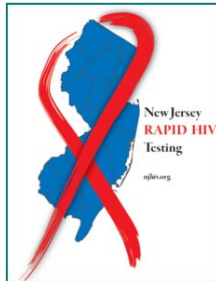


NJHIV – DMHAS

Rapid HIV Testing Program

Overview



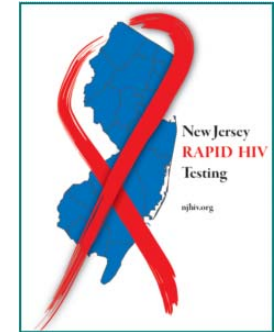
STATE OF NEW JERSEY

DEPARTMENT OF HUMAN SERVICES

Division of Mental Health and Addiction Services (DMHAS)

NJHIV – WHO WE ARE

- Rapid HIV testing support group
- Composed of laboratorians
 - MD, PhD, MT, RN
- Department of Pathology and Laboratory Medicine at Rutgers Robert Wood Johnson Medical School
 - Department of *Psychiatry* -Nina Cooperman, PsyD
 - Studies DMHAS sites to identify and eliminate barriers to HIV testing
- Built upon an existing Rutgers Robert Wood Johnson Medical School, multi-facility, point-of-care-testing program
- Develop a centralized quality assurance process
- Management by board certified Pathologists, experienced laboratory professionals, RNs and medical technologists
- Supervisory control through site coordinators



NJHIV

- Central lab oversees:
 - Regulatory and proficiency testing
 - Acquisition and validation of supplies
 - Inventory control
 - Common procedures and core policies
 - Uniform administration at all locations
 - Common training, certification of personnel, forms
 - Core communication hub: www.njhiv1.org
 - Quality Control Rules
 - Standardized monthly site visits

Quality Assurance Program

- Professional Oversight
- Monthly site visits by core staff
- Standardization of policies/procedures
- Proper test procedures (client and QC)
- Proficiency Testing
- Centralization of:
 - Training and operator certification
 - Proper test procedures
 - Quality control
 - Temperature monitoring
 - Regulatory requirements/licensure
 - Reagent purchase and validation
 - Inventory control
 - Technical support
 - Follow-up of discordant results

SCOPE OF THE CURRENT NJ HIV RAPID TEST SUPPORT PROGRAM

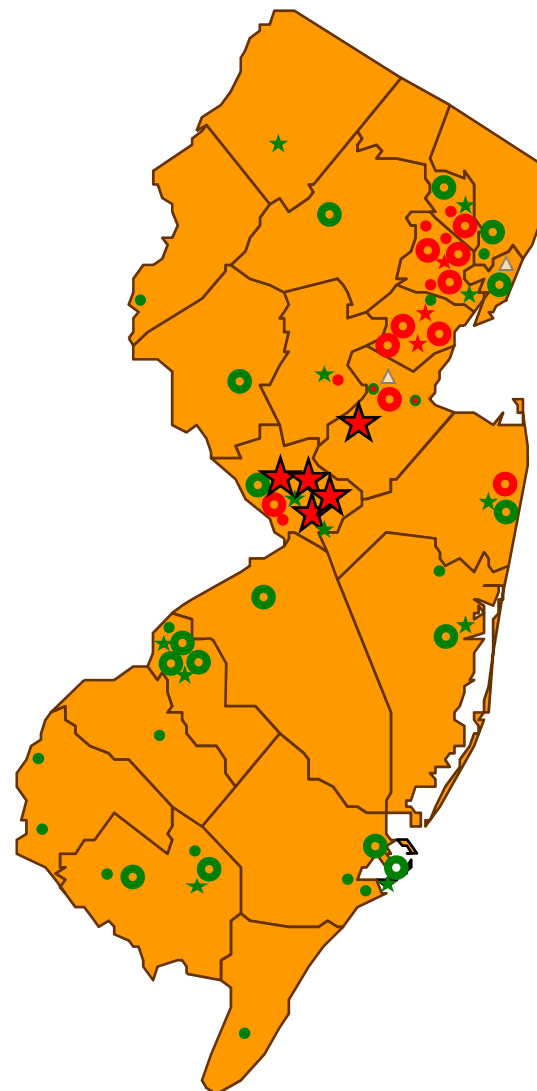
NJ HIV

New Jersey Rapid Testing

RWJ Sites: 97 Non RWJ Sites: 64

Rapid HIV Testing NJ	
RWJ sites:	
	60 Primary
	24 satellites
	13 mobile
Non RWJ site:	
	64 sites including 12 ERS

