

RUTGERS

Robert Wood Johnson Medical School

## Administrative Matters

Joanne Corbo, MT(ASCP, MBA)  
HIV PROGRAM MANAGER  
Rapid HIV Test Support



**Rutgers – Robert Wood Johnson Medical School**  
New Brunswick, NJ

## NJ HIV Rapid Testing Support Administrative Issues

Website for NJ HIV Rapid Testing Support:  
[njhiv.org](http://njhiv.org)

## NJ HIV Rapid Testing Support Administrative Issues

### **One Time Events**

#### **New Procedure:**

- **Letter to CLIS not required if testing at One Day Event location is clearly documented**
- **DHSTS will need to approve One Day Event Request-One Day Event request Form is still required**
- **New OTE Results form will document where testing was done**

## NJ HIV Rapid Testing Support Administrative Issues

- Requests should be sent 10 business days in advance (No exceptions)
- Must use current form (electronic version on NJ HIV.org)
- Send to Sonya Thompson/copy to Joanne Corbo,
- Approvals done by Sonya/PMO based on strict criteria for target population/prevalence (Criteria: zip code etc.)
- Results for One Day Events must be sent to Sonya Thompson/copy to Joanne Corbo within three business days of the event (electronic version on NJ HIV.org)
- Results form must also go to your site liaison by email/fax to document where testing was done

# NJ HIV Rapid Testing Support Administrative Issues

<b>One-Day Event Results Report</b>		
<b>Submit one form per event within three business days of event</b>		
Date of Event:		
Sponsoring Agency:		
Testing Agency (if different than sponsoring agency):		
Site Number of Testing Agency:		
Name of testing Location:		
Address of testing Location :		
Zip code of testing location:		
<b>Test Results</b>		
Target Population	# Positive	# Negative
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
<b>TOTAL</b>	0	0

\* General Population is any non targeted group

Please complete the entire form. Totals will automatically add for you. "SAVE AS" naming the file with your agency name and date of event.

Email to Joanne Corbo at [corbojo@RWJMS.rutgers.edu](mailto:corbojo@RWJMS.rutgers.edu)  
 and Sonya Thompson at [sonya.thompson@doh.state.nj.us](mailto:sonya.thompson@doh.state.nj.us) within three business days.  
 If you are under the RWJ license please email/fax this form to your liaison

# NJ HIV Rapid Testing Support Administrative Issues

## DIVISION HIV, STD AND TB SERVICES

### ONE-DATE TESTING EVENTS

DATE OF REQUEST

DATE OF EVENT

Name of agency

Address of agency

Contact

Contact phone number

1. Name or type of event
2. Name and address of event location
3. Zip Code(s) for the event (Zip code is in a high prevalence area per county maps)
4. Start and end time
5. Has the event been advertized or marketed? YES  NO
6. Is this event INDOOR  OUTDOOR
7. Has the area been personally inspected? YES  NO
8. Is the testing area temperature controlled? YES  NO
9. If mobile van, is there a secure parking location with easy access for the mobile unit and those who wish to test? YES  NO
10. Is there sufficient lighting and space for performing a rapid test and reading the result?  
YES  NO
11. If not a testing van, do you have a confidential area for testing? YES  NO
12. If not a mobile van, do you have suitable cooling equipment and a stable testing area?  
YES  NO

## DIVISION HIV, STD AND TB SERVICES

### ONE-DATE TESTING EVENTS

DATE OF REQUEST

DATE OF EVENT

Name of agency

Address of agency

Contact

Contact phone number

1. Name or type of event
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7. Has the area been personally inspected? YES  NO
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9. If mobile van, is there a secure parking location with easy access for the mobile unit and those who wish to test? YES  NO
10. Is there sufficient lighting and space for performing a rapid test and reading the result?  
YES  NO
11. If not a testing van, do you have a confidential area for testing? YES  NO
12. If not a mobile van, do you have suitable cooling equipment and a stable testing area?  
YES  NO

# NJ HIV Rapid Testing Support Administrative Issues

- 13. What is the number of anticipated HIV tests?
- 14. Do you have a plan for acquiring more kits if you run short?    YES     NO
- 15. Is this a targeted testing event    YES     NO
- 16. If targeted, what is your target population?
- 17. Target population consistent with DHSTS's high-risk target populations? YES     NO
- 18. Is the target area in the high incidence areas (refer to zip code maps)    YES     NO
- 19. Is this event for the general public?    YES     NO
- 20. Is this event a national testing day or other event day?    YES     NO
- 21. Will other services be offered?    YES     NO

Please explain

Please email to Sonya Thompson, 10 business days prior to event at [Sonya.Thompson@doh.state.nj.us](mailto:Sonya.Thompson@doh.state.nj.us) with a copy to [corbojo@rwjms.rutgers.edu](mailto:corbojo@rwjms.rutgers.edu) (do NOT fax or mail request). Please email results to Linda Berezny at [Linda.Berezny@doh.state.nj.us](mailto:Linda.Berezny@doh.state.nj.us) with a copy to [corbojo@rwjms.rutgers.edu](mailto:corbojo@rwjms.rutgers.edu) within 5 business days of the event.

RWJ Oversight <input type="checkbox"/>	Non RWJ Oversight <input type="checkbox"/>
For RWJ use only:	
Request approved    YES <input type="checkbox"/> NO <input type="checkbox"/> Approval date	
If denied please state the reason:	
Special Instructions:	

# NJ HIV Rapid Testing Support Administrative Issues

## ELIGIBILITY FOR ONE-DAY TESTING EVENTS

1. All agencies receiving kits and supplies from Robert Wood Johnson are required to submit this application approval.
2. The request for approval is received electronically [Sonya.Thompson@doh.state.nj.us](mailto:Sonya.Thompson@doh.state.nj.us) with a copy to ([corbojo@rwjms.rutgers.edu](mailto:corbojo@rwjms.rutgers.edu)) 10 business days prior to the event.
3. Testing venue/geographic area is considered a high prevalence location based on the County Zip code maps provided by DHSTS.
4. The target population is considered high risk for HIV as defined in the DHSTS HIV and Care Services Plan (available online at: <http://hpcpsdi.rutgers.edu/NJHPG/downloads/2012-16PCplan.pdf>)
5. Pre –event planning has occurred to assure the above criteria has been met.

## NJ HIV Rapid Testing Support Administrative Issues

### **NJHIV Positive Tracking Form**

- Use new form included in packet  
(available on [NJ HIV.org](http://NJHIV.org))
- Must be sent in as completed to RWJ
- Fax to 732-235-9012 or 732-743-3632

# NJ HIV Rapid Testing Support Administrative Issues

## NJ HIV Positive Tracking Form

### First Rapid HIV Test Result

**Client ID #** \_\_\_\_\_ **Date:** \_\_\_\_\_

**First Test Site ID Number** \_\_\_\_\_ **First Test Site Name** \_\_\_\_\_

**First Test Site Counselor Name** \_\_\_\_\_ **First Test Site Counselor Number** \_\_\_\_\_

**First Rapid HIV Test Type:** OraQuick      Clearview STAT-PAK      Determine      Other  
**Result:** Positive HIV 1/2 Antibody \_\_\_\_\_ Positive HIV Antigen (Determine) \_\_\_\_\_

Positive ANTIGEN ONLY (Determine)\_\_\_\_\_. No rapid tests can validate this result. Collect discordant work-up samples for confirmation, call NJHIV support for assistance and REFER client to care. This may represent an acute HIV case; confirmation may take 7-10 days.

**Specimen (circle one):** Oral    Fingerstick    Venipuncture    **Test Kit Lot Number:** \_\_\_\_\_

**For Single Rapid Test Sites and Non Clinical Rapid Rapid Test sites, this form must accompany the patient to test site where second test will be performed and must go to the treatment site. The form must be returned to the first test site to capture the positive result and referral to care.**

# NJ HIV Rapid Testing Support Administrative Issues

**Second Rapid HIV Test Result**

Date: \_\_\_\_\_

Enter site information if Second Test Site Is different from First Test Site:

Second Test Site ID Number \_\_\_\_\_ Also enter in Local Field 1 in Evaluation Web

Second Test Site Name \_\_\_\_\_

Second Test Site Counselor Name \_\_\_\_\_

Second Test Site Counselor Number \_\_\_\_\_ Also enter in Local Field 2 in Evaluation Web

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**Second HIV Test Type:** Rapid: Unigold      OraQuick      Result: Positive\_\_\_\_ Negative\_\_\_\_

**Sent to Laboratory:** Blood drawn for antigen confirmation\_\_\_\_ (see attached report)

Specimen (circle one):    Oral    Fingerstick    Venipuncture    Test Kit Lot Number: \_\_\_\_\_

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**Test Result:**

Check One:  Both Tests Positive

Evaluation Web Result Form with client information mailed to Surveillance

Date Mailed: \_\_\_\_\_ Mailed By: \_\_\_\_\_

Discordant Result (First test is positive and second test is negative. Also for **Antigen ONLY** positives). Draw 2 serum separator tubes and 2 white top tubes & Call NJ HIV Program at 732-743-3624 or 732-743-3620 for pickup. Process collected tubes according to instructions.

Second Test Not Done: Client refused - Contact Partner Services and complete Partner Services Referral Form.

**Fax to (732) 235-9012 when Rapid HIV Test Result part is completed**

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**Client Referral To Treatment**

Date client referred to treatment \_\_\_\_\_

Date of Appointment \_\_\_\_\_ Appointment Kept: Yes\_\_\_ No\_\_\_

If No, Why \_\_\_\_\_

Patient Navigated By: \_\_\_\_\_

**Fax to (732) 235-9012 when Appointment information is completed**

Form NJ HIV April, 2015

Section 2.3.1

# NJ HIV Rapid Testing Support Administrative Issues

## Rapid To Rapid Protocol

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
  - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive antibody result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

## NJ HIV Rapid Testing Support Administrative Issues

### **Discordant work up/ procedure:**

- If second rapid or confirmatory does not match first rapid the result is discordant
- Draw blood for work up:
  - Two white top tubes (must be spun down and frozen upside down)
  - Two serum separators (must be spun down and refrigerated)
- You must report all discordant results to RWJ
- Call 732-236-7013. Leave a message with contact information so RWJ pick up samples and process.

# NJ HIV Rapid Testing Support Administrative Issues

## Discordant Work Up in Rapid to Rapid Protocol

3. If the Second Rapid HIV Test is a negative result using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, you now have a **discordant result**. Call the NJ Rapid HIV Support Clinician at 732-236-7013 for guidance. Site staff should notify their medical director that a discordant has been identified and that additional testing will be done.
  - a. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes.

**Caution:** After collection, **BD Vacutainer® SST™ Serum Separation Tubes** should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection **BD Vacutainer® PPT™ Plasma Preparation Tubes (white top)** should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.

