2013 DHSTS Annual Coordinators Meeting

DIVISION OF HIV, STD, AND TB SERVICES
ANNUAL HIV COORDINATOR’S CONFERENCE

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UMDNJ – Robert Wood Johnson Medical School
Last Year’s Key Questions

1. What strategies will get more people to learn their HIV status?
2. How do we get more infected individuals into care AND encourage treatment earlier?
3. How does improved treatment (ART) impact efforts to reduce transmission?
21% Undiagnosed
31% Not linked / delayed
41% Not retained
19%-29% VL<50 c/mL

Gardner et al. Clin Infect Dis 2011;52; Marks et al. AIDS 2010;24
Success limited by Western Blot

- **People refuse confirmatory tests**
  - In NJ, 7.1% of positives could not be confirmed because specimens are not collected
- **Many don’t return to get their final results**
  - NJ: 25 – 30% fail to return for a second visit.
  - Los Angeles: 35-40% fail to return
  - Other cities: similar story; sometimes even worse

**Bottom line:**
- ONLY ~ 70 % actually get their confirmed + result!!
- Impact: **Linkage to Care is Delayed – Sometimes for years!**
Additional Focus. Why?

1. 40% of HIV transmission occurs in the earliest stages of the disease. New 4th generation HIV Tests are allowing us to identify infected individuals earlier...

2. Evolving HIV Prevention Strategies – Earlier treatment preserves immune function, improves morbidity, and reduces transmission…but by how much?

3. LINKAGE TO CARE – Underpins prevention & treatment …
   - Test to Treat
   - Treatment as Prevention
Transmission is a function of viral load!

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

Cohen and Pilcher, JID 191:1391, 2005
AHI – Acute HIV Infection

- 70-80% symptomatic, 3-12 weeks after exposure
- Surge in viral RNA copies to >1 million
  - Recently we had one 10 million copies!!
- CD4 count drop to 300-400 w/ rebound
- Recovery in 7-14 days

- Because individuals with AHI are highly infectious, have engaged in high risk behaviors, and are often unaware of their status they contribute substantially to the spread of HIV.

- Although AHI is short (typically 3-4 weeks), studies have consistently shown that 40-50% of new HIV transmissions are caused by onward transmission within the first six months after AHI.

SYMPTOMS - ACUTE HIV INFECTION
- Rash &/or fever(s), possibly in combination with:
  - Malaise
  - Loss of Appetite
  - Weight loss
  - Sore Throat
  - Mouth Sores
  - Joint Pain
  - Muscle Pain
  - Swollen lymph nodes
  - Diarrhea
  - Fatigue
  - Night sweats
  - Nausea/vomiting
  - Headache
  - Genital Sores
Events from HIV exposure to a reactive result

HIV Exposure

Infectiousness

Assay Reactivity (HIV-RNA/Ab)

Eclipse Phase

“Window” Period

[Time]

With thanks: M. Busch - UCSF
HIV Tests have come a long way.

**Sequence of Assay Reactivity Plasma**

- **Adimia (26)**
- **BioRad As/Ab combo (26)**
- **Architect As/Ab combo (15)**
- **BioRad + O (12)**
- **Vitros 3rd (13)**
- **Advia 3rd (14)**
- **Insti (9)**
- **Multisot (7)**
- **Statpak & Complete (3)**
- **Avodia (2)**
- **Oraquick (1)**
- **WB POSITIVE**

**Days before Western blot positive**

- 25
- 20
- 15
- 10
- 5
- 0

- **NAT**
- **4th gen IA**
- **3rd gen IA**
- **Rapid tests**
- **2nd gen IA**
- **1st gen IA**

Data indicates APTIMA reactivity is ~ 9-11 days after infection

Background: Linkage to Care

1. "In Care" Covers A Large Spectrum
2. Missed opportunities – Consequences
   - Additional spread of the infection
   - Additional morbidity for the patient
CONCEPT: “In care” encompasses relationships that vary in consistency and durability and change over time.

TERMS: *linkage to care, engagement/retention, and re-engagement in care and re-entry to care* - reflect degrees of relationship within the ‘care system’.

SOMETIMES A FOCUS ON DIAGNOSTIC PERFORMANCE MISSES THE FUNDAMENTAL ISSUE: BRINGING THOSE NOT IN CARE INTO CARE AND KEEPING THEM THERE.
“Category C” Proposal:

1. Convert 9 Rapid-Western blot testing sites to an RTA
2. Convert RTA sites to eRTA using either a POCT-based or a LAB-based 4\textsuperscript{th} generation HIV device.
   - “PLAN B” – “In the event that an enhanced POCT-based test is not available, we will utilize an FDA-approved 4\textsuperscript{th} gen. test in conjunction with ER testing to provide an RTA-based linkage to care.”
3. Use patient navigators to immediately link to care
BACKGROUND – RTA to improve Linkage to Care
NJ Rapid Testing Algorithm:

- 22 sites use RTA in NJ
- >126,000 tested since inception
  1. > 1000 HIV + IDENTIFIED
  2. << 1:200 REMOVED FROM CARE!
  3. Linkage to care has increased by ~20%
**ORTHOGONAL**

