Administrative Matters

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

Rutgers – Robert Wood Johnson Medical School
New Brunswick, NJ
Website for NJ HIV Rapid Testing Support: njhiv.org
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

One-Day Event Results Report
Submit one form per event within three business days of event

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: 

Test Results

<table>
<thead>
<tr>
<th>Target Population</th>
<th># Positive</th>
<th># Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* 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 and Sonya Thompson at 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

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

Name of agency
Contact

Address of agency
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 advertised 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 □
NJ HIV Rapid Testing Support Administrative Issues

13. What is the number of anticipated HIV tests?  
   YES □  NO □

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?  
   YES □  NO □

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 with a copy to corbojo@rwjms.rutgers.edu (do NOT fax or mail request). Please email results to Linda Berezny at Linda.Berezny@doh.state.nj.us with a copy to corbojo@rwjms.rutgers.edu within 5 business days of the event.

RWJ Oversight □  Non RWJ Oversight □

For RWJ use only:

Request approved  YES □  NO □  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 with a copy to 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)
- 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**

<table>
<thead>
<tr>
<th>Client ID #</th>
<th>Date:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>First Test Site ID Number</th>
<th>First Test Site Name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>First Test Site Counselor Name</th>
<th>First Test Site Counselor Number</th>
</tr>
</thead>
</table>

**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.

<table>
<thead>
<tr>
<th>Specimen (circle one):</th>
<th>Oral</th>
<th>Fingerstick</th>
<th>Venipuncture</th>
<th>Test Kit Lot Number:</th>
</tr>
</thead>
</table>

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

| 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 ____________________________ |
| Also enter in Local Field 2 in Evaluation Web |
| Second Test Site Counselor Number ____________________________ |

**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: ____________________________ |

**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

**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 RAPI 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.
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.
A few Not So Gentle Reminders
## Monthly Rapid-Rapid Tracking Form – Page 1

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Site Description</th>
<th>MONTH</th>
<th>(#) Screened</th>
<th>(#) Positive</th>
<th>(#) Rapid Performed</th>
<th>(#) Rapid REFUSED</th>
<th>(#) Rapid CONFIRMED</th>
<th>Discordant Results (#)</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>6493</td>
<td>NJCRI Office</td>
<td>12/2014</td>
<td>40</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>12/4/14 - 321628</td>
</tr>
<tr>
<td>6490</td>
<td>DOH Mobile 1</td>
<td>12/2014</td>
<td>29</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>12/7/14 - 321674 (DISC)</td>
</tr>
<tr>
<td>6487</td>
<td>CDC Mobile 2</td>
<td>12/2014</td>
<td>10</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>12/14/14 - 321687, 12/17/14 - 423542 (R2R)</td>
</tr>
<tr>
<td>6489</td>
<td>CDC Mobile 3</td>
<td>12/2014</td>
<td>14</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>12/15/14-321694 (INIT). Client tested out – see below.</td>
</tr>
</tbody>
</table>

**CUMULATIVE MONTHLY DATA FOR A SITE**
<table>
<thead>
<tr>
<th>SITE Number</th>
<th>Date</th>
<th>Positive or Discordant Client CTS Number</th>
<th>New Pos</th>
<th>Re-Engaged</th>
<th>Already In-Care</th>
<th>Client Refused Appointment</th>
<th>Appt. Date</th>
<th>Appt.</th>
<th>Charity</th>
<th>Appt. Kept? (Y or N)</th>
<th>Appt. No Show</th>
<th>Bus Days to Lab Intake</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>6493</td>
<td>12/4/2014</td>
<td>321658 (NJDH)</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>12/5/2014</td>
<td>Y</td>
<td>0</td>
<td>0</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6490</td>
<td>12/7/2014</td>
<td>321674 (DISC)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
<td>Determine FF RNA negative at Quest 12/12/14</td>
</tr>
<tr>
<td>5487</td>
<td>12/14/2014</td>
<td>32881</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>12/16/2014</td>
<td>Y</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6581 (Isiah House)</td>
<td>12/17/2014</td>
<td>423592 (K2K)</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>12/20/2014</td>
<td>Y</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
<td>Rapid-2-Rapid screened at Isiah House, transported to NJSBI for second rapid and linkage to care.</td>
</tr>
<tr>
<td>6480</td>
<td>12/15/2014</td>
<td>321604</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
<td>Client refused 2nd rapid and left mobile van. NAP notified to follow-up. Navigator outreach.</td>
</tr>
</tbody>
</table>