## NJ HIV Rapid testing Support Administrative Issues

**A few Not So Gentle Reminders**

# Monthly Rapid-Rapid Tracking Form – Page 1

<p>Please indicate what initial rapid and second rapid are used at your site == =&gt;</p>			<p><b>Initial Rapid:</b>          Determine ●          StatPak ○          Oraquick ○          UniGold ○          Insti ○          Architect ○</p>		<p><b>2<sup>nd</sup> Rapid:</b>          Oraquick ○          Determine ○          StatPak ○          UniGold ●          Insti ○</p>				<p>Please explain second rapid refusal or when a second rapid was Not Done. If you confirm with a different test please describe</p>
Site Number	Site Description	MONTH	(#) Number Screened	(#) Prelim Positive	(#) Second Rapid Performed	(#) Second Rapid REFUSED	(#) Second Rapid CONFIRMED	Discordant Results (#)	NOTES
6493	NJCRI- Office	12/2014	40	1	1	0	1	0	12/4/14 - 321628
6490	DOH Mobile 1	12/2014	29	1	1	0	0	1	12/7/14 – 321674 (DISC)
6487	CDC Mobile 2	12/2014	10	2	2	0	2	0	12/14/14 – 321687; 12/17/14 – 423542 (R2R)
6489	CDC Mobile 3	12/2014	14	1	0	1	0	0	12/15/14- 321694 (IN/IT). Client freaked out – see below.
<b>CUMULATIVE MONTHLY DATA FOR A SITE</b>									

# Monthly Rapid-Rapid Tracking Form – Page 2

SITE Number	IF R-2-R please indicate screening SITE Number	Date	Positive or Discordant Client CTS Number <b>DO NOT INCLUDE NJDH</b>	NEW POS	RE-ENGAGED	ALREADY IN-Care	CLIENT REFUSED APPOINTMENT	Appt. Date	CHARITY CARE REFUSED	Appt. Kept? (Y or N)	Appt. No Show	Bus Days to Lab Intake	COMMENTS
6493		12/4/2014	321628	1	0	0	0	12/5/2014	0	Y	0	1	
6490		12/7/2014	321674 (DISC)	0	0	0	0		0	-	0	0	Determine FP Ab – RNA negative at Quest 12/12/14
6487		12/14/2014	321687	0	1	0	0	12/16/2014	0	Y	0	2	
6487	6581 (Isiah House0)	12/17/2014	423542 (R2R)	1	0	0	0	12/20/14	0	Y	0	3	Rapid-2-Rapid screened at Isiah House, transported to NJCRJ for second rapid and linkage to care.
6489		12/15/14	321694	0	0	0	1		0		0	0	Client refused 2 <sup>nd</sup> rapid and left mobile van. NAP notified to follow-up. Navigator outreach.
INDIVIDUAL POSITIVE DATA (ONLY)													
<b>SUMMARY</b>				2	1	0	1		0	3	0		
<p><b>INSTRUCTIONS:</b> If your site provides Rapid-2-Rapid testing on behalf of another location, PLEASE enter their SITE NUMBER in the second column (gray section). Please use the first column to capture YOUR SITE NUMBER where the second (Unigold) rapid is being performed. PLEASE check off your INITIAL and Second Screening tests (Determine, StatPak, Unigold, Insti or Architect).</p> <p style="text-align: center;"><b>DO NOT RETURN PAGE 2 IF THERE ARE NO ENTRIES</b></p> <p style="text-align: center;"><b>DO NOT INCLUDE NJDH as part of the CTS number – it's redundant.</b></p>													

# NJ HIV Rapid testing Support Administrative Issues

## Test logs:

- RWJ test logs due the 10<sup>th</sup> of the month
- May also be sent as they are completed
- Please make sure logs are complete
  - Site Number, Contact Information, shipment number
  - Test information complete: Pos, Neg, Temperature, Start Time End Time, Operator Initials
  - If doing second test for another site indicate second test and site number of first site
- Fax to 732-235-9012 or 732-743-3632

## NJ HIV Rapid testing Support Administrative Issues

### **RWJ License renewals:**

- License renewals sent with a checklist
- Coordinator must sign checklist to indicate all items necessary for regulatory compliance are in place at the site
- Send copy of standing order indicating it has reviewed and is current must be included
- Copy of standing order template included in packet (available on [NJ HIV.org](http://NJHIV.org))

# NJ HIV Rapid testing Support Administrative Issues

## Checklist for License Renewal:

Site Name \_\_\_\_\_

- We have the current signed RWJ NJ Rapid HIV Testing Support Program Policy Manual available at our testing location.
  
- We are using the current signed Exposure Control Plan provided in the RWJ NJ Rapid HIV Testing Support Program Policy Manual.
  
- We have a current signed Exposure Control Plan available at our testing location if we are not using the plan provided in the RWJ NJ Rapid HIV Testing Support Program Policy Manual.
  
- We have a copy of the standing order for performing Rapid HIV Testing signed by our current Medical Director or Authorized Physician at our testing location. The standing order has to be reviewed this year; We have documented that it is current and that the medical director (who signed it) has not changed.
  
- We have attached a copy of the standing order with our license application for RWJMS records.**

Signed by:

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Site Testing Coordinator

# NJ HIV Rapid Testing Support Administrative Issues

## Standing Order Template

To Whom It May Concern:

This standing order shall constitute a request for rapid HIV testing for screenings performed at:

Name of Testing Site:

Address of Testing Site:

In cases where a client receives a preliminary positive result using a rapid HIV test, this authorizes:  
HIV Western Blot and/or a second Rapid HIV test (for all preliminary positives);  
and follow-up testing as appropriate to the clinical setting—which may include:

Additional HIV serology

HIV nucleic acid testing

Signature \_\_\_\_\_

Print Name \_\_\_\_\_

Medical Director

# NJ HIV Rapid Testing Support Administrative Issues

## Updated RWJ Rapid HIV Support Contact List



### Rapid HIV Testing Support Program Contact Information

Rutgers – RWJMS  
 Department of Clinical Pathology & Laboratory Medicine  
 NJ HIV Rapid Testing Support  
 One World's Fair Drive  
 Somerset, New Jersey 08873

732-743-3624 or 732-743-3630

732-235-9012 (fax)

732-236-7013 (Discordant Phone)

Website: [njhiv.org](http://njhiv.org)

Name	Position	Email	Telephone	Cell Phone
Eugene G. Martin, Ph.D.	PI and Co-Director	<a href="mailto:marlineu@rwjms.rutgers.edu">marlineu@rwjms.rutgers.edu</a>	732-743-3626	
Gratian Salaru, M.D.	PI and Director (DAS)	<a href="mailto:salarugr@rwjms.rutgers.edu">salarugr@rwjms.rutgers.edu</a>	732-743-3625	
Joanne Corbo, MBA, MT(ASCP)	Program Manager	<a href="mailto:corbojo@rwjms.rutgers.edu">corbojo@rwjms.rutgers.edu</a>	732-743-3620	
Latasha Adams BS, MT	Site Liaison POCT Coordinator	<a href="mailto:adamsli@rwjms.rutgers.edu">adamsli@rwjms.rutgers.edu</a>	732-743-3235	732-669-2327
Moeen Ahmed, BS, MT	Site Liaison POCT Coordinator	<a href="mailto:ahmedmo@rwjms.rutgers.edu">ahmedmo@rwjms.rutgers.edu</a>	732-743-3607	732-609-3425
Claudia Carron, MSN, RN	Site Liaison & RWJMS POCT Coordinator	<a href="mailto:carronc1@rwjms.rutgers.edu">carronc1@rwjms.rutgers.edu</a>	732 235-6045	732-947-1021
Aida Gilanchi, BS, MT	Site Liaison POCT Coordinator	<a href="mailto:gilanchi@rwjms.rutgers.edu">gilanchi@rwjms.rutgers.edu</a>	732-743-3629	732-453-4704
Franchesca Jackson, BS, MT	Site Liaison POCT Coordinator	<a href="mailto:jacksofn@rwjms.rutgers.edu">jacksofn@rwjms.rutgers.edu</a>	732-743-3628	732-947-1015
Nisha Intwala Patel, MT (ASCP)	Site Liaison POCT Coordinator	<a href="mailto:intwalni@rwjms.rutgers.edu">intwalni@rwjms.rutgers.edu</a>	732-743-3612	732-947-1020
Mariana Moreno	Public Health Representative	<a href="mailto:morenom2@rwjms.rutgers.edu">morenom2@rwjms.rutgers.edu</a>	732-743-3611	732-609-9136
Lisa May	Program Assistant	<a href="mailto:mayli@rwjms.rutgers.edu">mayli@rwjms.rutgers.edu</a>	732-743-3624	
Karen Williams	Administrative Assistant	<a href="mailto:Williak2@rwjms.rutgers.edu">Williak2@rwjms.rutgers.edu</a>	732-743-3630	

RUTGERS

Robert Wood Johnson Medical School

What's it all about....

From Screening through Diagnosis to Linkage!

Eugene G. Martin, Ph.D.

*Professor of Pathology & Laboratory Medicine*

**Rutgers – Robert Wood Johnson Medical School**

New Brunswick, NJ

&

***Co-Director, NJ HIV***

Rapid HIV Test Support

NJ Department of Health

Division of HIV, STD & TB Services,



# Agenda

1. A Ten Year Partnership: [DHSTS and Rutgers] – “ A Time to remember” .....And to Reflect on what we’ve accomplished and how much more remains!
2. Why we’re focusing on earlier stages of an HIV infection
3. Review the dynamics of an HIV infection
4. 4<sup>th</sup> Gen. POC Testing – Alere Determine (DC) HIV1/2 Combo
5. Roll-out Of DC in NJ – A work in progress. What to expect.
6. The NJ Rapid Testing Algorithm and Linkage to Care
7. Discordant Specimens:
  - A Little History
  - 2015
8. Special Projects:
  - HCV/HIV Initiative
  - Syphilis Initiative
9. What else is coming?!
  - Automated readers
  - POC molecular testing

