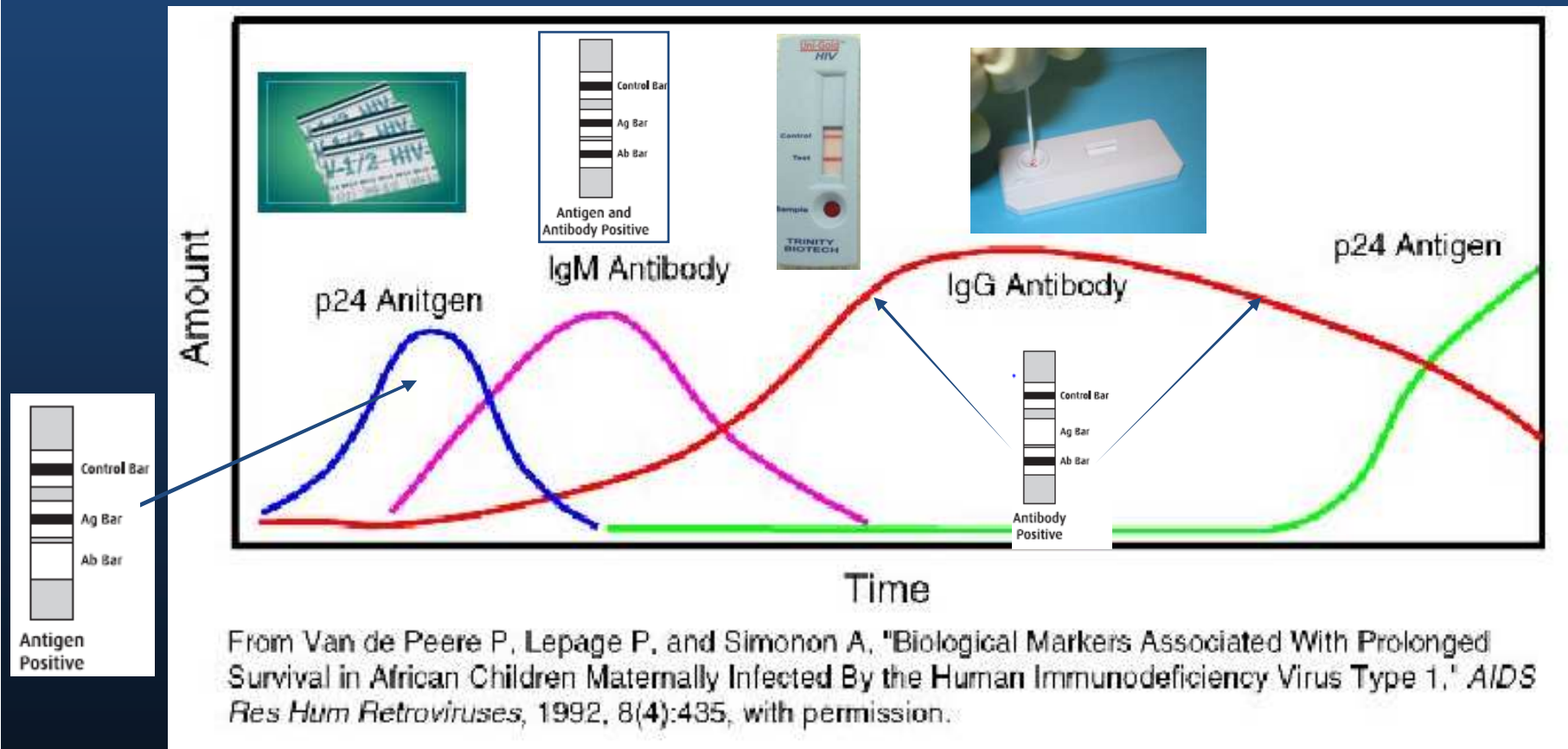
# Why worry about the '30 day window'?

- HIV transmission
  - 50% occurs PRIOR to the appearance of antibodies!