Testing volume Rapid-Rapid format:	
YTD	24,168
From Inception	143,991



Sites, laboratories and point-of-care locations supervised by the Department of Pathology at RWJMS

NJHIV

AtlantiCare Mission Health-Atlanti County Corrections
 Atlantic City Health Department
 Bergen County Health Department
 Burlington County Health Department
 Camden AHEC
 Camden County Health Department
 Catholic Charities-Hudson & Union County Corrections
 Check-Mate
 City of Trenton
 City of Vineland
 Complete Health Care
 Cumberland County Health Department
 Dooley House
 East Orange Health Department
 Eric B. Chandler Health Center
 FamCare
 Hamilton Township STD Clinic
 HiTops Inc.
 Henry J. Austin Health Center
 Horizon Health Center
 Hunterdon County Health Department
 Hyacinth Foundation
 John Brooks Recovery (IHD)
 Jersey Shore Addiction Services (JSAS)
 Kean University
 La Casa Don Pedro
 Liberation In Truth Drop In Center
 Middlesex County Department of Health
 NAP
 Neighborhood Health Centers
 Newark Community Health Centers
 Newark STD Clinic
 NJCRI

NJHIV

N. Hudson Community Action Corporation Health Ctrs.
 Oasis Drop In Center
 Ocean County Health Department
 Paterson Health Department
 Proceed
 Saint James Social Services
 Robert Wood Johnson Medical School
 Visiting Nurse Association of Central NJ
 Well of Hope
 William Paterson College

Hospitals /Laboratories

State Public Health Laboratories
 Bayshore Community Hospital
 Children's Specialized Hospital, New Brunswick
 Children's Specialized Hospital, Mountainside
 Robert Wood Johnson University Hospital
 Robert Wood Johnson University Hospital at Hamilton
 Southern Ocean County Hospital
 University Behavioral Healthcare, Piscataway

Medical offices POCT

New Brunswick/Piscataway:
 Chandler Health Center
 Clinical Academic Building
 Clinical Research Center
 Cancer Institute of New Jersey
 Medical Education Building
 Monument Square
 Icon Laboratories CRC

DMHAS testing numbers

- Currently, rapid testing done at 20 sites
- 13 additional sites in process of being licensed
- Testing volume since start of DMHAS collaboration

	Year	Tests	Positive
–	2009	698	7
–	2010	1903	14
–	2011	2915	15
–	2012	2938	7
–	2013 YTD	1953	3

HIV EPIDEMIC IN THE US

CDC estimates

- 1.2 million people (US) are living with HIV
- One in five (20%) are unaware of their infection
- Annual number of new US HIV infections has remained relatively stable for several years
- The new HIV infection rate is substantial →
 - About 50,000 become HIV infected each year
- Cumulative Reported AIDS cases nationally:

1. New York	174,908
2. California	142,254
3. Florida	104,084
4. Texas	69,735
5. New Jersey	48,750
6. Illinois	33,620
7. Pennsylvania	33,417
8. Georgia	31,734
9. Maryland	30,252
10. Puerto Rico	29,511