# ASTHO VISION AWARDS – 1<sup>st</sup> Place

## RAPID HIV TESTING PROGRAM

- 2006 -



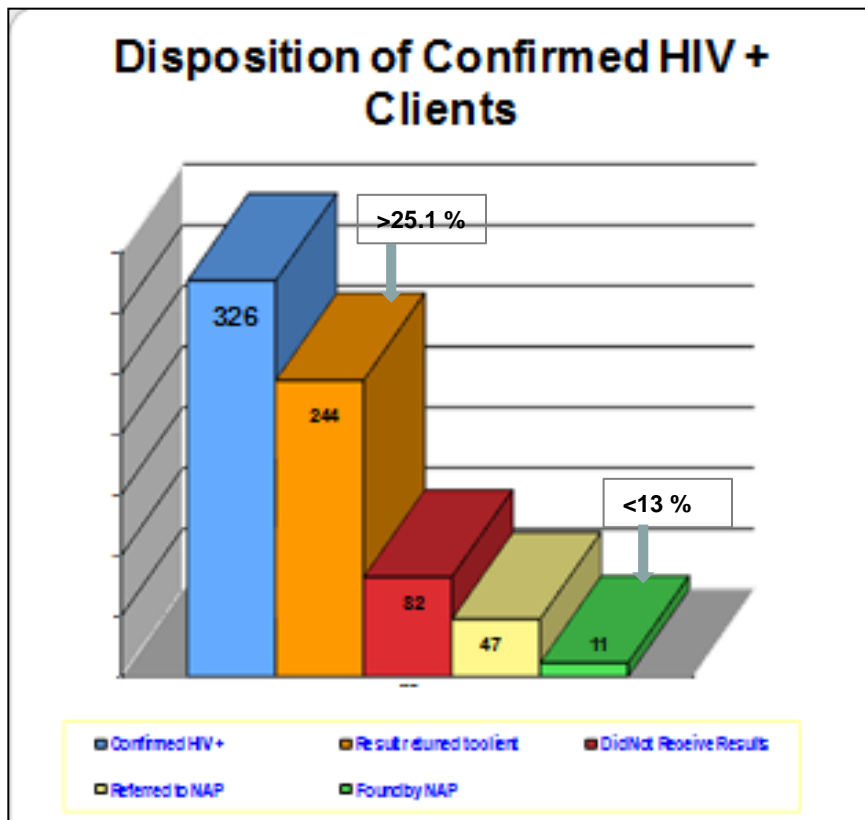
## PATIENT NAVIGATOR PROGRAM

-2013-

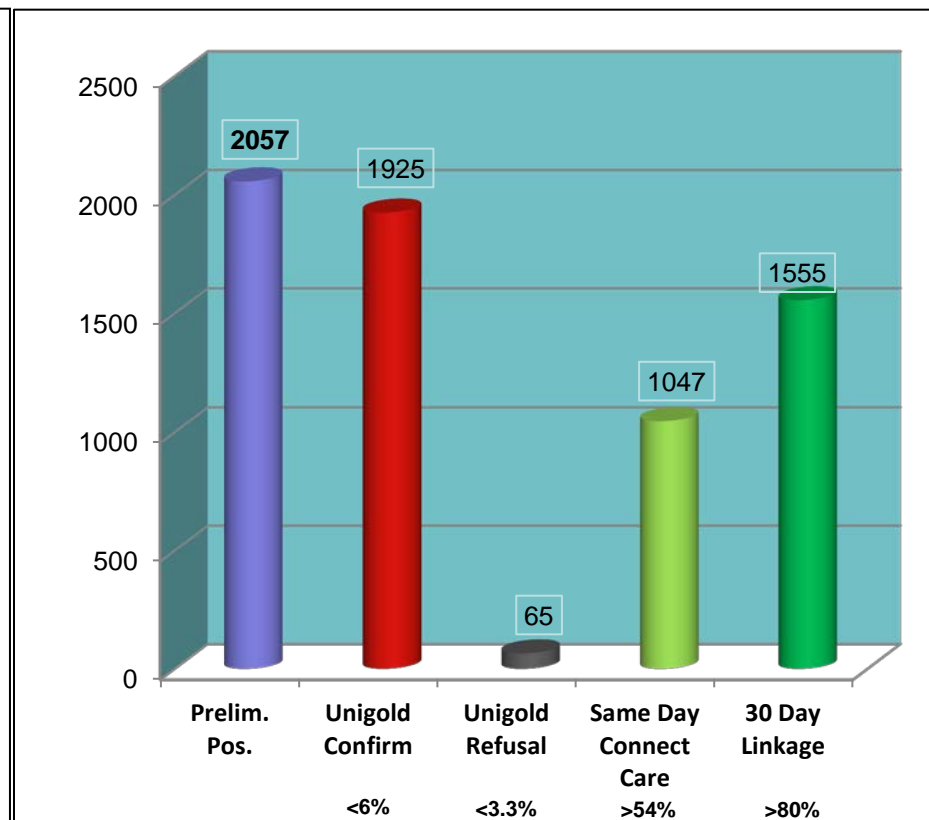


# A Long Ways in a Decade!

**Rapid Plus Western blot (2004)**



**Rapid Test Algorithm (2009-2014)**

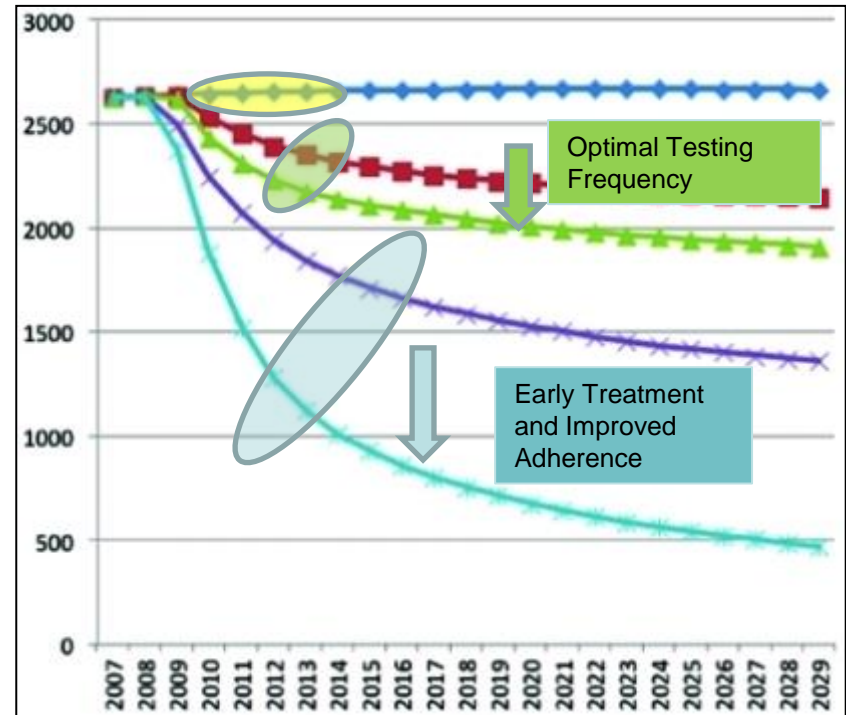
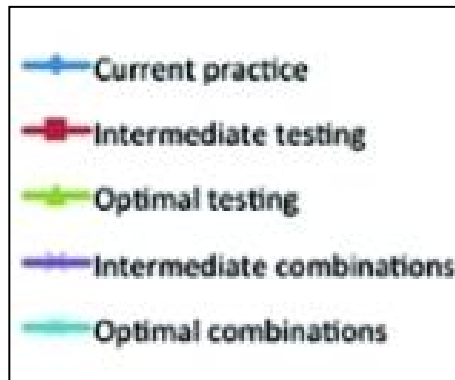


*It's not just a question of how sensitive a test is...  
it's also a question of how often we test, how  
effectively we link the affected into care, and how  
well we retain clients in care...*

## **BACKGROUND & PERSPECTIVE**

# Optimal Testing, Early Treatment & Improved Adherence.

Annual number of new HIV infections over 20 years for MSM in New York City



Test-and treat interventions may increase the numbers of patients initiating ART early BUT without stabilizing the back end of treatment continuum (i.e., care retention and ART adherence), test-and-treat strategies fall short of their potential

NOT linking infected clients early → substantial treatment delay.

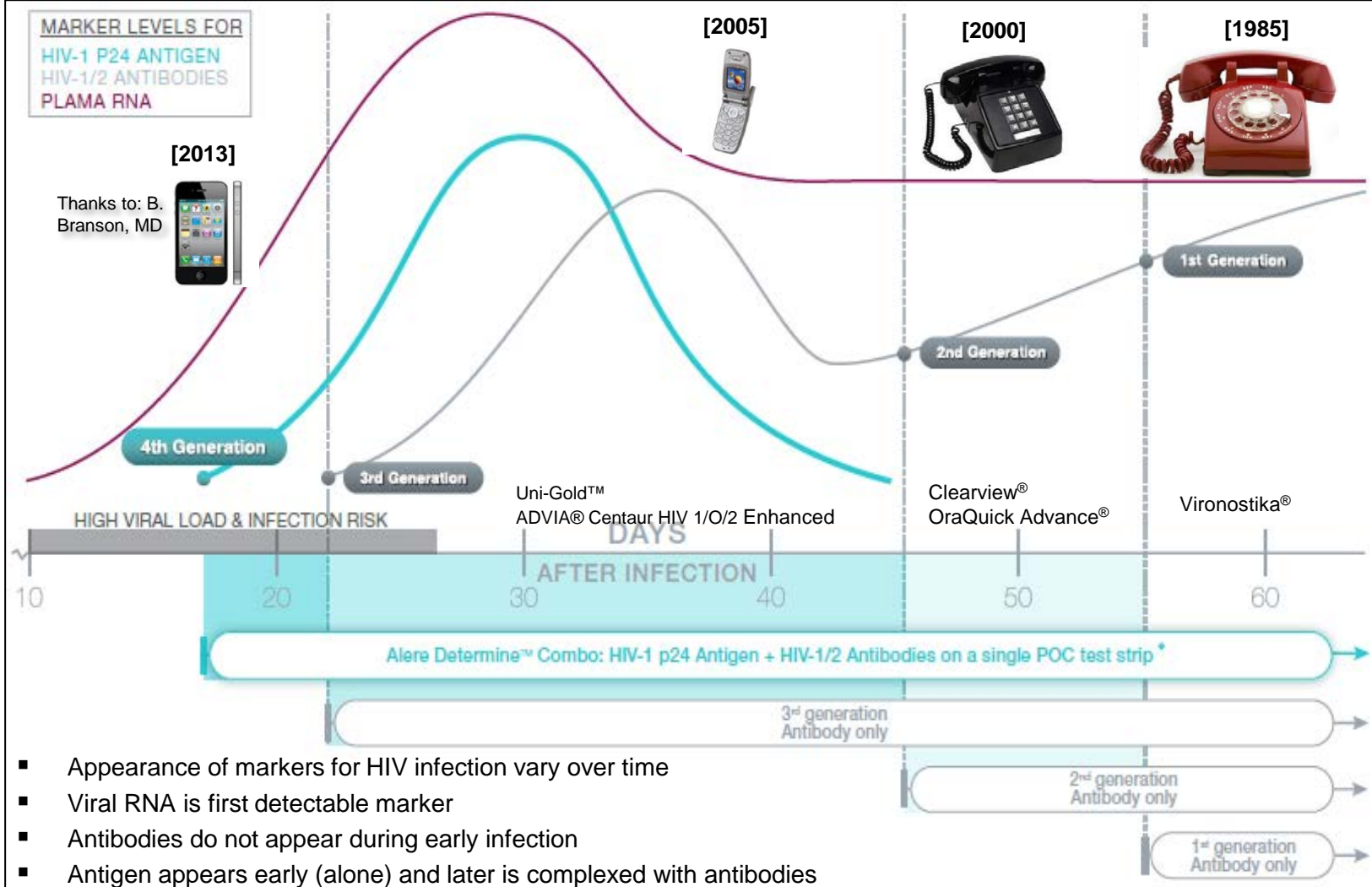
– CDC Diagnostics 2010 - Piatek and Delaney

- Clients who receive the result of a confirmed test were 3.6 times more likely to be in treatment
- After 3 months, median time to treatment was 524 days, or almost 1.5 years after diagnosis
- In NJ – only 69% of blacks received ‘confirmed results’ compared to 80% of whites
- Only 60% of drug users received ‘confirmed results’
- A second rapid reduces false positive results AND permits faster linkage to care
- As our focus shifts towards AHI → delays in evaluation and linkage become problematic – i.e. transmission risk, non-optimized management
- **Trade-offs:** Increased Sensitivity with Lab-based testing vs. Reduced Linkage

New Possibilities – New Directions

# **A NEW GENERATION OF HIV DIAGNOSTICS**

# HIV Detection Improves Over 30 Years



Graph was modified from data Fiebig et al. Fiebig EW, Wright DJ, Rawal BD, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. *AIDS*. 2003;17(13):1871-1879.