**NJ RAPID TESTING ALGORITHM**

1. **Perform 1st Rapid:** Oraquick OR StatPak
2. **First rapid HIV +**
   - PRELIMINARY POSITIVE
   - PERFORM 2nd Rapid – Trinity Unigold
3. **2nd rapid HIV +**
   - HIV Verified – Refer to Care IMMEDIATELY
   - GOAL: 20 MIN VERIFIED RESULT SAME DAY REFERRAL
4. **2nd rapid HIV -**
   - DISCORDANT PROCESS
   - Notify NJ HIV Clinicians for follow-up
   - White top tubes picked up -> Reference Lab
   - GOAL: 96 HR. DISCORDANT RESOLUTION
5. **First rapid HIV - Negative**
   - Negative for HIV Antibodies
   - Collect Blood for HIV-1 Western blot (NJ PHEL)
   - White top tube for possible NAAT: spin/freeze
6. **Negative for HIV Antibodies**
   - Notify NJ HIV Clinicians for follow-up
   - NJ HIV Techs pickup process and follow-up
<table>
<thead>
<tr>
<th>RTA Sites – New Jersey:</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlantic Care- ER Regional Medical Center</td>
<td>Atlantic City</td>
</tr>
<tr>
<td>Atlantic City Health Department</td>
<td>Atlantic City</td>
</tr>
<tr>
<td>Bergen County Health Department</td>
<td>Hackensack</td>
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<tr>
<td>Burlington County Health Department</td>
<td>West Hampton</td>
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<tr>
<td>Camden County Health Department</td>
<td>Camden</td>
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<tr>
<td>Catholic Charities of Archdiocese of Newark</td>
<td>Cranford</td>
</tr>
<tr>
<td>Checkmate</td>
<td>Asbury Park</td>
</tr>
<tr>
<td>East Orange Health Department</td>
<td>East Orange</td>
</tr>
<tr>
<td>Eric B. Chandler Health Center</td>
<td>New Brunswick</td>
</tr>
<tr>
<td>Fam Care</td>
<td>Bridgeton</td>
</tr>
<tr>
<td>Henry J Austin Health Center</td>
<td>Trenton</td>
</tr>
<tr>
<td>Hyacinth Foundation</td>
<td>North Plainfield</td>
</tr>
<tr>
<td>Morristown Memorial Hospital</td>
<td>Morristown</td>
</tr>
<tr>
<td>NAP-Trenton</td>
<td>Trenton</td>
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<tr>
<td>Neighborhood Health Services</td>
<td>Plainfield</td>
</tr>
<tr>
<td>Newark Community Health Center</td>
<td>Newark</td>
</tr>
<tr>
<td>NJCRI</td>
<td>Newark</td>
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<tr>
<td>Ocean County Health Dept</td>
<td>Toms River</td>
</tr>
<tr>
<td>Paterson Department of Health</td>
<td>Paterson</td>
</tr>
<tr>
<td>Proceed, Inc.</td>
<td>Elizabeth</td>
</tr>
<tr>
<td>St. Michael's</td>
<td>Newark</td>
</tr>
<tr>
<td>UMDNJ/RWJMS ER</td>
<td>New Brunswick</td>
</tr>
</tbody>
</table>
### NJ RTA SUMMARY - 2012

<table>
<thead>
<tr>
<th>SINCE INCEPTION (DECEMBER, 2009)</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refusing Western blot</td>
<td>119,823</td>
<td>7.1%</td>
</tr>
<tr>
<td>Refusing Unigold Verification</td>
<td></td>
<td>2.9%</td>
</tr>
<tr>
<td>Prelim Positive Results not Verified by Unigold</td>
<td></td>
<td>5.9%</td>
</tr>
<tr>
<td>UG Verified - Connected to Care on Same Day</td>
<td></td>
<td>70.3%</td>
</tr>
</tbody>
</table>

#### NJ Cumulative RTA Testing

- **Tested**: Total number of tests performed over time.
- **StatPak**: StatPak tests.
- **PP**: Preliminary positive tests.
- **UG**: Unigold tests.
- **WB**: Western blot tests.

#### NJ Cumulative HIV Positives

- **PP**: Positive Preliminary results.
- **UG**: Positive Unigold tests.
- **WB**: Positive Western blot tests.
One Visit Scenario: Rapid-Rapid

- 74% of ‘verified’ HIV positives are linked to care on the same day

15% More than traditional rapid testing….

15% LESS than our Category C goal!
First six months of RTA program, 62 RTA positives identified: 76.7% - appointments for treatment made that day

Location matters:
- Medical Facilities were best able to achieve and retain linkage. 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 are needed in non-traditional healthcare settings

Can navigators help us reduce this difference?
"PRESumptIVE DIAGNOSIS"

- When Rapid HIV Tests are used as a part of an RTA, a diagnosis can be made with a CONFIRMATORY Western blot; OR by a second (but different manufacturer’s) rapid test.

- If the diagnosis is made by a second rapid:
  - "Presumptive Diagnosis" - and requires further testing at the treatment site as a part of staging the infection.
In order to be eligible for RWHAP-funded medical care, patients must have a “diagnosis of HIV disease” (Sections 2604(c)(1), 2611, 2651(c)(1) and 2671(a) of the Public Health Service (PHS) Act). There is no legislative requirement for a “confirmed” HIV diagnosis prior to linkage to RWHAP-funded medical care, nor is there any specific statutory or program requirement related to the use of Western blot testing as the only means of confirmatory testing. Confirmatory testing may occur at the RWHAP-funded medical clinic. Tests to confirm the diagnosis of HIV disease could include the following:\1:

- Positive HIV immunoassay and positive HIV Western blot
- Positive HIV immunoassay and detectable HIV RNA
- Two positive HIV immunoassays (should be different assays based on different antigens or different principles)

Translation….for Ryan White eligibility:
- No more Western Blot required
- No more waiting
- No more return visits
RTA is enough
But another important question remains

- How often do we screen individuals and tell them they’re negative, when, in fact, they are most likely to infect others?
  -or-
- How often do we miss an early infection?
HIV Tests have come a long ways

Sequence of Assay Reactivity Plasma

-25 - 0

Days before Western blot positive

NAT  4th gen IA  3rd gen IA  Rapid tests  2nd gen IA  1st gen IA

Data indicates APTIMA reactivity is ~ 9-11 days after infection

Transmission is a function of viral load!