New Jersey

New Jersey is a high prevalence state

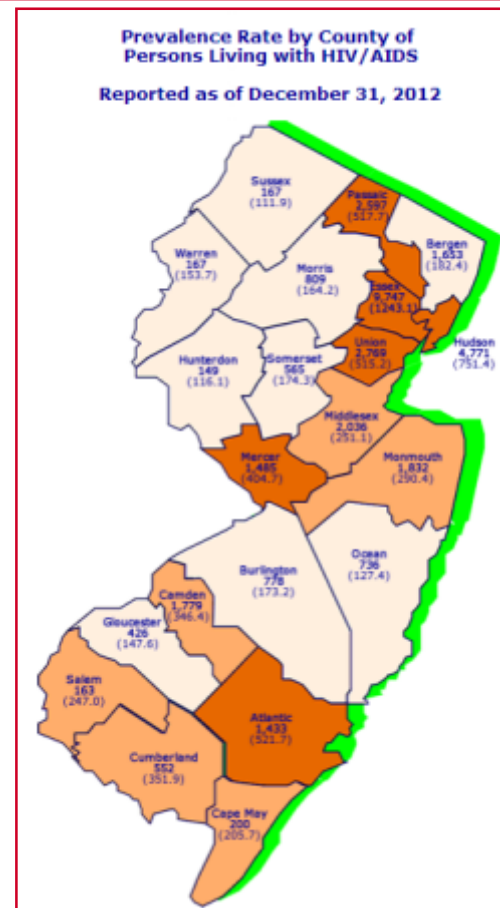
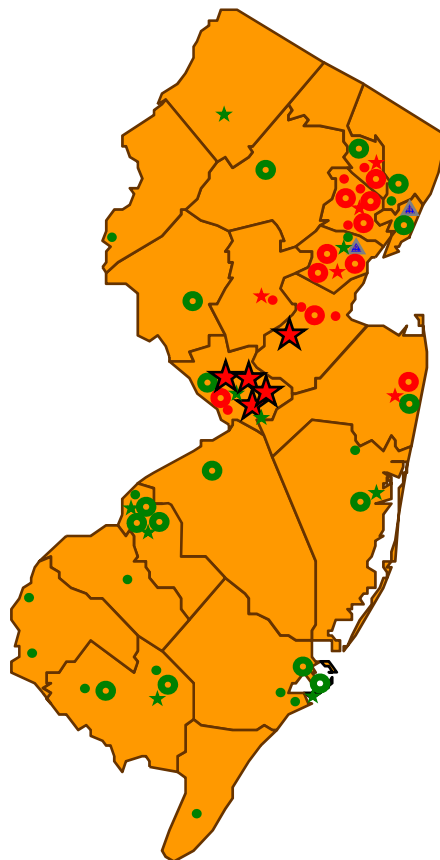
- 5th in the US in cumulative reported AIDS cases,
- 3rd in cumulative reported pediatric AIDS cases,
- 1st in the proportion of women with AIDS among its cumulative reported AIDS cases.

Statewide Prevalence of Persons Living with HIV/AIDS – 2010

- Persons Living with HIV/AIDS - 36,648 Total
- Population, Estimate 7/1/10 - 8,799,593
- Prevalence Rate/100,000 pop - 416.5

Distribution of Testing Locations Tracks Prevalence

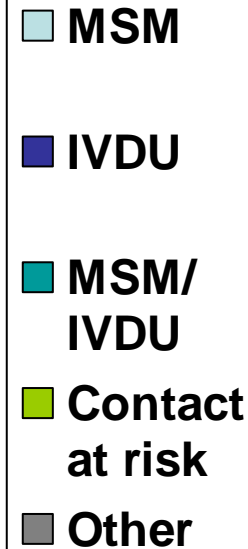
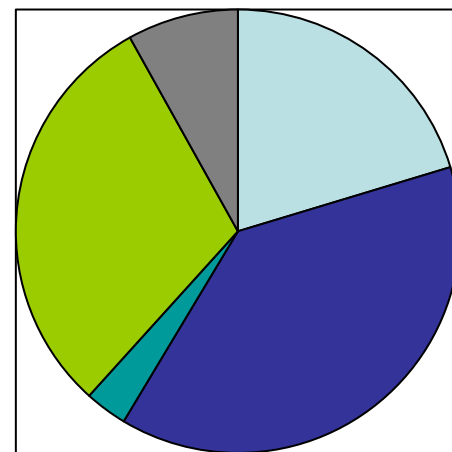
LEGEND	Symbol
Rapid Testing PROGRAM	
COMMUNITY BASED ORG. (CBO)	
MEDICAL CTR. ER	
MOBILE VAN	
PRISONS	