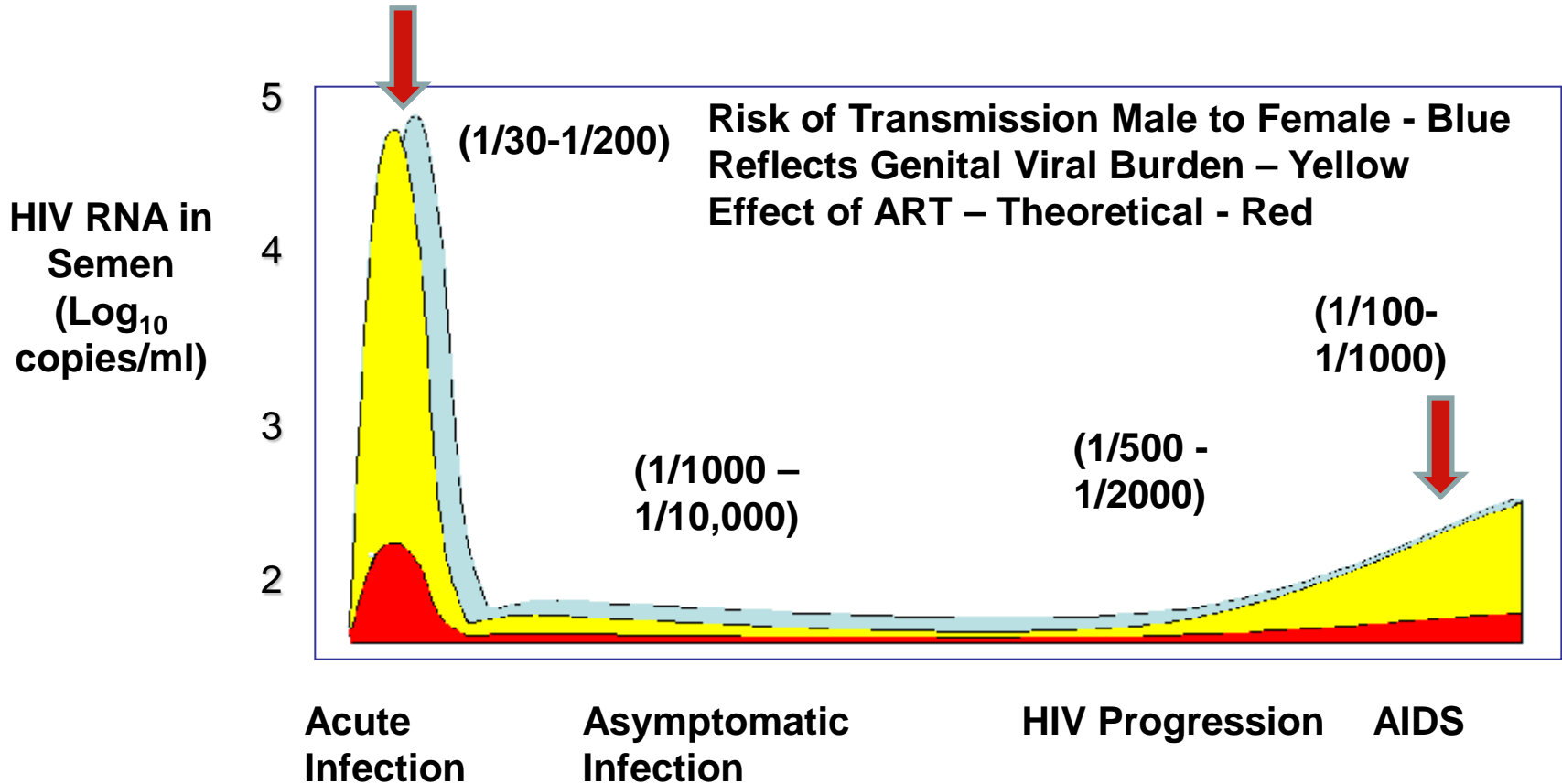
## NAAT Testing of 2<sup>nd</sup> gen. Rapid HIV Negative Individuals

- When compared against CURRENT RAPID HIV TESTS, NAAT tells us we're missing between 6-8% of those infected when we screen using traditional rapid HIV tests
- Those with the highest risk of infecting others are the one's that are being missed!!
- The same issues with patient return and process completion occur with NAAT that occur with traditional testing!!!
- **Solution:** A test that picks up p24 Ag COULD identify a substantial proportion of the same population. A POCT device could increase the pickup without losing the ability to link patients to care.

# NAAT Testing of Antibody Negative Blood

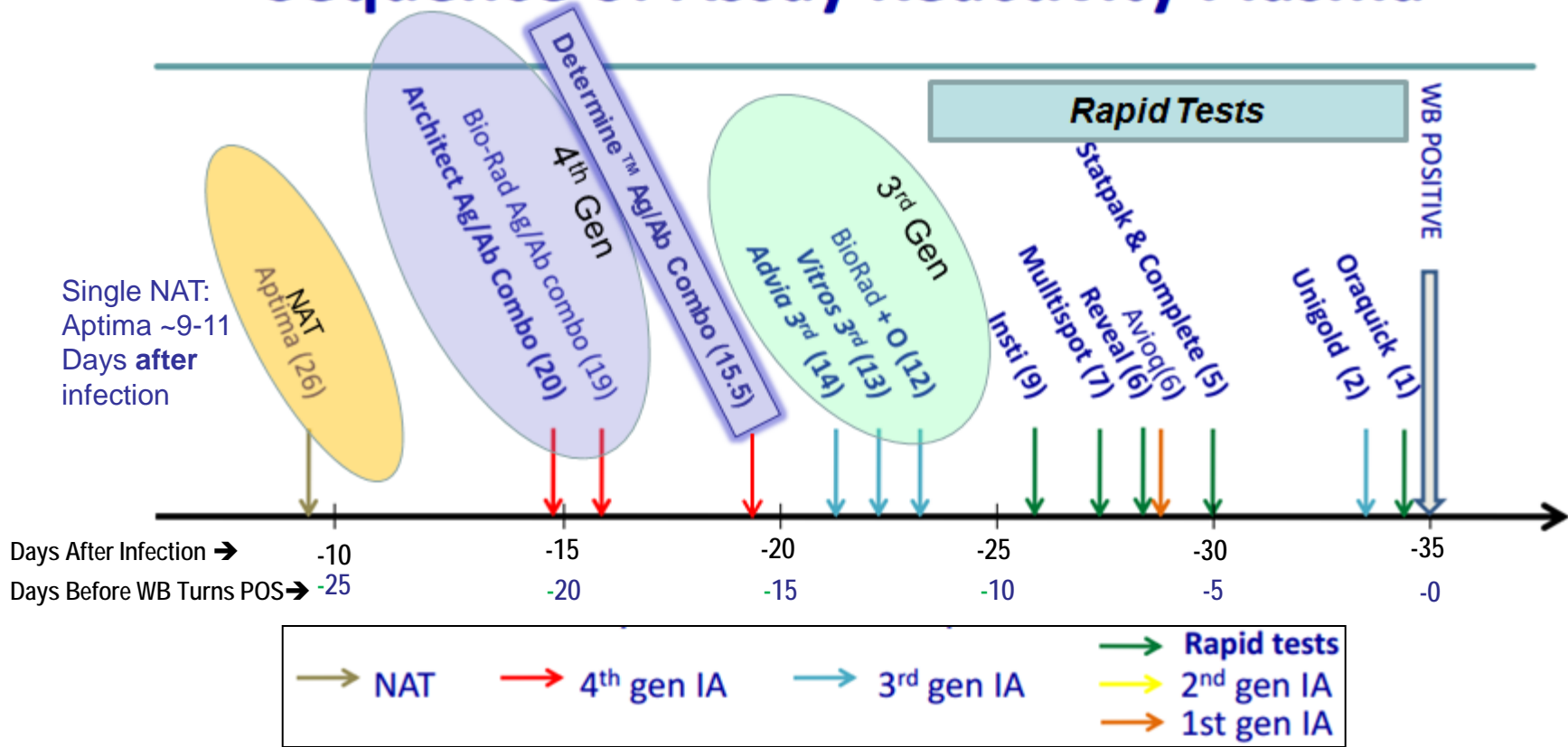
Program	Dates	Description	Rapid Tested	NAAT Tested	AHI	HIV Ab+	% HIV Ab +	% Inc in Yield	% Yield AHI
<b>Maryland</b>	6/06-3/08	HIV Ab neg adults seen at two STD clinics (6/06--3/08); multiple venues 7/07-3/08)		58,925	7	1,709	2.90%	0.41%	0.01%
North Carolina	11/02-10/03	HIV Ab neg persons in North Carolina seeking HIV testing at 110 publicly funded sites (n = 109,250)		108,667	23	583	0.54%	3.95%	0.02%
<b>Los Angeles</b>	2/04-4/04	HIV Ab neg men seeking HIV testing at three STD clinics (n = 1712)		1,698	1	14	0.82%	7.14%	0.06%
<b>NEWARK, NJ</b>	2/10 to 1/12	HIV Ab neg adults receiving testing and counseling at two high risk urban hospitals in Newark, NJ	12,390	6,785	<b>8</b>	116	0.94%	6.90%	0.12%
<b>Seattle King County</b>	9/03-1/05	HIV Ab neg MSM seeking HIV testing through Seattle-King County (n = 3525)		3,439	5	81	2.36%	6.17%	0.15%
<b>Atlanta</b>	10/02-1/04	2202 adults receiving HIV testing and counseling at three high risk urban sites in Atlanta, Georgia		2,136	4	66	3.09%	6.06%	0.19%
<b>San Francisco</b>	10/03-7/04	HIV Ab neg persons seeking HIV testing at San Francisco Municipal STD clinic (n = 3075)		2,722	11	105	3.86%	10.48%	0.40%