How do we *EFFECTIVELY* narrow the 'HIV window'

- Implement alternative technologies to identify
  - Other serologic markers that appear earlier
  - Utilize nucleic amplification technologies to look for the virus

# Future Developments

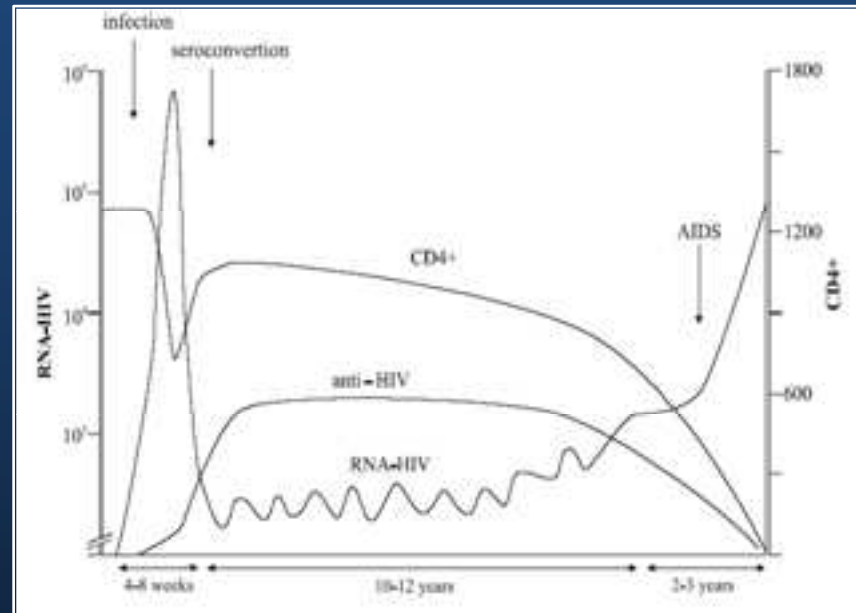


# AHI Study in Emergency Rooms

- High prevalence area – central ward Newark
- ? How frequently do individuals present in the ER with evidence of acute HIV infection?
  - AHI: Appearance of HIV virus associated with burst of infectivity. No antibody present. Possibly p24 Ag is present
- University Hospital ER and St. Michael's ER

# Acute HIV Infection

- HIV virus is associated with burst of infectivity.
- No detectable antibody present for ~ 22 days
- Possibly p24 Ag present
- ?: If we screen with a POCT product detecting p24 Ag can we:
  - Detect most or all of the AHI episodes?
  - Is that good enough?
  - Does the immediate result offset the delay issues?



# Technology trade-offs

- POOLED NAT

- ~ 14 days
  - Sensitive
  - labor intensive
  - Expensive
  - Often referred
  - Reporting delays: Days  
→ Weeks

- P24 Ag Detect

- ~ 16 days
- Originally a lab-based technology
- Approaching licensure is a POCT like rapid HIV
  - ? Pricing
  - ? How to utilize

# Ongoing Efforts

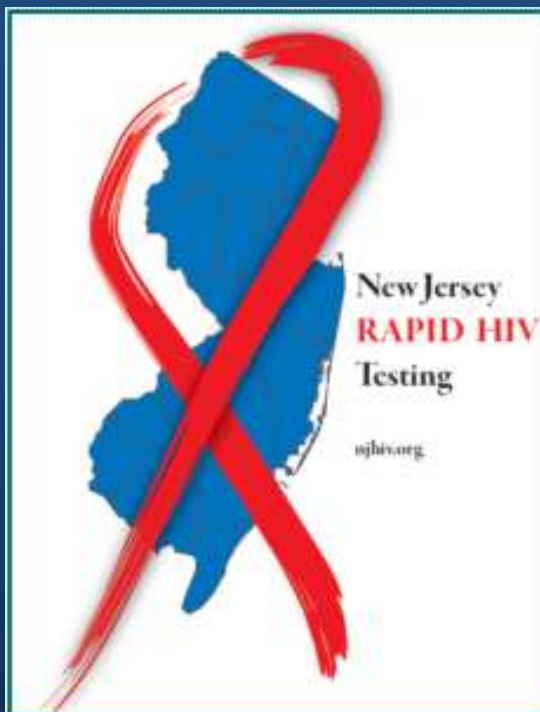
- Expanding Rapid-Rapid – focusing on the ‘linkage to care’
- Determining whether p24 Ag detection is an acceptable alternative to NAT in a screening environment.