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

Cohen and Pilcher, JID 191:1391, 2005
Pooled NAAT – Early Linkage

- The risk of HIV transmission is largely a function of HIV viral load and can often be very high before antibodies can be detected.
  - Pilcher and Cohen\(^1\) estimate the risk of heterosexual transmission at \(1/30 - 1/200\) per exposure during the acute phase, and \(1/1000 - 1/10,000\) during the asymptomatic phase.....That’s about 30 times as high.

- RNA testing (NAAT) of HIV antibody negative clients finds some who have been recently infected and are therefore more likely to transmit HIV to others.
  - Combining rapid HIV tests assays with pooled NAAT helps identify acute HIV infection (AHI) in a particular locale.
  - This may play a critical role in the success of both ‘treatment as prevention’ and in the development of ongoing behavioral prevention strategies.

- Studies in other urban settings have suggested that it is possible to increase the yield of individuals identified as infected by anywhere from 6-10\%.
Between Feb 2010 and Aug 2011 pooled NAAT testing in addition to rapid HIV screening was offered to emergency department (ED) patients and outpatients (OP) seen at University Hospital in Newark.

Rapid HIV antibody screening (12,390) was performed using Clearview HIV 1/2 Stat-Pak.

For those negative by rapid HIV and agreeing to NAAT testing (6785), plasma samples were collected, centrifuged and stored frozen until a 27 sample batch could be pooled and transported frozen to the University of Washington for viral load testing, able to detect and measure 30 to 1,000,000 copies/mL.
Results

- 12,390 screened,
- 5605 (45.3%) had rapid HIV testing, (3139 female, 2466 male) alone,
- 6785 (54.7%) (3259 female, 3524 male) agreed to add NAAT.
- Rapid testing identified 116 antibody positive individuals (0.94 %).
- Pooled NAAT increased HIV case detection by 6.9% identifying 8 additional cases.
- Overall, AHI yield was 0.12% of those tested by NAAT.
- An additional 8.1 individuals might have been identified in the Rapid Only group had they agreed to NAAT testing, with a total increased case detection of 13.8%.
- While 48.4% of those tested were male, all NAAT positive screens were male.
## Results

### Distribution of Risk Factors by Test Groups

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>NAAT</th>
<th>Acute HIV Infection</th>
<th>HIV(+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male-to-Male</td>
<td>2.8%</td>
<td>3 male (37.5%)</td>
<td>14.7%</td>
</tr>
<tr>
<td>Heterosexual Sex</td>
<td>97.1%</td>
<td>5 male (62.5%)</td>
<td>82.7%</td>
</tr>
<tr>
<td>Injection drug use</td>
<td>0.1%</td>
<td>0 AHI (0%)</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

### Program Dates

<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>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>
</tbody>
</table>
# NAAT Testing of Antibody Negative Blood: Results Nationwide

<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>58925</td>
<td>7</td>
<td>1709</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>108667</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>1698</td>
<td>1</td>
<td>14</td>
<td>0.82%</td>
<td>7.14%</td>
<td>0.06%</td>
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</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>12390</td>
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<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>3439</td>
<td>5</td>
<td>81</td>
<td>2.36%</td>
<td>6.17%</td>
<td>0.15%</td>
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</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>2136</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>2722</td>
<td>11</td>
<td>105</td>
<td>3.86%</td>
<td>10.48%</td>
<td>0.40%</td>
<td></td>
</tr>
</tbody>
</table>
Conclusions:

- NAAT tells us we’re missing of 6-8% of those infected when we screen for antibodies alone!
- Those with the highest risk of infecting others are the ones being missed!!
- NAAT is expensive.
- The same issues with patient return and process completion occur with NAAT that occur with traditional testing!!!

Solution: EIA’s that pick up p24 Ag COULD pick up a substantial proportion of the same population. A POCT device could increase the pickup without losing the ability to link patients to care.
4th Generation tests
Determine HIV-1/2 Ag/Ab Combo Whole Blood Procedure

(Refer to package insert for assay procedures) (Refer to the other side for Serum/Plasma procedure)

1. Remove tests
2. Remove cover
3. Add sample

Note: Removal of the test units should start from the right side of the test card to preserve the lot number which appears on the left side of the card.

Add sample (50μl) to sample pad (finger stick or venipuncture)

4. Add chase buffer
5. Read results

Wait 1 minute

Control Bar
p24 Antigen Bar
Antibody Bar

Invalid
FDA Approval – 4th gen. Lab Based Assays:

1. **18 June 2010 – Abbott Architect HIV Ag/Ab Combo Assay**
   - First diagnostic test approved by FDA for use in children as young as 2 years of age, and pregnant women.
   - Specific for the detection of the HIV-1 p24 antigen, as well as antibodies to HIV-1 groups M and O, and as antibodies to HIV-2.

2. **22 July 2011 - GS HIV Combo Ag/Ab EIA, (Bio-Rad Laboratories)**
   - Neither test distinguishes between HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody.
   - Patients … who identify a specific risk occurring more than 4 weeks previously, should not be made to wait three months (12 weeks) before HIV testing. They should be offered a 4th generation laboratory HIV test and advised that a negative result at 4 weeks post exposure is very reassuring/highly likely to exclude HIV infection.
     
     An additional HIV test should be offered to all persons at three months (12 weeks) to definitively exclude HIV infection. Patients at lower risk may opt to wait until three months to avoid the need for HIV testing twice.
Proposed Algorithm for HIV Testing with 4th Generation Immunoassays

4th Generation
HIV-1/2 Immunoassay

Positive Result

HIV-1/HIV-2
Discriminatory Immunoassay

HIV-1 Antibody Positive – Initiate Care

HIV-2 Antibody Positive – Initiate Care

HIV-1/2 Antibody Negative

NAAT

NAAT Positive
Acute Infection – Initiate Care

NAAT Negative
Negative for HIV Infection

Negative Result
All 7 false positive p24 Ag sera were correctly identified by the Determine Combo test as negative.