# Why is this Important?



# The Range of HIV Sensitivity – Screening to Diagnosis

## Sequence of Assay Reactivity Plasma

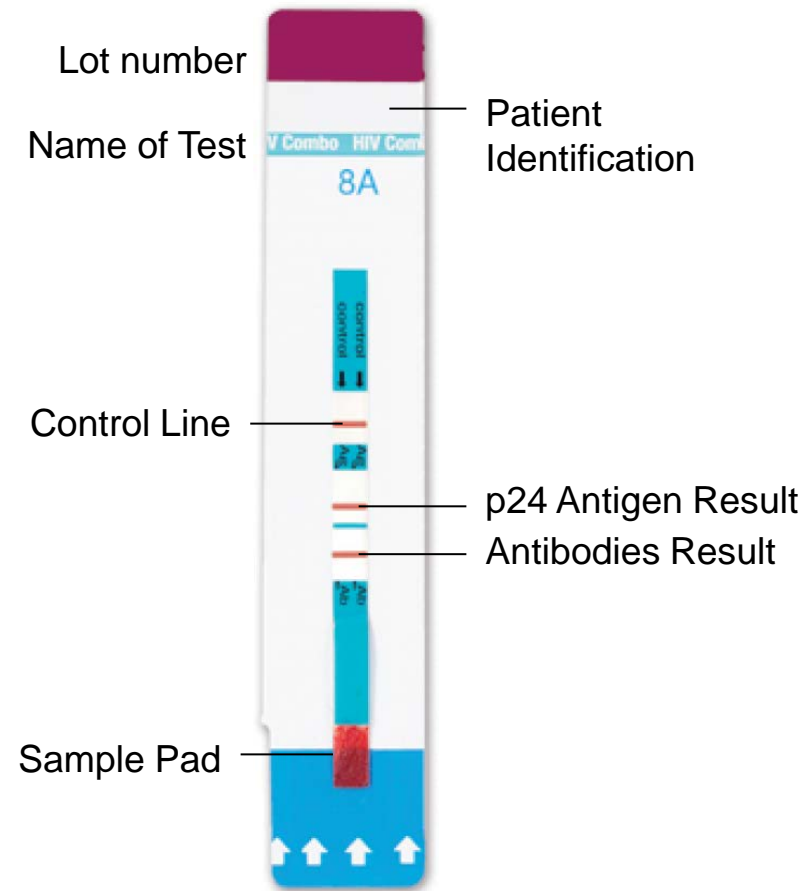


Adapted from Owen et al J Clin Micro 2008 and Masciotra et al J Clin Virol 2011

# Point Of Care Based – 4<sup>th</sup> Gen. HIV Screening

## Alere Determine Ag/Ab Combo

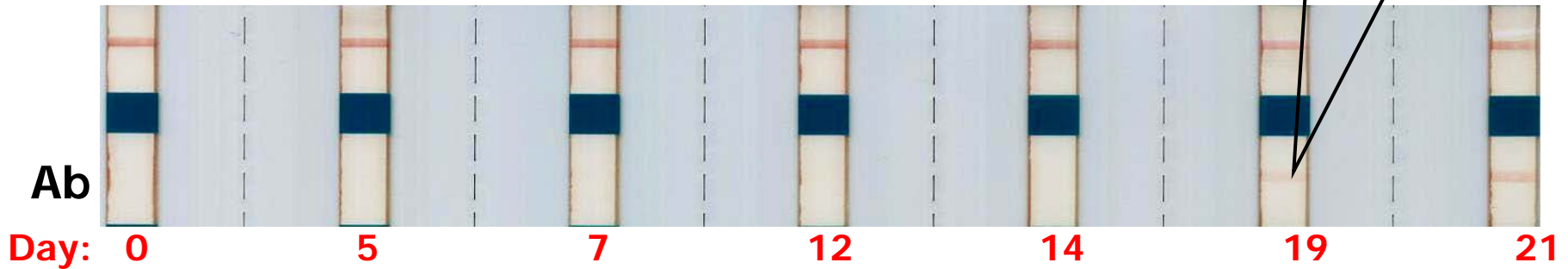
- Tests for the **simultaneous and separate** qualitative detection of **free HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2.**
- It is intended for use as a point-of-care test *to aid in the diagnosis of infection with HIV-1 and HIV-2, including an acute HIV-1 infection, and may distinguish acute HIV-1 infection from established HIV-1 infection* when the specimen is positive for HIV-1 p24 antigen and negative for anti-HIV-1 and anti-HIV-2 antibodies.



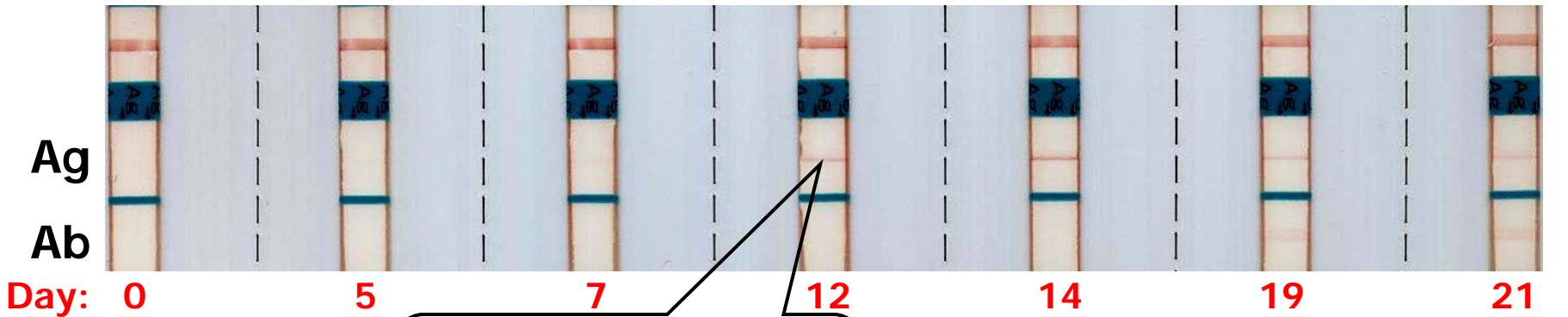
# Panel AS PRB943 (BBI, Seracare)

Somewhat Later – Ab

## Determine HIV-1/2 (3<sup>rd</sup> gen)

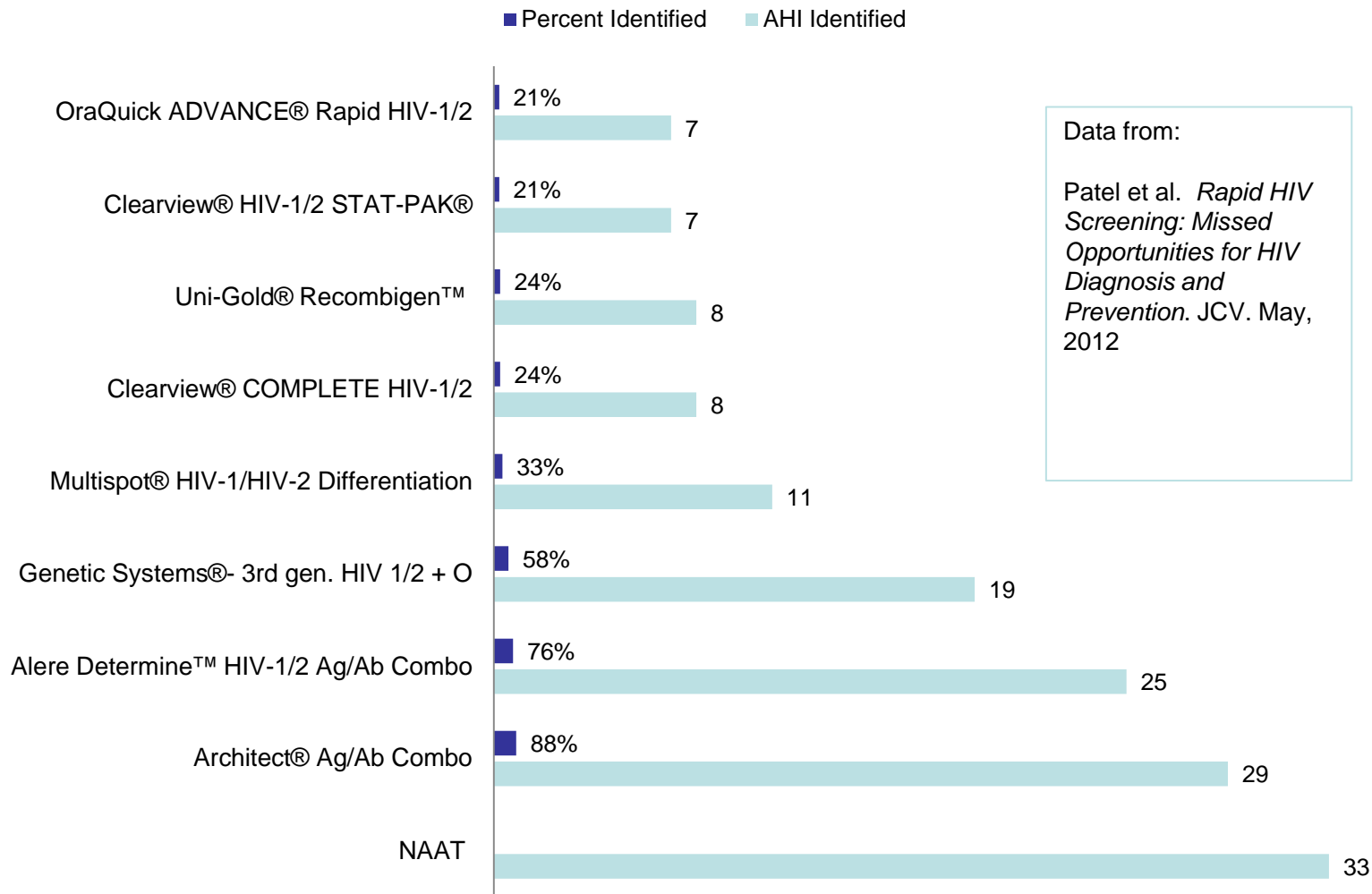


## Determine Combo (4<sup>th</sup> gen)



Early – free p24 Ag

## EARLY HIV INFECTION IDENTIFIED



# - Picking up AHI with Determine Combo

Determine™ HIV-1/2 Ag/Ab Combo  
*NO Detection of p24 in Blood*

<u>Population</u>	<u>P24 Sensitivity</u>	<u>Reference</u>
United France	0% (0/2)	Pavie, 2010
United Kingdom	0% (0/2)	Taegtmeyer, 2011
Malawian STI attendees	0% (0/8)	Rosenberg, 2012
United Kingdom	0% (0/2)	Jones, 2012
Australia	0% (0/9)	Conway, 2014
South Africa	0% (0/18)	Chetty, 2012

1. Limited studies (worldwide) of acute HIV infection suggest that Determine Combo may lack sufficient sensitivity to pickup *documented* p24Ag in fingerstick samples.
2. AN ANSWER IS COMING!
  - CDC has just awarded a \$6M grant to the Univ. of Washington to conduct a **multi-year field study** including seroconversion sensitivity for all the new HIV tests.