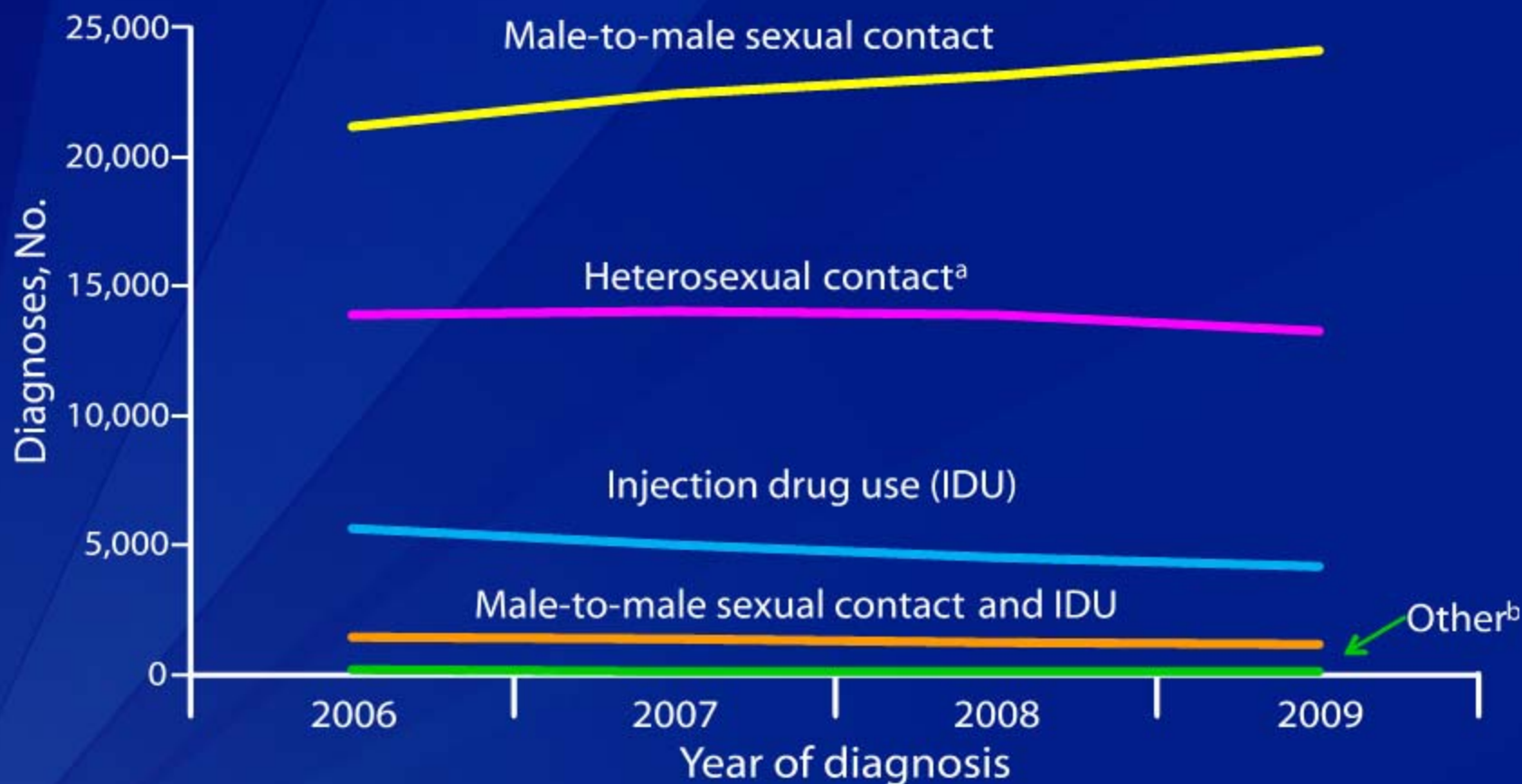
HIV AND IVDU

HIV cases among IVDU

- Historically (1995-2000) , up to 41% of HIV cases in New Jersey were among IVDU
- In the past 2-3 years only 8% of reported HIV cases were from IVDU



Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2006–2009—40 States and 5 U.S. Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing risk-factor information, but not for incomplete reporting.

^a Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

^b Includes hemophilia, blood transfusion, and risk factor not reported or not identified.