**Individual Positive Data (Only)**

<table>
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<tr>
<th>SUMMARY</th>
<th>2</th>
<th>1</th>
<th>0</th>
<th>1</th>
<th>0</th>
<th>3</th>
<th>0</th>
</tr>
</thead>
</table>

**Instructions:** 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 (Ungold) rapid is being performed. Please check off your INITIAL and Second Screening tests (Determine, StatPak, Ungold, Inst, or Architect).

Do not return page 2 if there are no entries.

Do not include NJDH as part of the CTS number – it's redundant.
Test logs:

- RWJ test logs due the 10\textsuperscript{th} 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)
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:

________________________________________________________________________

Site Testing Coordinator
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Email</th>
<th>Telephone</th>
<th>Cell Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eugene G. Martin, Ph.D.</td>
<td>PI and Co-Director</td>
<td><a href="mailto:martineg@rwjms.rutgers.edu">martineg@rwjms.rutgers.edu</a></td>
<td>732-743-3626</td>
<td></td>
</tr>
<tr>
<td>Gratian Salaru, M.D.</td>
<td>PI and Director (DAS)</td>
<td><a href="mailto:salaranp@rwjms.rutgers.edu">salaranp@rwjms.rutgers.edu</a></td>
<td>732-743-3625</td>
<td></td>
</tr>
<tr>
<td>Joanne Corbo, MBA, MT(ASCP)</td>
<td>Program Manager</td>
<td><a href="mailto:corbood@rwjms.rutgers.edu">corbood@rwjms.rutgers.edu</a></td>
<td>732-743-3620</td>
<td></td>
</tr>
<tr>
<td>Latasha Adams BS, MT</td>
<td>Site Liaison POCT Coordinator</td>
<td><a href="mailto:adamsli@rwjms.rutgers.edu">adamsli@rwjms.rutgers.edu</a></td>
<td>732-743-3235</td>
<td>732-665-2327</td>
</tr>
<tr>
<td>Moeen Ahmed, BS, MT</td>
<td>Site Liaison POCT Coordinator</td>
<td><a href="mailto:ahmedmo@rwjms.rutgers.edu">ahmedmo@rwjms.rutgers.edu</a></td>
<td>732-743-3607</td>
<td>732-609-3425</td>
</tr>
<tr>
<td>Claudia Carron, MSN, RN</td>
<td>Site Liaison &amp; RWJMS POCT Coordinator</td>
<td><a href="mailto:carronc1@rwjms.rutgers.edu">carronc1@rwjms.rutgers.edu</a></td>
<td>732-235-6045</td>
<td>732-947-1021</td>
</tr>
<tr>
<td>Aida Gilanchi, BS, MT</td>
<td>Site Liaison POCT Coordinator</td>
<td><a href="mailto:gilanchai@rwjms.rutgers.edu">gilanchai@rwjms.rutgers.edu</a></td>
<td>732-743-3629</td>
<td>732-453-4704</td>
</tr>
<tr>
<td>Francesca Jackson, BS, MT</td>
<td>Site Liaison POCT Coordinator</td>
<td><a href="mailto:jacobjf@rwjms.rutgers.edu">jacobjf@rwjms.rutgers.edu</a></td>
<td>732-743-3628</td>
<td>732-947-1015</td>
</tr>
<tr>
<td>Nisha Intwala Patel, MT (ASCP)</td>
<td>Site Liaison POCT Coordinator</td>
<td><a href="mailto:intwanim@rwjms.rutgers.edu">intwanim@rwjms.rutgers.edu</a></td>
<td>732-743-3612</td>
<td>732-947-1020</td>
</tr>
<tr>
<td>Manuela Moreno</td>
<td>Public Health Representative</td>
<td><a href="mailto:morenom2@rwjms.rutgers.edu">morenom2@rwjms.rutgers.edu</a></td>
<td>732-743-3611</td>
<td>732-609-9136</td>
</tr>
<tr>
<td>Lisa May</td>
<td>Program Assistant</td>
<td><a href="mailto:mayli@rwjms.rutgers.edu">mayli@rwjms.rutgers.edu</a></td>
<td>732-743-3624</td>
<td></td>
</tr>
<tr>
<td>Karen Williams</td>
<td>Administrative Assistant</td>
<td><a href="mailto:williak2@rwjms.rutgers.edu">williak2@rwjms.rutgers.edu</a></td>
<td>732-743-3630</td>
<td></td>
</tr>
</tbody>
</table>
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. 4th 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 – 1st Place