Thanks to:  
Myron Cohen, MD

## Determine HIV Combo Assay when Used for Point of Care Testing in a High Risk Clinic-Based Population – Sydney, Australia

**Table 2.** Characteristics of cases of early HIV infection.

Group	Case	Rapid test result		Last negative HIV test (months)	4 <sup>th</sup> Gen HIV Ag/Ab	Supp HIV Ab	Western blot	HIV p24 Ag titre (pg/ml)	HIV RNA (copies/ml)	CD4 count (cells/mm <sup>3</sup> )	HIV subtype
		Antibody	Antigen								
Acute	1	NR	NR	11	POS	NEG	NEG	701	3898751	510	B
	2	NR	NR	9	POS	NEG	NEG	86	93197	480	NA
	3	NR	NR	4	POS	NEG	NEG	115	99171	380	B
Recent	4	NR	NR	65	POS	WK POS	IND	217	376879	920	B
	5	R	NR	8	POS	POS	IND	66	568763	840	C
	6	R	NR	6	POS	POS	IND	143	274918	440	B
	7	R	NR	3	POS	POS	IND	NEG	13003	870	B
	8	R	NR	5	POS	POS	IND	NEG	23843	580	B
	9	R	NR	2	POS	POS	POS	NEG	8422	260	CRF02_AG
	10	R	NR	3	POS	POS	POS	NEG	37591	600	B
	11	R	NR	4	POS	POS	POS	NEG	102326	510	B
	12	R	NR	6	POS	POS	POS	NEG	29500	515	B

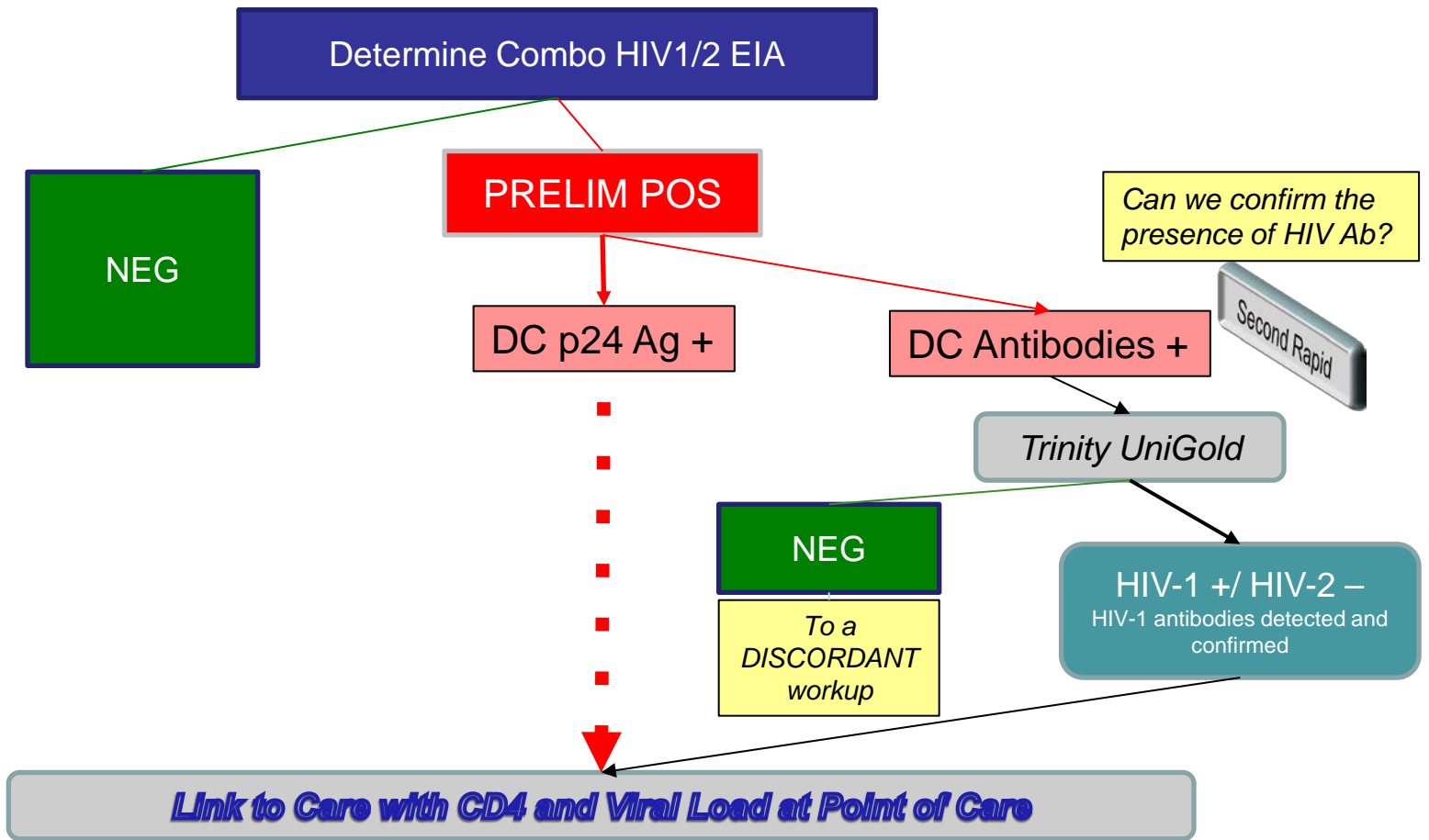
Acute = HIV RNA or p24 antigen positive, but HIV antibody negative; Ag = antigen; Ab = antibody; IND = indeterminate; ml = millilitre; mm<sup>3</sup> = cubic millimetre; NA = not available; NEG = negative; NR = non-reactive; R = reactive; recent = HIV antibody positive, but infected within last 6 months; pg = picograms; POS = positive; WK POS = weak positive.

Conway DP, Holt M, McNulty A, Couldwell DL, Smith DE, et al. (2014) Multi-Centre Evaluation of the Determine HIV Combo Assay when Used for Point of Care Testing in a High Risk Clinic-Based Population. PLoS ONE 9(4): e94062. doi:10.1371/journal.pone.0094062

## Determine Combo Summary

1. Determine Combo (DC) for early HIV infection is slightly better than current 3<sup>rd</sup> generation assays –BUT, *a huge improvement at the Point of Care!*
2. DC performance is superior to all rapid POC HIV tests currently in the US market.
3. But, it may also be fair to suggest that the Ag component of DC may have limited benefit as part of a POC screen for Acute HIV infection. ☹'
4. BUT THINK ABOUT IT... *we actually miss more cases by failing to link identified cases than are missed by failure to detect cases in the first place*

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DISCORDANT WORKUP

RNA Testing



## Implementation of DC in New Jersey

1. **VALIDATE** the test using a commercially available (Seracare PRB205(M)) HIV mixed titer Performance Panels (April-May, 2014) – 24 specimens – 22 are reactive at varying titers
2. **WRITE** procedures, policies, report forms:  
<http://www.njhiv.org>
3. **PILOT** the test in 2-3 sites over 6 months, working out the ‘bugs’\
  - Discordant results – 3.
4. **WAIT FOR CLIA waiver** ☹ => Granted December 9, 2014! ☺
5. **DEVELOP** a training program for new sites →
6. Determine trainings since February 1 =>
  - 56 DHSTS and addictions sites trained during 50 training sessions
7. Testing volume is beginning to ramp-up.

# ISSUES WITH IMPLEMENTATION

## *DEVIL IS ALWAYS IN THE DETAILS!*

- OPERATORS – Learning Curve.. How fast do operators move through it? Importance of our technical liaisons!
  - Small details can be very important...droppers.
  - TEST DEVICES – How are they functioning?
  - NEW PROCEDURES – How are we adapting?
- 
- EXPECTATIONS:
    1. Short term increase in the number of discordants observed
    2. Modest Increase in the number of identified HIV Ab+ specimens
    3. Uncertain whether we will see HIV p24Ag+ fingerstick specimens

# What do discordants and hiccups have in common?

Answer:

They are unusual, but not unexpected!