New York City IVDU study

- 1990s >30% seropositivity
- 2000s 5-6% seropositivity
- Most cases are old
- New cases < 1% per year
- incidence parallels Herpes Virus infection
- incidence does not parallel Hep C Virus infection
- IVDU population engages in high-risk sexual activity

Importance of early detection

- Early treatment may delay clinical disease
- Treatment prolongs survival-HAART
- ½ of transmission is from someone infected within the prior 6 months
- Risk reduction counseling does work
- Treatment reduces perinatal transmission
- High risk behaviors put others at risk
- High risk behaviors include high risk sexual behaviors
- Evidence from HIV Prevention that much of the transmission among drug addicts is of a sexual nature (NY)



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 from individuals within 6 months of 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**

MMWR September 22, 2006 / 55(RR14);1-17

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

Bernard M. Branson, MD¹ H. Hunter Handsfield, MD²

Margaret A. Lampe, MPH¹ Robert S. Janssen, MD¹

Allan W. Taylor, MD¹ Sheryl B. Lyss, MD¹ Jill E. Clark, MPH³

¹Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (proposed)

²Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (proposed) and University of Washington, Seattle, Washington

³Northrup Grumman Information Technology (contractor with CDC)

- Routine HIV testing for adolescents and adults in health-care settings
- Test everybody unless specifically denied
- Screen for HIV regardless of prevalence (as effective in very low prevalence as in high prevalence areas).
- **High-risk individuals at least annually, recommended every 6 months**
- **Drug users are by definition high-risk**
 - Addiction treatment centers
 - Methadone programs
 - Needle exchange programs
 - ...strange advantage – patients keep returning to the center, so counseling, linkage to care or additional tests can be performed

HIV Testing Recommendations for Substance Abuse Treatment Providers

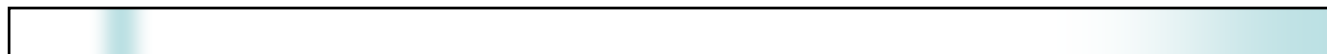
- **Recommend opt-out testing to your clients, if possible**
 - More effective strategy than risk-based testing only
- **Test everyone at your agency unless specifically denied**
 - Request information on why client denies testing and document it
- **High-risk individuals should be tested every six (6) months**

HIV Testing

- 1980s -T-cell assays
- 1985 – HIV Antibody testing
- 1987 – HIV Western Blot criteria
- 1996 – Oral mucosal transudate testing- OraSure
- 2003 – Rapid testing (blood and then oral transudate)
- Current: Rapid 3rd gen assays and laboratory 4th gen assays with available nucleic acid amplification testing (NAAT)
- Current: Rapid 4th gen assays with both antibody and antigen p24 testing (Determine, FDA approved)
- Future: Rapid CD4/CD8 assays and rapid viral load assays