5/14 of the p24 Ag true positive sera (early seroconversion) were missed by the Determine Combo test and tested negative for both p24 Ag and antibodies.

Even though there is a 64% improvement over a third generation (Ab only) POCT, health care professionals should still be aware that the Determine HIV-1/2 Ag/Ab Combo is not as sensitive as 4th generation Lab-based EIAs in diagnosing primary HIV-1 infections!!
QUESTION: Will Determine Combo Deliver?

In this study presented at CROI - 2011 which tested rapid negative blood by NAT and the Determine POCT test, Determine missed 8 of 8 individuals with acute infection in Malawi.
Questions for 4th Gen. Assays

- How well do they pickup AHI?
- Are the issues of contamination associated with the product format?
- Do we have an unusual number of falsely positive tests? What about false negative tests?
- How well will they resolve ‘real world’ discordant specimens?
- Will a Point-of-Care test perform as well as a laboratory-based test?
Dovetail Projects

Dovetail (defn) – A type of woodworking joint widely used in drawers that enormously strengthens the overall joint.

- Independent projects related to Category C, but not funded by CDC
- Privately funded
- IRB approvals obtained
- IMPORTANCE: Strengthen our Category C efforts

1. **“Real World” Evaluation of 4th Generation Algorithm**
   1. Kara Johnson, Ph.D., Abbott Scientific Affairs Manager
   2. Evaluating CDC algorithm of 4th gen followed by HIV 1/ HIV 2 differentiating test (BioRad Multispot) in repository specimens including:
      - discordant library,
      - library of HIV + specimens
      - NAAT + specimens from HIV pool negative clients
   3. Analysis of 1500 repository specimens on the Abbott Architect RWJUH@H – purposely stressing the capabilities of the 4th gen. assay. Data was returned to us last week, we have not yet reviewed it in detail.

2. **Alere Determine pre-market approval (PMA) studies** -
   1. Training materials developed
   2. RWJMS staff and site staff trained and experienced with Determine
   3. Provided 406/1000 specimens used from low prevalence sites (HJ Austin FQHC, Neighborhood Health FQHC
   4. Protocols to be updated to meet FDA approval standards before roll-out to POCT eRTA sites
Real World Validation

- Run > 1100 specimens
- 17% were HIV+ previously identified and characterized in NJ
  - Results agreed 98.96%
- 83% were reportedly HIV- specimens provided by PHEL
  - This is the area where we may see additional HIV+ specimens based upon low levels of antibody or antigen picked up by the Abbott 4th gen. assay
  - Unfortunately, we have not yet completed the analysis at this juncture.
Anticipated comparisons

- How much of an improvement does the 4th gen assay really offer?
- The POCT – Alere Determine Combo has been called a 3 ½ gen. test.
  - How well will it behave using real world specimens, we’ve collected and characterized using our RTA plus EIA/Wblot
  - Our data from the PMA project with Alere suggests that the assay is highly specific and you’re unlikely to experience many False Pos results when we finally have access to the materials.
“Category C” Proposal:

1. Convert 9 Rapid-Western blot testing sites to an RTA
2. Convert RTA sites to eRTA using either a POCT-based or a LAB-based 4th generation HIV device.
   - “PLAN B” – “In the event that an enhanced POCT-based test is not available, we will utilize an FDA-approved 4th gen. test in conjunction with ER testing to provide an RTA-based linkage to care.”
3. Use patient navigators to immediately link to care
# First Year Timeline – Category C - NJ

<table>
<thead>
<tr>
<th>STRATEGY</th>
<th>6 Months (Sept 2012)</th>
<th>9 Months (Dec 2012)</th>
<th>11 Months (Feb 2013)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Detailed and comprehensive project plan to CDC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) RTA</td>
<td></td>
<td>Expand RTA by 9 additional sites</td>
<td></td>
</tr>
<tr>
<td>(2) eRTA</td>
<td>Evaluate currently available HIV tests to develop eRTA</td>
<td>Develop eRTA training materials, policies and procedures Pilot eRTA at 1 site</td>
<td></td>
</tr>
<tr>
<td>(3) Navigators</td>
<td></td>
<td></td>
<td>Hire, train, implement Navigators</td>
</tr>
</tbody>
</table>

Grant Award – March, 2012. Proposed goals and projected dates for completion are
Category C

PROJECT REVIEW – 2013
## RTA (Strategy 1) Review:
### RTA Sites Added:

<table>
<thead>
<tr>
<th>DESCRIPTION:</th>
<th>Location</th>
<th>Start Date:</th>
<th>Issues:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Jersey Shore Medical Center</td>
<td>Neptune</td>
<td>June, 2012</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>April, 2013?</td>
<td><em>NEW RTA</em>: Lab-Based with 4(^{th}) gen HIV and StatPak as 2(^{nd}) test</td>
</tr>
<tr>
<td>2. Trinitas Hospital</td>
<td>Elizabeth</td>
<td>June, 2012</td>
<td>None</td>
</tr>
<tr>
<td>3. Camden County Jail</td>
<td>Camden</td>
<td>Sept, 2012</td>
<td>None</td>
</tr>
<tr>
<td>4. Jersey City Medical Center</td>
<td>Jersey City</td>
<td>January, 2013</td>
<td>None</td>
</tr>
<tr>
<td>5. Raritan Bay Medical Center</td>
<td>Perth Amboy</td>
<td>January, 2013</td>
<td>None</td>
</tr>
<tr>
<td>6. St. Joseph’s</td>
<td>Paterson</td>
<td>January, 2013</td>
<td><em>NEW RTA</em>: Lab-Based with 4(^{th}) gen HIV and StatPak as 2(^{nd}) test</td>
</tr>
<tr>
<td>7. City of Trenton</td>
<td>Trenton</td>
<td>January, 2013</td>
<td>None</td>
</tr>
<tr>
<td>8. Our Lady of Lourdes</td>
<td>Camden</td>
<td>March, 2013</td>
<td><em>NEW RTA</em>: Lab-Based with 4(^{th}) gen HIV and StatPak as 2(^{nd}) test</td>
</tr>
</tbody>
</table>