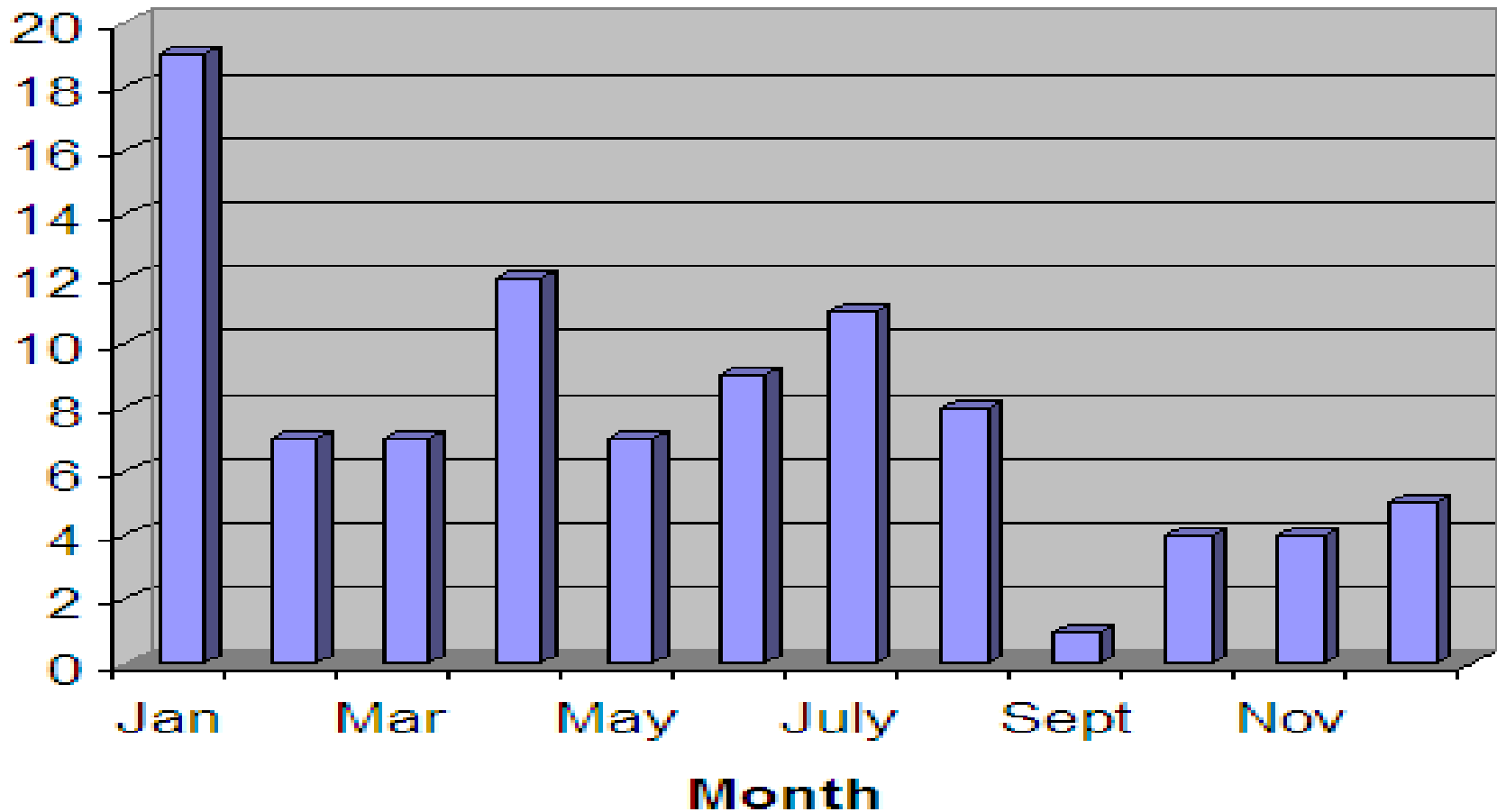


Ruzomberok,  
Slovakia

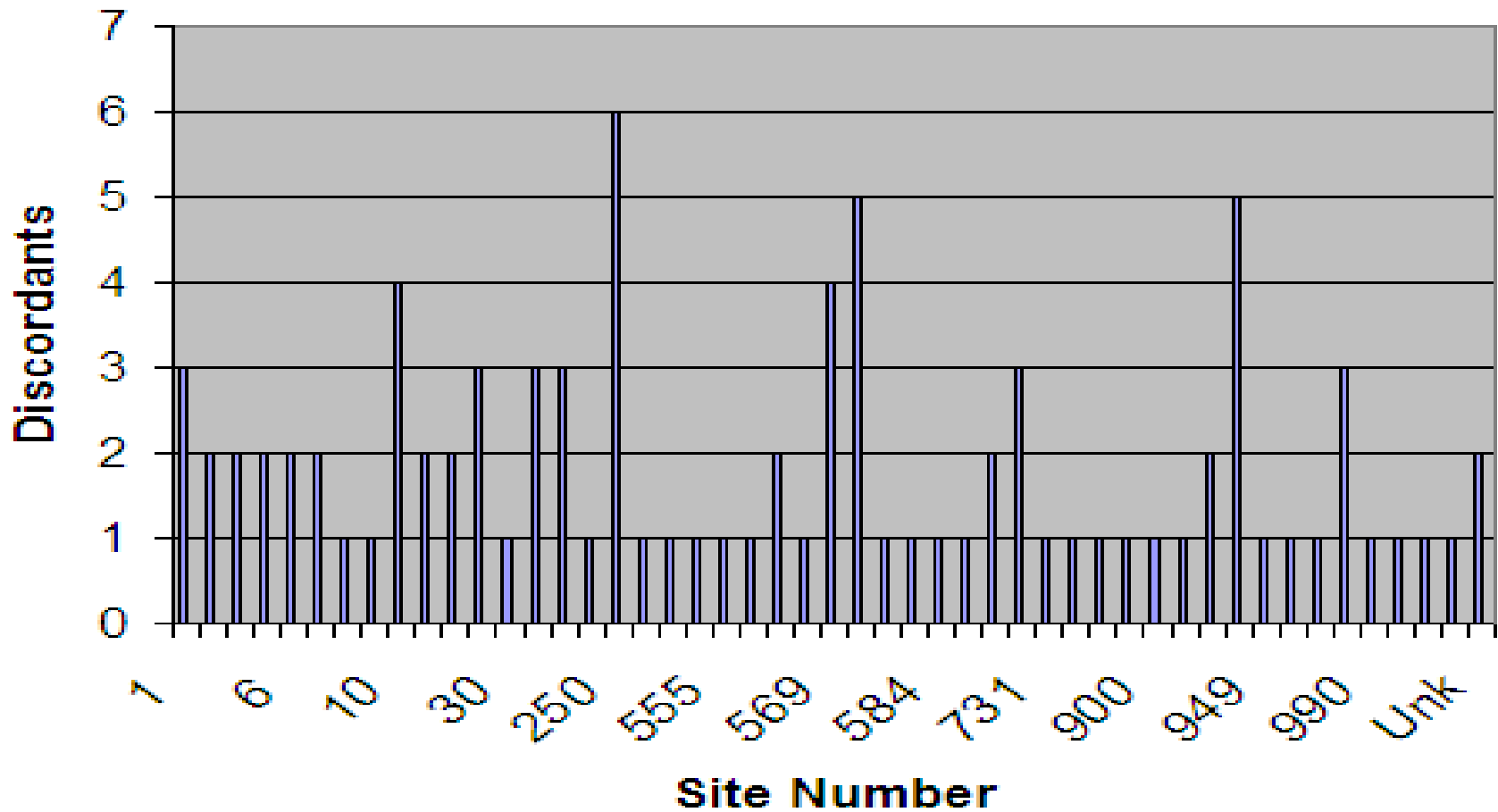
# 2007 Discordant Analysis - Orasure Oraquick

Month	Number	Primary Site	Site Number	CTS #	Date	EIA result	WB result	OraQuick	OQ Lot (DEVICES	Demographic		
Jan	7-1	Camden AHEC	718	70104569	1/5/2007	0.842/0.423	IND: p17=8,p24=8,p 55=8,gp160-1	oral pos	1106611	White	T<C	p17,24,55(8) gp160(1) NAP unable to locate
Jan	7-2	Morristown Mem 9		70184478	1/15/2007	0.285/0.422	no bands	oral pos	1006715	White	T<C	ARUP, False Pos
Jan	7-3	Ocean County	11	70094826	1/16/2007	0.128/0.422	no bands	fingerstick	1106611	White	T<C	ARUP, False Pos
Jan	7-4	Ocean County	11	70094828	1/16/2007	0.126/0.404	no bands	fingerstick	1106611	Af.Amer	T<C	NAP contacted but refused testing/closed
Jan	7-5	Plainfield	905	70177255	1/17/2007	0.117/0.404	no bands	fingerstick	1106611	multi-racial?	T<C	ARUP, False Pos
Jan	7-6	Burlington	16	61621431	1/23/2007	0.133/0.406	no bands	oral pos	1106611	Af.Amer	T<C	NAP 42028772 3/30/07 negative
Jan	7-7	Plainfield	905	70177276	1/19/2007	0.199/0.425	no bands	oral pos	1106611	White-Hisp	T<C	ARUP, False Pos
Jan	7-8	Burlington	16	37111486	1/29/2007	0.130/0.416	no bands	oral pos	1106611	Af.Amer	T<C	ARUP, False Pos

# Monthly Frequency -2007



# Site Frequency - 2007



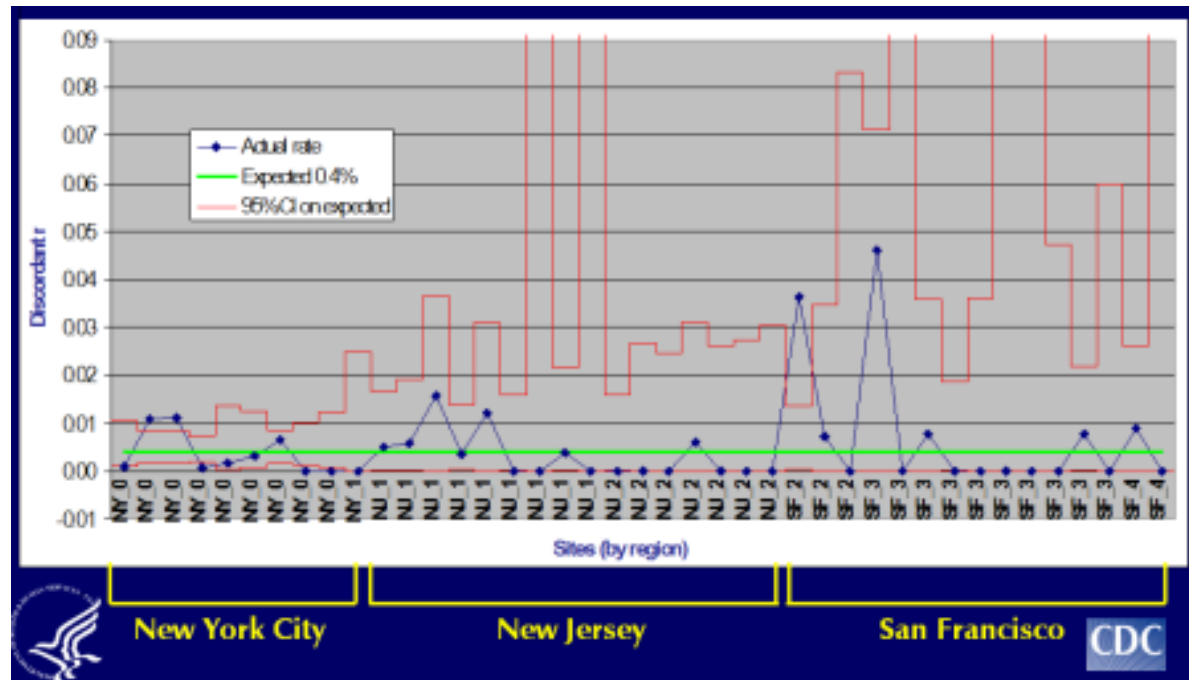


# Discordant Analysis - 2007

- Discordant events:  
(i.e. Rapid HIV +, Western blot -)
  - Infrequent event at each site
  - Not infrequent across all of NJ
- Goals for NJHIV:
  - Analyze each event -
  - Guide sites specifically on the handling of follow-up
  - Consolidate information
  - Look for trends
  - Alert manufacturers if lot performance becomes suspect

## Outcome:

- NJ HIV became a resource for both CDC & Rapid HIV Manufacturers



New York City

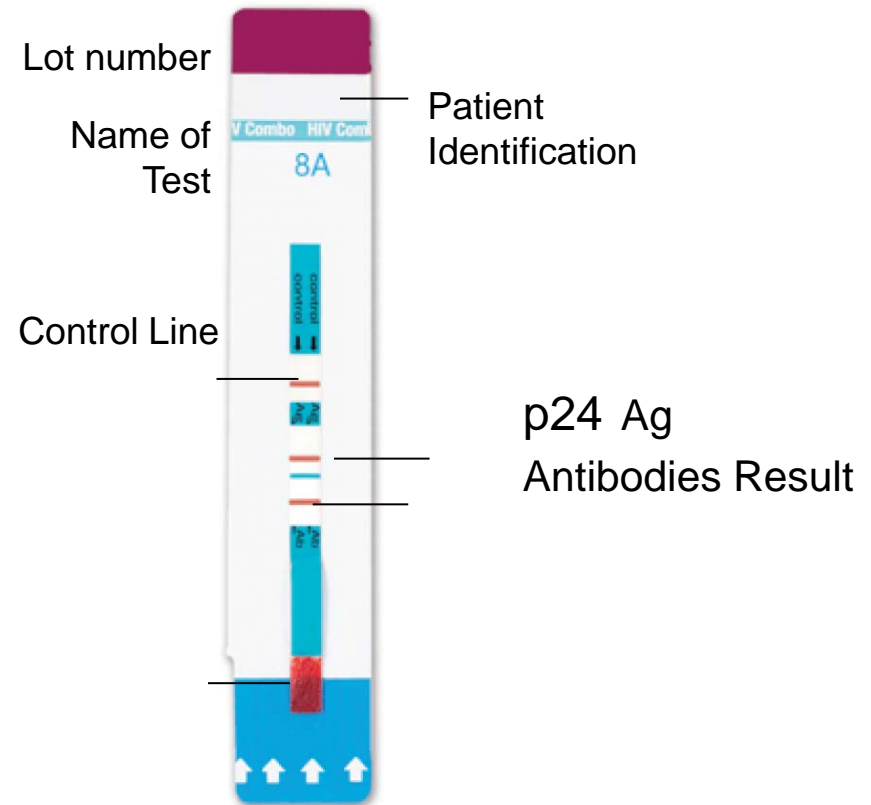
New Jersey

San Francisco



## DETERMINE COMBO OBSERVATIONS

- **Controls:**
  - Ag -, Ag +, Neg,
- **CLIA waived product** is supposed to be simpler, but it has introduced some **complications:**
  - Pipets – Precision vs. Transfer
    - **Control Drop size**
  - Application of blood directly to the specimen pad - OK
- **Discordant workups:**
  - RNA and MultiSpot
- **WHEN IN DOUBT TRUST THE PACKAGE INSERT!**