RAPID HIV TESTING PROGRAM
- 2006 -

PATIENT NAVIGATOR PROGRAM
- 2013 -
A Long Ways in a Decade!

Rapid Plus Western blot (2004)

Disposition of Confirmed HIV + Clients

- Confirmed HIV+: 326
- Prelim. Pos.: 244
- Same Day Connect: 47
- Unigold Confirm: 82
- 30 Day Linkage: 11
- Refused/untestable: 7
- Referred to NAP: 0
- Foun by NAP: 0

Rapid Test Algorithm (2009-2014)

- Prelim. Pos.: 2057
- Unigold Confirm: 1925
- Same Day Connect Care: 1047
- 30 Day Linkage: 1555
- Unigold Refusal: 65

- <25.1%
- <13%
- >6%
- <3.3%
- >54%
- >80%
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
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 AHF → 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

NOT linking infected clients early → substantial treatment delay.
New Possibilities – New Directions

A NEW GENERATION OF HIV DIAGNOSTICS
HIV Detection Improves Over 30 Years

- Appearance of markers for HIV infection vary over time
- Viral RNA is first detectable marker
- Antibodies do not appear during early infection
- Antigen appears early (alone) and later is complexed with antibodies

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\textsuperscript{nd} gen. Rapid HIV Negative Individuals

• When compared against \textit{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!!!
• \textbf{Solution:} A test that picks up p24 Ag \textbf{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

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

HIV RNA in Semen ($\log_{10}$ copies/ml)

- Risk of Transmission Male to Female - Blue
- Reflects Genital Viral Burden – Yellow
- Effect of ART – Theoretical - Red

- Acute Infection
- Asymptomatic Infection
- HIV Progression
- AIDS

$\frac{1}{30} - \frac{1}{200}$

$\frac{1}{1000} - \frac{1}{10,000}$

$\frac{1}{500} - \frac{1}{2000}$

$\frac{1}{100} - \frac{1}{1000}$

Cohen and Pilcher, *Amplified HIV transmission and new approaches to HIV prevention* JID 191:1391, 2005
The Range of HIV Sensitivity – Screening to Diagnosis

Sequence of Assay Reactivity Plasma

Single NAT: Aptima ~9-11 Days after infection

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)

Determine HIV-1/2 (3\textsuperscript{rd} gen)

Determine Combo (4\textsuperscript{th} gen)