**Newark Beth Israel**
- Newark
- ANTICIPATE: Feb/ March, 2013
- Approval needed by Bioanalytical Lab Director

**UMDNJ/UH ER**
- Newark
- ANTICIPATE: Jan/Feb, 2013
- Waiting approval by Bioanalytical Lab Director


**eRTA (Strategy 2) Review**

- **4th Generation POCT Option**
  - Alere Determine
    - submitted to the FDA for approval
    - completed FDA inspection of manufacturing facility
    - anticipate approval later in the Spring, 2013
  - Strategic implementation within 6 months of product approval.
    - Site selection dependent on CLIA status of product and site
    - Model on existing rapid-rapid program
    - Formal policies awaiting receipt of Determine package insert.

- **Lab-Based eRTA using Abbott Architect 4th generation assay**
  - Two sites underway
    - Testing has begun at SJRMC and OLL
    - **St. Joseph's Regional Medical Center (SJRMC), Paterson – Jan 2013 start**
      - Emergency Department
      - Series algorithm (4th gen assay first)
    - **Our Lady of Lourdes Medical Center (OLL), Camden – Feb 2013 start**
      - Emergency Department and High Risk Clinic
      - Parallel algorithm
    - **Jersey Shore Medical Center, Neptune – Possible Start Date – April, 2013**
      - Agreement in Principle
      - Awaiting funds to allow us to pay JSUMC for their testing
  - Additional possible sites
    - **St. Francis Medical Center, Trenton –**
'Enhanced' Lab-based Linkage to Care

- Abbott Architect 4th gen. assay
- Pkg. Insert requires
  - Initial Singlet Run
  - If REACTIVE
    - Centrifuge Specimen
    - Duplicate Repeat Run
- Orthogonal verification of Antibody Pos by use of Rapid Assay: Trinity UniGold
  - IF POS – Possible immediate Referral to Care
  - DISCORDANT RESULTS →
    - ARCHITECT +, Unigold –
      - POSSIBLE p24 Ag -→
      - PCR Viral Load
- Our Lady of Lourdes – StatPak run on everybody precedes Architect run
- St. Joseph’s – StatPak performed on Architect HIV + Only.
- Jersey Shore Univ. Med. Center – location dependent
Lady Of Lourdes Model eRTA:

- **eRTA**: Run both a StatPak AND the Abbott Architect
  - **Initial Screen – StatPak Rapid HIV**:
    - If NEG (SP) → Abbott Architect → [Looking for false negative SP]
      - If NEG --- STOP
    - If POS (SP) - Abbott Architect →
      - IF POS : → LINK TO CARE while completing analysis  [Why: Laboratory delays]
      - IF POS : → Duplicate Repeat
        - If either are POS → CONFIRMED RESULT
        - If neither are POS → DRAW WHITE TOP TUBES → NAAT
  - Implemented March 2013

<table>
<thead>
<tr>
<th>Tests - SP</th>
<th>NEG - SP</th>
<th>NEG - Architect</th>
<th>POS - SP</th>
<th>POS - Architect</th>
<th>Discordant</th>
<th>NEG - NAAT</th>
<th>POS - NAAT</th>
<th>NEG</th>
<th>POS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our Lady of Lourdes - All</td>
<td>348</td>
<td>346</td>
<td>348</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>348</td>
</tr>
</tbody>
</table>
Why use an eRTA with a Lab-based HIV Assay?

Our Lady of Lourdes:
Time to NEG Result on Architect

Avg.: 57.7 min

Avg.: 3.35 min
St. Joseph’s Model eRTA

- Initial Abbott Architect Screen
  - If NEG → STOP
  - If POS →
    - RUN STATPAK →
      - IF also POS (Orthogonal Confirmation) → LINK TO CARE IMMEDIATELY
      - IF NEG – COLLECT 2 white top tubes → NAAT – DISCORDANT ANALYSIS
  - RUN DUPLICATE REPEAT →
    - IF either is POS (Completes Package Insert) → POS
    - If BOTH are NEG
      - REPORT as NEG
      - COLLECT 2 white top tubes → NAAT – DISCORDANT ANALYSIS
- Implemented January 2013

<table>
<thead>
<tr>
<th></th>
<th>NEG - Architect</th>
<th>POS - Architect</th>
<th>POS - SP</th>
<th>NEG - SP</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Joseph's Med. Ctr - All</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Laboratory Component

- Analysis to include demographic and risk information;
- Monthly, annual, and project data to date - for RTA and eRTA sites:
  1) Established infections;
  2) AHI;
  3) How many people are tested and how many (percentage) test positive?
  4) How many (percentage) people testing positive are linked to care and in what timeframe?
  5) How many (percentage) people testing positive are retained in care?
  6) What is the most sensitive testing algorithm? What is the most cost-effective testing algorithm?
  7) How many new cases have been reported and/or identified from the cities or counties with the eRTA and RTA sites annually and is this a changing trend?
  8) Is turnaround time acceptable for Emergency Department patients? Would this model be time-effective in other settings.
Navigators (Strategy 3) Review:

- **Laboratory component of Rapid-to-Rapid (R2R) testing in support of Test-to-Treat, Linkage to Care Program**
  - Detailed Procedures were developed permitting
    - Testing via Rapid-2-Rapid format
    - DHSTS Reporting permits assessment of linkage to care
    - Patient Results Reporting to permit community based sites to refer screen positive individuals to a secondary clinical location for entry or re-entry into care
    - Data collection systems modified to capture rapid testing from multiple sites per client
    - Surveillance reporting

- **Navigator component of Test-to-Treat Program**
  - Regional networks established
  - People not in care referred to the navigator
  - Navigators facilitate and track progression from testing to care to reengagement
# Status Report: First Year Goals

<table>
<thead>
<tr>
<th>Objective</th>
<th>Lab-based: Abbott – p24Ag/Ab Combo</th>
<th>POCT: Alere – Determine Combo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate currently available POCT HIV tests to develop a POCT eRTA algorithm within 6 months of FDA Approval;</td>
<td></td>
<td>Evaluation complete pre-FDA</td>
</tr>
<tr>
<td>Develop eRTA training materials, forms, policies, proced., along with competency and PT exercises; hire and train MTs to assist eRTA sites (9 months)</td>
<td></td>
<td>Awaiting FDA approval</td>
</tr>
<tr>
<td>Select and pilot eRTA at 1 Lab-based site from current RTA sites</td>
<td>3 Lab-based eRTA sites selected; protocols developed, 2 in process</td>
<td></td>
</tr>
<tr>
<td>Expand RTA to 5 high seropositivity sites (9 months)</td>
<td></td>
<td>9 new RTA sites 2 in process</td>
</tr>
<tr>
<td>Submit Institutional Review Board applications for eRTA and RTA project evaluation (9 months)</td>
<td>Covered by existing IRB approval</td>
<td>Covered by existing IRB approval</td>
</tr>
<tr>
<td>Hire, train, &amp; implement the navigators (11 months)</td>
<td>Done</td>
<td>Done</td>
</tr>
</tbody>
</table>
Thanks To:

RWJMS
- Evan Cadoff, MD
- Eugene Martin, Ph.D.
- Gratian Salaru, MD
- Joanne Corbo, MBA, MT (ASCP)
  - Moeen Ahmed, BS, MT (ASCP)
  - Claudia Carron, RN, MSN
  - Aida Gilanchi, BS, MT
  - Nisha Intwala, BS, MT (ASCP)
  - Franchesca Jackson, BS (Biology)
  - Patricia Riberio, BS, MT (ASCP)
- Lisa May
- Karen Williams

NJDHSS/DHSTS
- Connie Calisti-Meyers
  - Sindy Paul, MD, MPH
  - Steven Saunders, MS
  - Raj Patel, MD, MSPH
  - Linda Berezny, RN
  - Loretta Dutton
  - Aye Maung Maung

All site coordinators and counselors throughout New Jersey
Administrative ISSUES
Administrative /Program Logistics

- UMDNJ becomes Rutgers July 1, 2013
  - No changes for the program (just a different name)
  - We will still be Robert Wood Johnson Medical School
- Communications:
  - RWJ NJHIV Program & DSHTS are trying to improve the communication of new information in a timely fashion to all testing sites.
  - Send emails via UMDNJ list serve
    - We need correct email addresses: If not receiving these emails please send you address to one of the following to be added to the list
      - corbojo@umdnj.edu
      - mayli@umdnj.edu
      - williak2@umdnj.edu
Administrative/Program Logistics

- One Time Events
  - Follow New Procedure
  - Send Request to Sonya Thompson and Joanne Corbo
  - Use new One Time Event request form
  - Send results to Linda Berezny and Joanne Corbo
- Updated Forms and Presentations can be found on njhiv1.org
Administrative /Program Logistics

- Need timely submission of monthly statistics
- Use New Logs
  - PEMS Site Numbers
  - Complete Name of Site, Contact Name & Number
- Fax Pages as you complete them
- Send all pages by the 10th of the month
- Send Completed Forms ASAP-We Have a Report Due to the State
Administrative /Program Logistics

- Preliminary Positive Data Capture
  - Need timely submission of NJ Positive Tracking Forms
  - Make Sure You Are Using New Form
  - Enter Client ID # at top of form
  - Enter Complete Site Name
  - Enter Counselor Name not Client Name
  - Enter Counselor ID Number
  - Fax Confirmatory Result If Applicable ASAP
  - Fax Referral To Care Info ASAP
  - Need Completed Forms ASAP-We Have a Report Due to the State
Administrative /Program Logistics

Discordant Results

- Call NJHIV if you have a discordant result: First result is preliminary positive but the second result is negative or indeterminate. Draw two white top tubes and we will pick them up.
- We wish to work directly with staff from any institution that experiences a discrepant result.
- Call our physician discordant phone: (732) 236-7013
Rapid 2 Rapid (R2R) HIV Testing

- Email went out February 27th to describe process
- Last year, we were able to use a second HIV test to confirm an initial HIV screening test.
- This means that we did not have to confirm a positive rapid test with a Western Blot.
- Our goal is to move toward the Test to Treat or Rapid 2 Rapid testing and to no longer be doing any Western blot testing to confirm an initial Rapid HIV positive screening result.
- Your site should be making arrangements for a rapid confirmatory test if the first rapid test is positive and linking that client to care.
- The Patient Navigator Program can help make that happen.
Rapid 2 Rapid (R2R) HIV Testing

- From this point forward counselors should contact the local Navigator for your area to arrange for your client to have a second rapid test done.

- If your site can perform the second rapid test but you are not a treatment site, the Navigator can help to get your client into treatment.