# DISCORDANT RESULTS 2015

	Site	Product	Ag/Ab/both	UG	Resolution	RNA copies/mL	Ref lab: MS (MultiSpot), EIA
1	Site A	Determine/Unigold	DC Ag	UG-	FP DC	<20	3rd gen EIA -
2	<b>RWJMS-003</b>	<b>Determine/Unigold</b>	<b>DC Ab</b>	<b>UG-</b>	<b>FN UG</b>	<b>1,515,677 c/mL</b>	<b>MS HIV-1 Ab +</b>
3	Site B	Determine/Unigold	DC Ag Ab	UG -	FP DC	<20	3rd gen EIA -
4	Site B	Determine/Unigold	DC Ag (20 min ONLY)	UG-	FP DC	<20	3rd gen EIA -
5	Site C	Determine/Viral Load	DC Ag Ab (Partial line)	UG-	FP DC	<20	3rd gen EIA -
6	Site B	Determine/Unigold	DC Ab	UG-	FP DC	<20	3rd gen EIA -
7	Site DI	Determine/Unigold	DC Ab	UG-	FP DC	<20	3rd gen EIA -
8	Site B	Determine/Unigold	DC Ab	UG-	FP DC	<20	3rd gen EIA -

- Discordant Frequency is a function of a number of factors:
  - Operator Experience
  - Technical Limitations of the assay
  - Nuances: ~ 50 uL sample volume,
  - The first year we introduced Orasure - Oraquick we documented >130 discordant specimens in screening ~50,000. The bulk of these occurred in the first 6 months. There was a nationwide Post Marketing Surveillance process in place.
  - It is too early for the analysis from 2007, but it will follow later in the year

HCV AND SYPHILIS SCREENING AT THE POINT-OF-CARE  
**SPECIAL PROJECTS:**

# What's Old is New Again!

## Limited Pilot Study Underway

- HCV screening - NJ
  - Oasis Drop-In – Atlantic City
  - Camden AHEC – Camden
  - Hyacinth AIDS Foundation – Jersey City
  - NJCRI – Newark
  - Well of Hope – Paterson
- Goal: Screen 25 patients/month at each site Any visit to ARCH nurse is asked to be screened for HIV and HCV.
- March – June goal: 300 tests

## Orasure Rapid HCV Test



## Co-Morbidities:

Why we're interested in more than one marker at a time?

- An ~ 16% of all patients and ~ 28% of men infected with syphilis have co-infection with HIV in the United States
- Syphilis facilitates HIV acquisition (~ increase 2-4 fold) and transmission (~ increase 2-9 fold)
  - The presence of genital ulcers can increase HIV acquisition by disrupting natural and mucosal epithelial barriers.
  - Syphilis can enhance HIV transmission by increasing viral shedding.
  - *Treponema pallidum* infection **DECREASES** CD4 counts in HIV-infected patients and **INCREASES** HIV viral load, both of which have been linked to **INCREASE IN HIV transmission!**

# A Very limited study NOT YET underway in NJ

**–News Release –  
December 15, 2014**

- FDA grants CLIA waiver expanding the availability of rapid screening test
- 
- ✓ Results in 10 minutes
  - ✓ 98% agreement to other treponemal tests
  - ✓ Finger-stick sample collection for whole blood

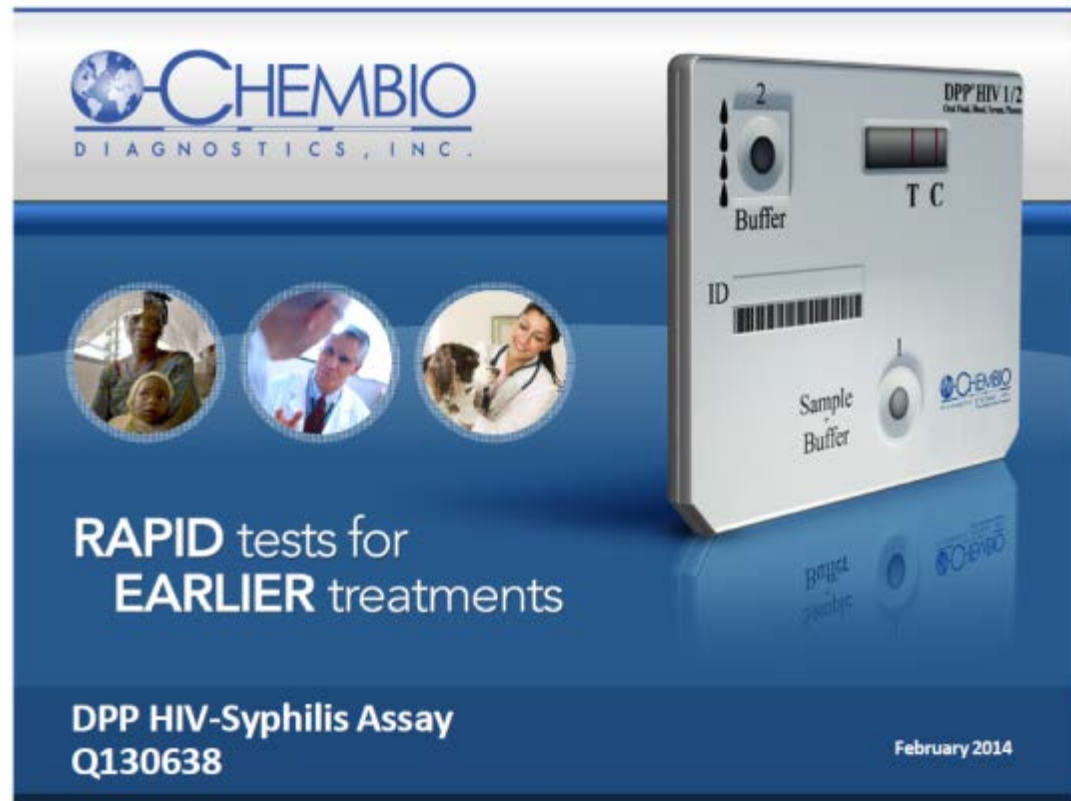
***Syphilis Health Check™***  
Syphilis Antibody Rapid



# **NEWER TECHNOLOGIES:**

## A COMBINATION HIV-SYPHILLIS ASSAY *in development*

- Launched in Brazil
- Completing Pre-PMA Studies in the US with submission to the FDA planned for winter, 2015
- CDC has looked at this device with repository serum:
  - 99.5% positive agreement with Biorad HIV EIA results in testing >1400 specimens
  - 98.8% positive agreement with TP-PA (*Treponema pallidum* particle agglutination (TP-PA))



## Transforming the mobile phone a diagnostic device

### iSTOC



[https://www.youtube.com/watch?feature=player\\_embedded&v=rwcpyOwnCRE#t=0](https://www.youtube.com/watch?feature=player_embedded&v=rwcpyOwnCRE#t=0)

### Reading a Rapid Test

- Laboratory test readers exist, but - typically bulky and costly.
- Using the power of the smartphone to scan, analyze, display results to the user, and transmit for medical consultation.

POC NAT: for infant HIV-1/2 diagnosis – 52 min  
 NOT YET APPROVED IN USA

<https://www.youtube.com - Alere q Infant Dx Video>



- NAT-based viral load systems currently require testing to be performed in a laboratory setting
  - Lack of return -> Lack of treatment
- Currently no POC viral load assays are on the market, a number are in development:
  - Alere NAT system - integrated platform for quantitative measurement of HIV-1 and HIV-2 viral load from approximately 25  $\mu$ L of whole blood.
    - Detects HIV-1 Groups M, N, and O and HIV-2.
    -



## Lab-based - Bio-Rad 5th Generation HIV Test

- Lab-based test identifying which individual HIV 1 and HIV 2 marker is positive.
- Sidesteps the need for the MultiSpot
- Indicates:
  - Recent infection
  - Guides follow-up testing
  - Delivers patient results faster - Sidesteps the MultiSpot



BioPlex<sup>®</sup> 2200



BioPlex HIV Ag-Ab kit

**RWJMS**

- Eugene Martin, Ph.D.
- Gratian Salaru, MD
  
- Joanne Corbo, MT (ASCP), MBA
  - Latasha Adams BS,MT
  - MoeenAhmed BS,MT
  - Claudia Carron, RN. MSN
  - Aida Gilanchi, BS,MT
  - Nisha Intwala, BS,MT (ASCP)
  - Franchesca Jackson, BS

**DAS Mobile HIV Counselor**

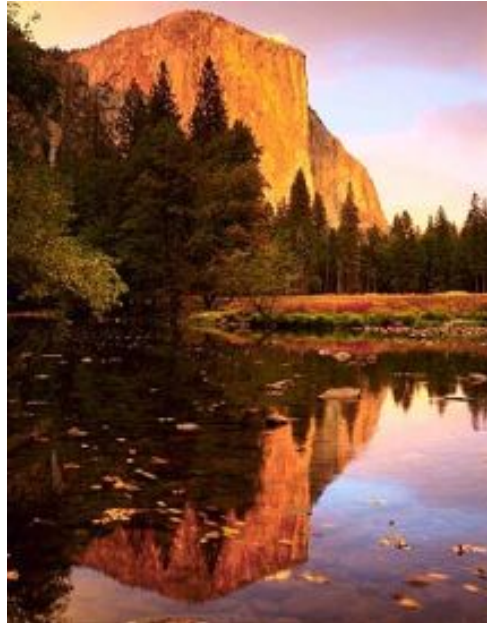
- Marianela Moreno

**Administration:**

- Lisa May
- Karen Williams

**RETIRED/MOVED ON:**

- Evan Cadoff, MD
- Jaclyn Kollinger



**NJDOH/DHSTS**

**Connie F. Calisti-Meyers**

- *Assistant Commissioner-*
- Loretta.Dutton

**Steve Saunders, MS\***

- *Prevention -*
- Cynthia Mimmo
- Rekha Damaraju
- Shwetha Kamath
- Chelsea Betlow
- Iris Chittams
  
- Stephanie Moore
- *Partner Notification -*
  
- 
- Aye Maung Maung
- - *Surveillance-*

**RETIRED/MOVED ON:**

- Raj Patel
- Linda Berezny, RN

**Thanks To:**

**Site coordinators and counselors  
throughout New Jersey**

Thanks for your attention!  
I'd be happy to answer any questions.

**THE END**