- Early – free p24 Ag
- Somewhat Later – Ab
EARLY HIV INFECTION IDENTIFIED

<table>
<thead>
<tr>
<th>Test</th>
<th>Percent Identified</th>
<th>AHI Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick ADVANCE® Rapid HIV-1/2</td>
<td>21%</td>
<td>7</td>
</tr>
<tr>
<td>Clearview® HIV-1/2 STAT-PAK®</td>
<td>21%</td>
<td>7</td>
</tr>
<tr>
<td>Uni-Gold® Recombigen™</td>
<td>24%</td>
<td>8</td>
</tr>
<tr>
<td>Clearview® COMPLETE HIV-1/2</td>
<td>24%</td>
<td>8</td>
</tr>
<tr>
<td>Multispot® HIV-1/HIV-2 Differentiation</td>
<td>33%</td>
<td>11</td>
</tr>
<tr>
<td>Genetic Systems®- 3rd gen. HIV 1/2 + O</td>
<td>58%</td>
<td>19</td>
</tr>
<tr>
<td>Alere Determine™ HIV-1/2 Ag/Ab Combo</td>
<td>76%</td>
<td>25</td>
</tr>
<tr>
<td>Architect® Ag/Ab Combo</td>
<td>88%</td>
<td>29</td>
</tr>
<tr>
<td>NAAT</td>
<td></td>
<td>33</td>
</tr>
</tbody>
</table>

Data from:
Patel et al. Rapid HIV Screening: Missed Opportunities for HIV Diagnosis and Prevention. JCV. May, 2012
- Picking up AHI with Determine Combo

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.

---

**Determine™ HIV-1/2 Ag/Ab Combo**

**NO Detection of p24 in Blood**

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

---

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.

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

Determine Combo Summary

1. Determine Combo (DC) for early HIV infection is slightly better than current 3\textsuperscript{rd} generation assays –\textit{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. \textbf{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}
Determine Combo HIV1/2 EIA

If PRELIM POS:
- DC p24 Ag +
- DC Antibodies +

Can we confirm the presence of HIV Ab?

HIV-1 +/- HIV-2 – HIV-1 antibodies detected and confirmed

To a DISCORDANT workup

Link to Care with CD4 and Viral Load at Point of Care

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](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.
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

<table>
<thead>
<tr>
<th>Month</th>
<th>Number</th>
<th>Primary Site</th>
<th>Site Number</th>
<th>CTS #</th>
<th>Date</th>
<th>EIA result</th>
<th>WB result</th>
<th>OraQuick</th>
<th>OQ Lot (DEVICES)</th>
<th>Demographic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan</td>
<td>7-1</td>
<td>Camden AHEC</td>
<td>718</td>
<td>70104569</td>
<td>1/5/2007</td>
<td>0.842/0.423</td>
<td>oral pos</td>
<td>1106611</td>
<td>White</td>
<td>T&lt; C</td>
</tr>
<tr>
<td>Jan</td>
<td>7-2</td>
<td>Morristown Mem</td>
<td>9</td>
<td>70184478</td>
<td>1/15/2007</td>
<td>0.285/0.422</td>
<td>no bands</td>
<td>oral pos</td>
<td>1006715</td>
<td>White, ARUP, False Pos</td>
</tr>
<tr>
<td>Jan</td>
<td>7-3</td>
<td>Ocean County</td>
<td>11</td>
<td>70094828</td>
<td>1/16/2007</td>
<td>0.129/0.422</td>
<td>no bands</td>
<td>fingerstick</td>
<td>1106611</td>
<td>White, ARUP, False Pos</td>
</tr>
<tr>
<td>Jan</td>
<td>7-4</td>
<td>Ocean County</td>
<td>11</td>
<td>70094828</td>
<td>1/16/2007</td>
<td>0.125/0.404</td>
<td>no bands</td>
<td>fingerstick</td>
<td>1106611</td>
<td>Af.Amer, NAP contacted but refused testing/closed</td>
</tr>
<tr>
<td>Jan</td>
<td>7-5</td>
<td>Plainfield</td>
<td>905</td>
<td>70177255</td>
<td>1/17/2007</td>
<td>0.117/0.404</td>
<td>no bands</td>
<td>fingerstick</td>
<td>1106611</td>
<td>mult-racial?, ARUP, False Pos</td>
</tr>
<tr>
<td>Jan</td>
<td>7-6</td>
<td>Burlington</td>
<td>16</td>
<td>61621431</td>
<td>1/23/2007</td>
<td>0.133/0.406</td>
<td>no bands</td>
<td>oral pos</td>
<td>1106611</td>
<td>Af.Amer, NAP 42028772 3/30/07 negative</td>
</tr>
<tr>
<td>Jan</td>
<td>7-7</td>
<td>Plainfield</td>
<td>905</td>
<td>70177276</td>
<td>1/19/2007</td>
<td>0.199/0.425</td>
<td>no bands</td>
<td>oral pos</td>
<td>1106611</td>
<td>White-Hisp, ARUP, False Pos</td>
</tr>
<tr>
<td>Jan</td>
<td>7-8</td>
<td>Burlington</td>
<td>16</td>
<td>37111488</td>
<td>1/29/2007</td>
<td>0.130/0.416</td>
<td>no bands</td>
<td>oral pos</td>
<td>1106611</td>
<td>Af.Amer, ARUP, False Pos</td>
</tr>
</tbody>
</table>
Monthly Frequency - 2007