- All testing sites have now been informed that they should join one of the existing collaborations formed among the 21 counties in NJ. These collaborations are working with the Navigator Program to get clients to a testing site that can perform the second rapid test and get the client into treatment within the same or next business day.
Protocol for Rapid to Rapid (R2R) HIV testing:

- Outlines the process for the *Test to Treat Program* to link HIV screen positive clients into treatment as quickly as possible.
- Under this program, an individual who has tested positive by 2 different HIV testing methods can be immediately linked to care.
- Process may differ slightly as to data handling and client linkage to treatment depending on which of three categories your site falls into.
Rapid 2 Rapid (R2R) HIV Testing

Three categories your site may fall under:

- Category 1: Rapid-Rapid Testing Site and Treatment Site
- Category 2: Rapid-Rapid Testing Site and Non Treatment Site
- Category 3: Rapid Testing Site
Rapid 2 Rapid (R2R) HIV Testing

Category 1
Rapid-Rapid Testing Site and Treatment Site

- Your testing site is a Rapid-Rapid Testing Site (StatPak then confirm with a UniGold/OraQuick test)
- Clinical treatment is available onsite.
- Your client is referred to treatment within your organization within one business day.
- Please utilize Navigator Program to link client to care.
Rapid 2 Rapid (R2R) HIV Testing

Category 2
Rapid-Rapid Testing Site and Non Treatment Site

- Your testing site is a Rapid-Rapid Testing Site (StatPak then confirm with a UniGold/OraQuick test).
- Clinical treatment is **NOT** available at your site.
- Your client is referred to a 2nd clinical treatment site that your organization has an MOA with permitting linkage to care.
- The initial site to arrange client transportation to 2\textsuperscript{nd} clinical treatment site.
- Please utilize Navigator Program to link client to care.
Rapid 2 Rapid (R2R) HIV Testing

Category 3
Rapid Testing Site

- You use StatPak as the first Rapid Test and confirm by sending client to a Category 1 Site (Rapid-Rapid Testing and Treatment Site).
- Your client is referred to a Category 1 clinical treatment site that your organization has an MOA with permitting linkage to care.
- Your site should arrange for client transportation to the clinical treatment site.
- Please utilize Navigator Program to link client to care.
Rapid 2 Rapid (R2R) HIV Testing

Your Client tested positive and you need to get the client to another location for a second test, treatment or both

- Call the Navigator in your area:
  - If you can't get the navigator or are unsure as to which navigator to call, contact the AIDS Hotline in NJ 800-624-2377. The AIDS/HIV/STD Hotline is available 24/7
  - If you have questions about what to do and can’t get the navigator or don’t feel comfortable calling the hotline:
    - Call Loretta Dutton, of the NJDOH, DHSTS on her cell at 609-892-6989
    - If you cannot reach Loretta, please call Linda Berezny, of the NJDOH on her cell at 609-203-1949. Please make sure that everyone at your site who is an HIV counselor/tester is aware of this procedure and follows it
  - Please do not give the cell phone number of the Navigators, Loretta or Linda to the clients.

- Please make sure that everyone at your site who is an HIV counselor/tester is aware of this procedure and follows it
Rapid 2 Rapid (R2R) HIV Testing

Responsibilities of the Testing Site Counselors/Coordinators

- Fill out NJHIV Positive Tracking Form for all positives
- Perform or arrange for a second test
  - On-site (different rapid test)
  - Arrange for transport of client (Navigator can help)
  - Collect and send specimen (only if no other choice)
- Add second test information to the NJHIV Positive Tracking Form
- Fax NJHIV Positive Tracking Form to 732-235-9012
- First testing site fills out Eval Web for all testing
- NJHIV Positive Tracking Form and Rapid HIV Test Report must go with the client or be sent to second test/treatment site
- Send Rapid HIV Test Report to second test site or a treatment center ONLY. Do not send it to NJHIV
Rapid 2 Rapid (R2R) HIV Testing

Responsibilities of the Testing Site Counselors/Coordinators

- Call NJHIV if you have a discordant result: First result is preliminary positive but the second result is negative or indeterminate. Draw two white top tubes and we will pick them up.
- We wish to work directly with staff from any institution that experiences a discrepant result.
- Call our physician discordant phone: (732) 236-7013
Rapid 2 Rapid (R2R) HIV Testing

Data and Forms/Reports for R2R
# Rapid HIV Test Report

**CONFIDENTIAL**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>MI</th>
<th>CTS (Barcode for unique ID code)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date of Birth:**

<table>
<thead>
<tr>
<th><strong>1st Rapid Test</strong></th>
<th>OraQuick</th>
<th>StatPak</th>
<th>Unigold</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- NEGATIVE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- PRELIMINARY POSITIVE</td>
<td>Reference Range: Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Site:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Director:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site telephone#:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2nd Rapid Test</strong></th>
<th>OraQuick</th>
<th>StatPak</th>
<th>Unigold</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- NEGATIVE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- POSITIVE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Site:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Director:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site telephone#:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rapid HIV testing considerations:
- If the 1st rapid test is NEGATIVE, the screen is considered Negative for HIV antibodies
- If the 1st rapid test is POSITIVE, confirmatory testing (Western blot or molecular tests) is required for interpretation. Or, a second rapid test was performed, see below
- Two orthogonal (different) rapid tests have been performed and are both POSITIVE. Based on current guidelines, we consider the patient positive for HIV and have referred for care. Additional testing will be performed at the treatment center, to confirm and further evaluate the condition.
- Two orthogonal (different) rapid tests have been performed with the second test NEGATIVE. The results are DISCORDANT and require further investigation before release. Refer to DISCORDANT procedures and call NJHIV support for assistance with interpretation at 732-236-7013.

A Medical Records Release Form was signed.