HIV Infection

Symptoms



Antibody
by 1st gen EIA



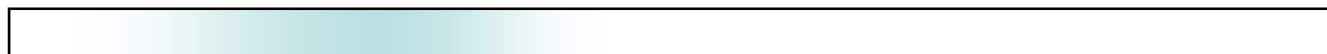
Antibody
by Western Blot



Antibody
by 3rd gen EIA



Antigen



RNA / NAAT



Acute Infection

Silent Infection

AIDS

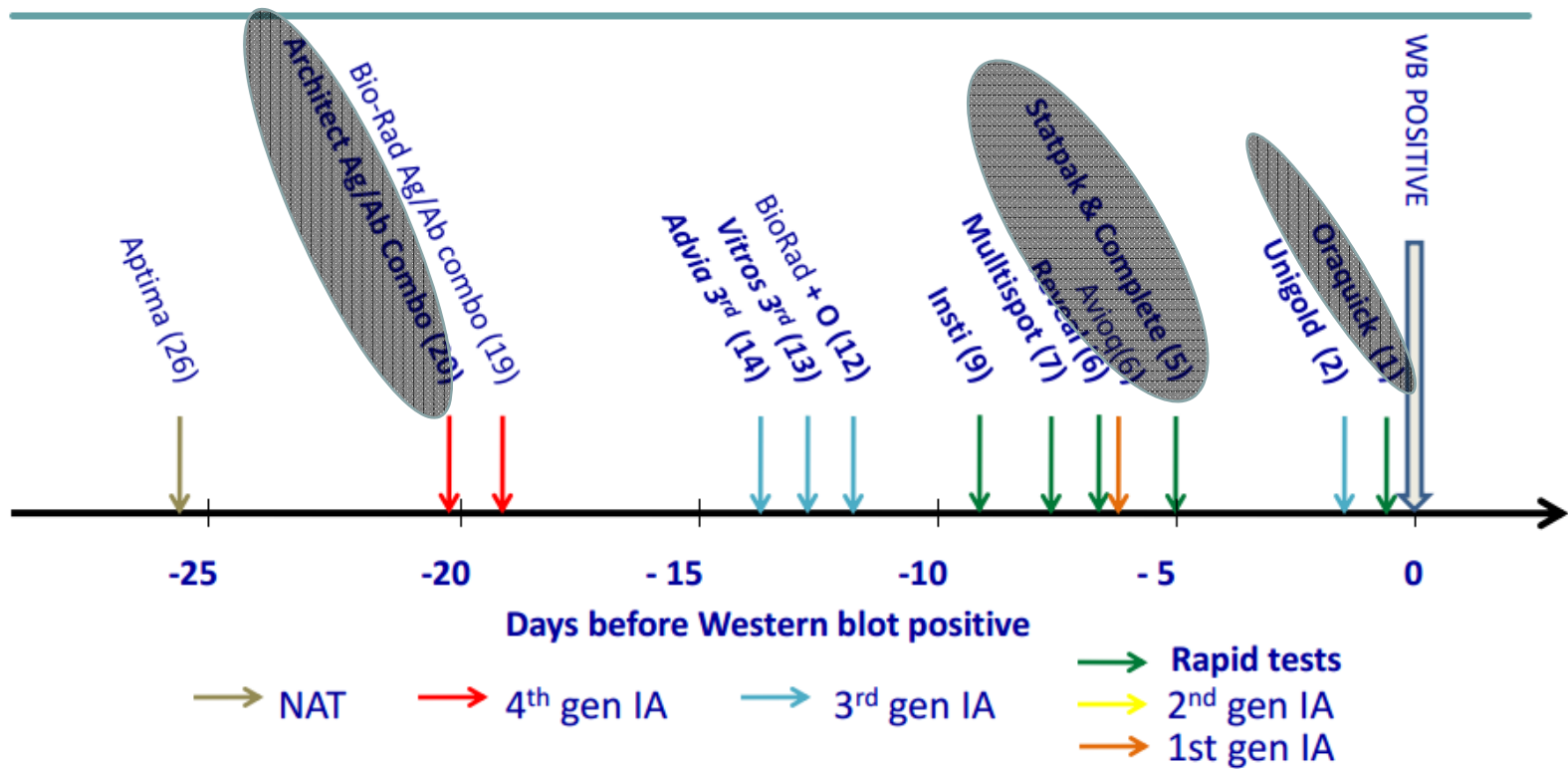
Weeks after infection

5-10 years

1-3 years

HIV Tests have come a long ways

Sequence of Assay Reactivity Plasma



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

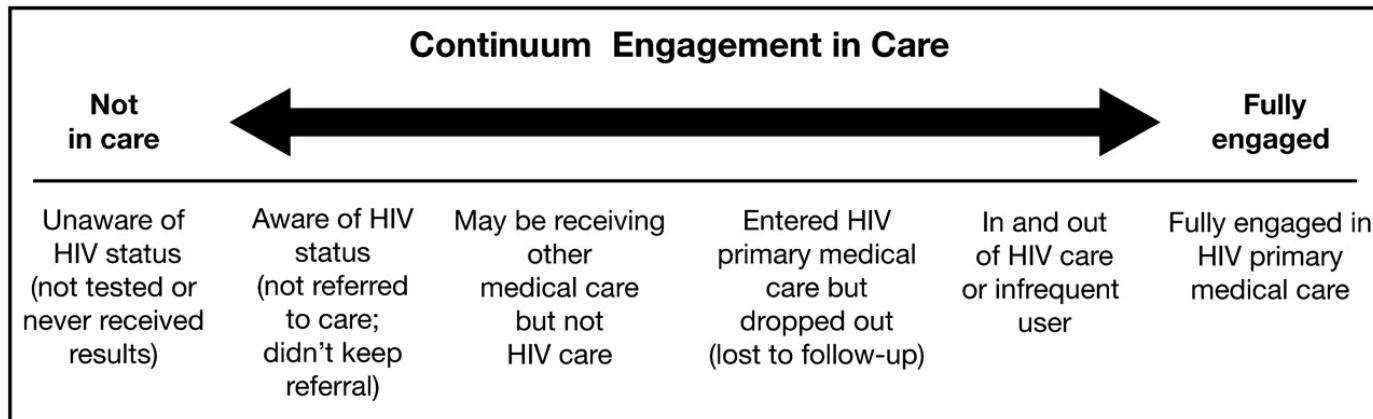
Adapted from Owen et al J Clin Micro 2008 and Masciotra et al J Clin Virol 2011