The diagram above shows the frequency of an event per month in 2007. The highest frequency is observed in January with 20 occurrences, followed by May and July with 12 occurrences each. The lowest frequency is in September with only 1 occurrence. Other months, March, June, August, and November, have frequencies of 7, 10, and 5, respectively.
Site Frequency - 2007
Lot Frequency - 2007

• Lot 1100611
  - Distributed among 13 different sites
  - 5 Planned Parenthood sites accounted for 7/19
  - Training issues identified at 3 of the PP sites

• Lot 6602291
  - Distributed among 6 sites
  - NJCRI accounted for 4/15
  - Training issue identified at NJCRI
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
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

<table>
<thead>
<tr>
<th>Site</th>
<th>Product</th>
<th>Ag/Ab/both</th>
<th>UG</th>
<th>Resolution</th>
<th>RNA copies/mL</th>
<th>Ref lab: MS (MultiSpot), EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Site A</td>
<td>Determine/Unigold</td>
<td>DC Ag</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
<tr>
<td>2</td>
<td>RWJMS-003</td>
<td>Determine/Unigold</td>
<td>DC Ab</td>
<td>UG-</td>
<td>FN UG</td>
<td>1,515,677 c/mL</td>
</tr>
<tr>
<td>3</td>
<td>Site B</td>
<td>Determine/Unigold</td>
<td>DC Ag Ab</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
<tr>
<td>4</td>
<td>Site B</td>
<td>Determine/Unigold</td>
<td>DC Ag (20 min ONLY)</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
<tr>
<td>5</td>
<td>Site C</td>
<td>Determine/Viral Load</td>
<td>DC Ag Ab (Partial line)</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
<tr>
<td>6</td>
<td>Site B</td>
<td>Determine/Unigold</td>
<td>DC Ab</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
<tr>
<td>7</td>
<td>Site DI</td>
<td>Determine/Unigold</td>
<td>DC Ab</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
<tr>
<td>8</td>
<td>Site B</td>
<td>Determine/Unigold</td>
<td>DC Ab</td>
<td>UG-</td>
<td>FP DC</td>
<td>&lt;20</td>
</tr>
</tbody>
</table>

- 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
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 into a diagnostic device

**iSTOC**

**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.

https://www.youtube.com/watch?feature=player_embedded&v=rwcpyOwnCRE#t=0
POC NAT: for infant HIV-1/2 diagnosis – 52 min
NOT YET APPROVED IN USA

- 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 µL of whole blood.
    - Detects HIV-1 Groups M, N, and O and HIV-2.

https://www.youtube.com - Alere q Infant Dx Video
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® 2200

BioPlex HIV Ag-Ab kit
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Site coordinators and counselors throughout New Jersey
Thanks for your attention!
I’d be happy to answer any questions.

THE END