<table>
<thead>
<tr>
<th>Signature of Patient</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This form goes to the ordering physician with a copy kept in the patient chart. The rapid tests used have been evaluated and approved for use by the FDA. The rapid testing has been interpreted by a trained operator, competent in the performance of these tests and reflect the HIV status of the patient identified above at the time of the testing. A copy of the form can be released to referring/treatment centers, provided the results of the rapid tests were used for referral AND the patient signed the medical records release above.

*Form NJ HIV 20 August 2012*
**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*

Result: Positive [ ] Negative [ ]

Specimen (circle one): [ ] Oral  [ ] Fingerstick  [ ] Venipuncture  [ ] Test Kit Lot Number: 

For Single Rapid Test Sites and Non Clinical 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.

**Second Rapid HIV Test Result**

Date: 

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

Second Test Site ID Number: 

Second Test Site Name: 

Second Test Site Counselor Name: 

Second Test Site Counselor Number: 

*Second Rapid HIV Test Type: [ ] Unigold [ ] OraQuick*

Result: Positive [ ] Negative [ ]

Specimen (circle one): [ ] Oral  [ ] Fingerstick  [ ] Venipuncture  [ ] Test Kit Lot Number: 

**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). Draw 2 white tops tubes & Call NJ HIV Program at 732-743-3624 or 732-743-3620 for pickup.

- [ ] Second Test Not Done: Client refused - Contact NAP and complete NAP 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 10-March 2013
# 2012 HIV Test Template

## Part One

### Sample Date

<table>
<thead>
<tr>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
</tr>
</thead>
</table>

### Worker ID

<table>
<thead>
<tr>
<th>Worker ID</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Election</td>
<td>Test not offered</td>
<td>Test not offered</td>
<td>Test not offered</td>
</tr>
<tr>
<td>Anonymous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confidently</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Declined Testing</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Test Technology

<table>
<thead>
<tr>
<th>Test Technology</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAAT/RNA Testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

### Test Result

<table>
<thead>
<tr>
<th>Test Result</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive/Reactive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indeterminate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invalid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Result</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Result Provided

<table>
<thead>
<tr>
<th>Result Provided</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### If Results Not Provided, Why?

<table>
<thead>
<tr>
<th>If Results Not Provided</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declined Notification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not return</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Could not locate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Choose one if

- Client completed a behavioral risk profile
- Client was not asked about behavioral risk factors
- Client was asked, but no behavioral risks identified
- Client declined to discuss behavioral risk factors

### In the past 12 months has the client identified the following:

- Vaginal or Anal Sex with
  - Without using a condom
  - With a person who is an IDU
  - With a person who is HIV +
- Has the client had vaginal or anal sex with an MSM? FEMALE ONLY
- Has the client used injection drugs?
- If yes, did client share drug injection equipment?

### Additional Risk Factor(s)

<table>
<thead>
<tr>
<th>Additional Risk Factor(s)</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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### Optional Session Activities

<table>
<thead>
<tr>
<th>Optional Session Activities</th>
<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
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<tbody>
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### Local Use Field

<table>
<thead>
<tr>
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<th>HIV Test 1</th>
<th>HIV Test 2</th>
<th>HIV Test 3</th>
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<tbody>
<tr>
<td>L1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L2</td>
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<td>L3</td>
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<td></td>
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<tr>
<td>L4</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td></td>
<td>4/22/13</td>
<td>70° B</td>
<td>Y</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Clients</th>
<th>Total</th>
<th>Supervisor review</th>
<th>NJHIV MT review</th>
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<tbody>
<tr>
<td>positive:</td>
<td>Proficiency:</td>
<td></td>
<td></td>
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<tr>
<td>Clients</td>
<td>Total</td>
<td>Total</td>
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</tr>
<tr>
<td>negatives:</td>
<td>Controls:</td>
<td>Invalids:</td>
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### RAPID HIV TEST LOG

**TESTING TYPE CODES DHSTS:**
STD- STD Services, FQHC- Federally Qualified Health Centers, TB- TB Services, PP/FP- Planned Parenthood / Family Planning, OTE- One Time Event

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Site ABC</th>
<th>BOX LOT #</th>
<th>EXPIRATION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipment NUMBER</td>
<td>TC000</td>
<td>Kits # 20</td>
<td>5-17-13</td>
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</table>

<table>
<thead>
<tr>
<th>Site ID (PEMS or EvalWeb)</th>
<th>#2222</th>
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| Contact Name | |
|--------------||
| Phone# | |

<table>
<thead>
<tr>
<th># Testing</th>
<th>DATE:</th>
<th>ROOM TEMP</th>
<th>Oral/Blood Control Proficiency</th>
<th>CONTROL PRESENT</th>
<th>CONTROL CODES</th>
<th>RESULTS:</th>
<th>POS NEG INV</th>
<th>START/END TIMES:</th>
<th>OPERATOR</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>4/22/13</td>
<td>NJDH000000</td>
<td>70°</td>
<td>B</td>
<td>Y</td>
<td>S</td>
<td>Pos</td>
<td>10:39</td>
<td>JC</td>
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<table>
<thead>
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<tbody>
<tr>
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<td>5</td>
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<td>6</td>
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</table>
Thanks To:

RWJMS

- Evan Cadoff, MD
- Eugene Martin, Ph.D.
- Gratian Salaru, MD
- Joanne Corbo, MBA, MT (ASCP)
  - Moeen Ahmed, BS, MT (ASCP)
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  - Franchesca Jackson, BS (Biology)
  - Patricia Riberio, BS, MT (ASCP)
  - Lisa May
  - Karen Williams

NJDHSS/DHSTS
- Connie Calisti-Meyers
  - Sindy Paul, MD, MPH
  - Steven Saunders, MS
  - Raj Patel, MD, MSPH
  - Linda Berezny, RN
  - Loretta Dutton
  - Aye Maung Maung

All site coordinators and counselors throughout New Jersey
THE END