### RWJMS

- Evan Cadoff, MD
- Eugene Martin, Ph.D.
- Gratian Salaru, MD
  
- Joanne Corbo
- Claudia Carron, RN
- Maryann Garrihy, MT
- Aida Gilanchi, MT
- Franchesca Jackson, BS
- Nisha Intwala, MT
- Patricia Ribero, MT
  
- Lisa May
- Karen Williams



### NJDHSS/DHAS

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- Linda Berezny, RN
- Maureen Wolski, BS
- Aye Maung Maung

### CDC

- Kevin Delaney, MPH

# THANKS!

### NJDHS/DAS

- Molly Green
- Adam Bucon



# Signs and Symptoms of an early HIV Infection

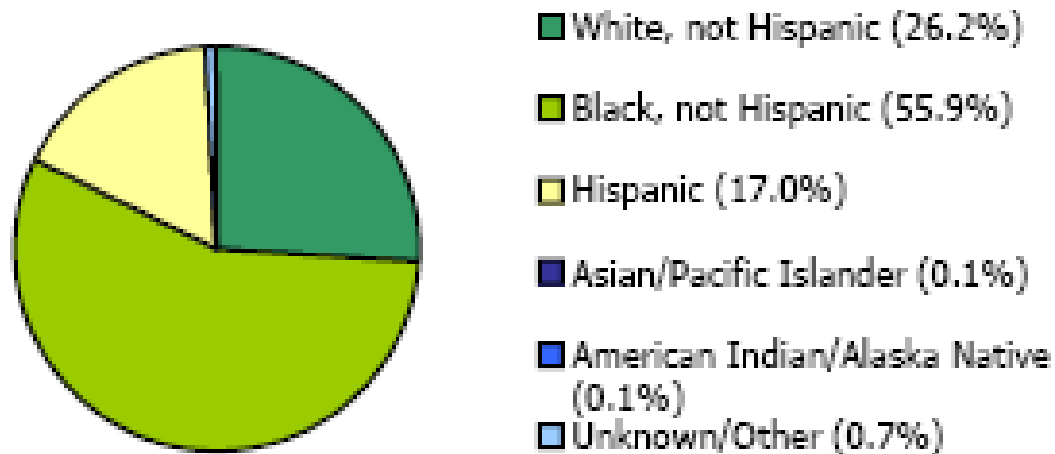
- Fever
- Headache
- Tiredness
- Nausea
- Diarrhea
- Enlarged lymph nodes in the neck, armpits or groin
- Usually these symptoms disappear in 1 – 4 weeks
- Signs and symptoms of HIV infection - similar to those for many different viral infections
- The only way to know is to test for infection

# Key Dates in HIV Timeline

- **1981** – NY TIMES reports rare form of cancer among gay men in New York and California
- **1982** - CDC links the new disease to blood.
- **1983** – French researchers isolate a retrovirus
- **1984** - Canadian flight attendant, "patient zero" dies of AIDS.
- **1985** – Rock Hudson dies of AIDS
- 1985 – Abbott – First lab test for HIV infection. 3hrs
- 1995 –
  - **Saquinavir**. First protease inhibitor.
  - **3TC (lamivudine)** First nucleoside reverse transcriptase inhibitor.

# HIV AIDS in NJ

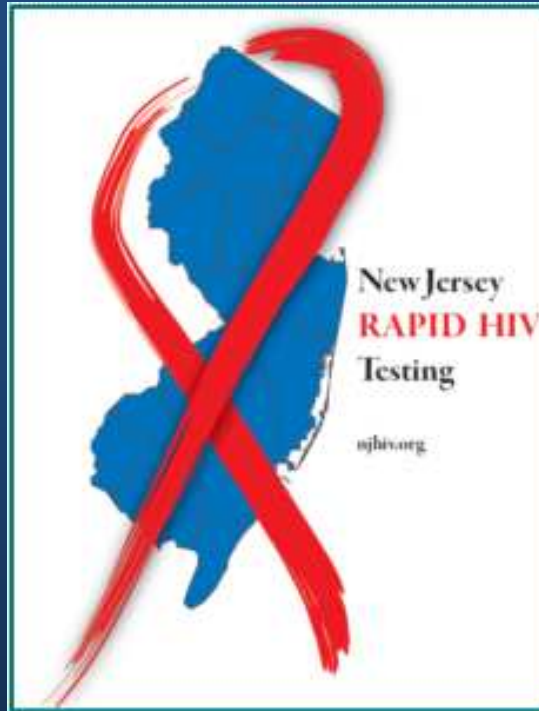
**Reported AIDS Cases by Race/Ethnicity,  
Cumulative through 2005, New Jersey  
N = 48,431**





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- Maryann Garrihy, MT
- Aida Gilanchi, MT
- Franchesca Jackson, BS
- Nisha Intwala, MT
- Patricia Ribero, MT
  