Rapid Testing

- Currently in New Jersey
 - Rapid HIV tests, several
 - FDA approved
 - CLIA-waived complexity
- OraQuick HIV 1/ 2 (OraSure Technologies)
- StatPack (Clearview HIV 1/ 2, Alere)
- Unigold (Trinity Biotech)
- Insti
- Multispot (BioRad) moderate complexity
- Determine, moderate complexity (for now)

Test on site vs. Refer for testing

- Results available during intake session
- Takes probably less time to perform testing than to follow-up and obtain outside HIV results

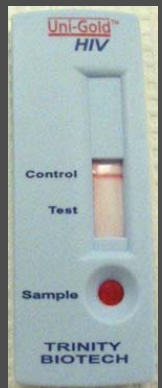
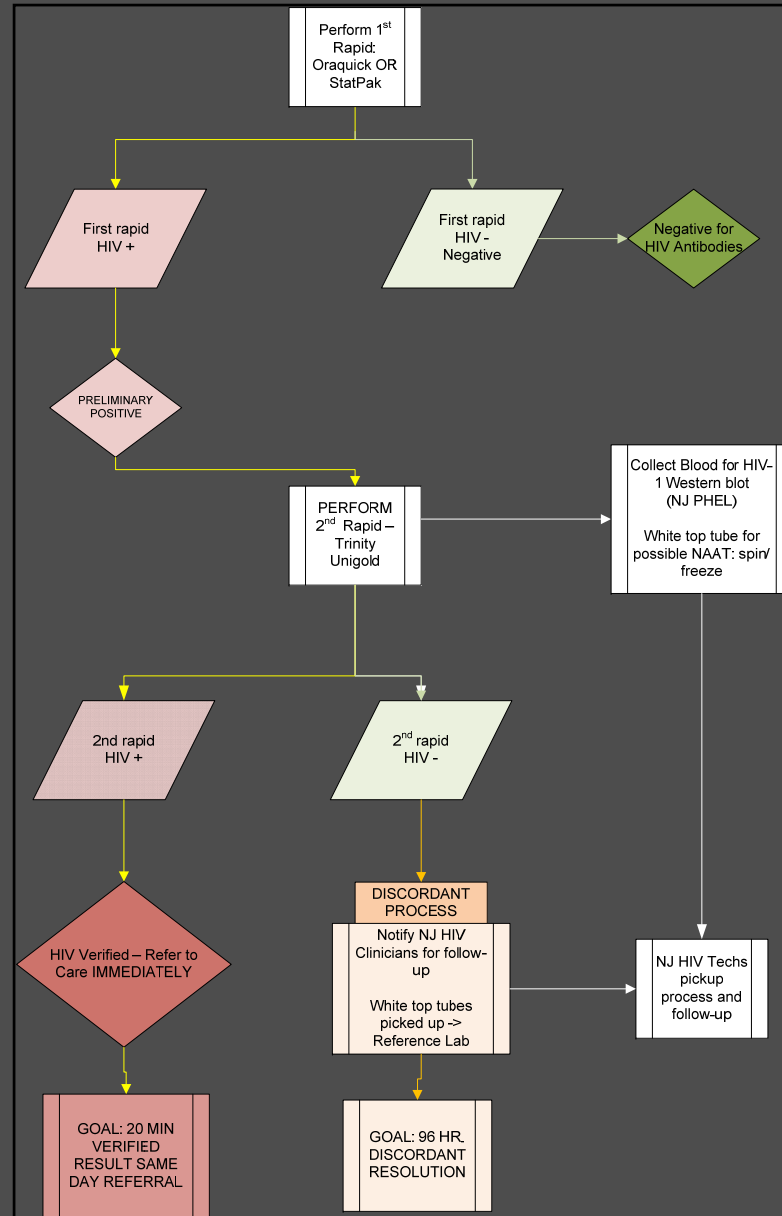
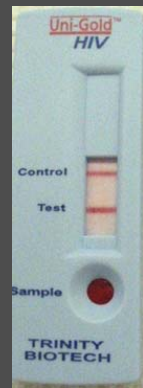