- Lisa May
- Karen Williams



# NJ HIV



## NJDHSS/DHAS

- Laurence Ganges
- Carmine Grasso
- Sindy Paul, MD, MPH
- Linda Berezny, RN
- Maureen Wolski, BS

## CDC

- Kevin Delaney, MPH

## NJDHS/DAS

- Molly Green
- Adam Bucon



# 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.

# Validation of a Testing Algorithm

“Validation is the process of demonstrating that an analytical procedure is suitable for its intended use” - CBER

- The use of other rapid tests to confirm a rapid HIV test is **not new or novel** - WHO recommends this approach for countries in which the prevalence of HIV exceeds 10% for a number of years
- What was new and novel was using this approach in sites with 2% or lower prevalence



# Validation of an RTA – 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



# Status of Rapid-Rapid in New Jersey

February, 2010

# The Traditional HIV Testing Paradigm

- Blood → LAB
- Urine HIV test → LAB
- Orasure Oral Fluid HIV 1 test → LAB DAYS

POSITIVE Antibody Screening must be confirmed by Western Blot confirmation DAYS

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- Rapid HIV EIA tests
    - Blood
    - Fingerstick
    - OMT – Oral mucosal testing 10- 20 MINUTES
- 

– UNFORTUNATELY A PRELIMINARY POSITIVE RAPID HIV TESTS IS STILL CONFIRMED BY A WESTERN BLOT

# What is a rapid HIV test?

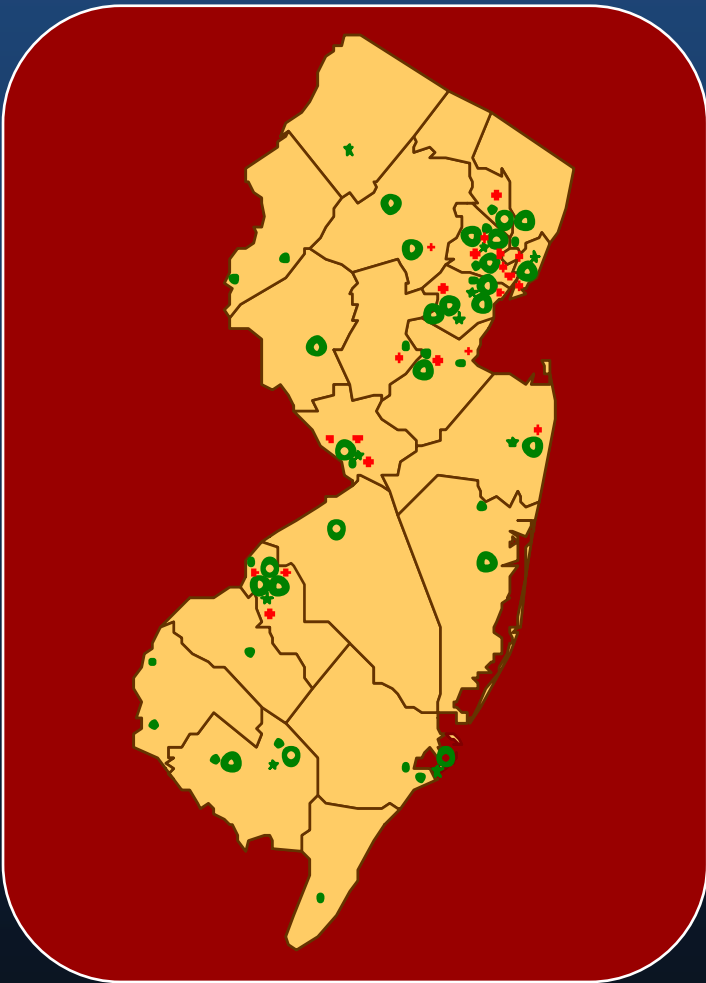


- RAPID HIV ASSAY–
  - Performed and interpreted at the site of care/counseling
  - Varying formats:
    - Whole blood
    - Fingerstick
    - Oral
  - From 20-40 minutes

Oraquick Rapid HIV 1/2

# New Jersey

## Rapid HIV Testing



- Counseling sites - mid-1980s
- Testing added - late 1980s
- Rapid testing added - late 2003
- Currently:
  - 73 laboratory licenses
  - Over 90 CTS testing sites:
    - Hospitals/EDs (23), STD clinics, CBOs, Health Depts., Mobile Vans, Prisons, Faith-based Initiatives, Methadone treatment programs, substance abuse programs
- 2006 ASTHO Vision Award