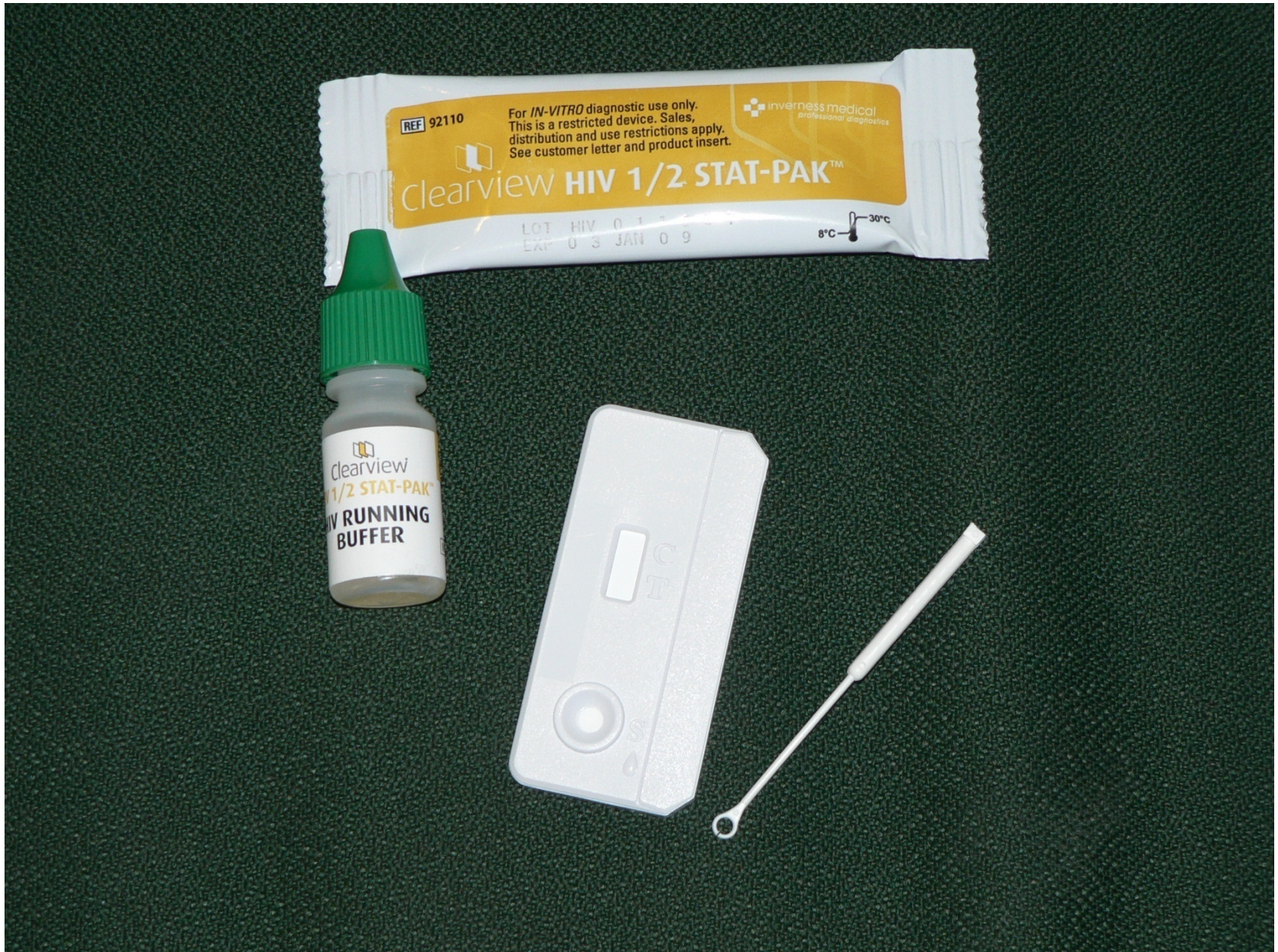
- **CONCEPT:** “In care” encompasses relationships that vary in consistency and durability and change over time.
 - TERMS:** *linkage to care, engagement/retention, and re-engagement in care and re-entry to care* - reflect degrees of relationship within the ‘care system’.

- SOMETIMES A FOCUS ON DIAGNOSTIC PERFORMANCE MISSES THE FUNDAMENTAL ISSUE: BRINGING THOSE NOT IN CARE → INTO CARE AND KEEPING THEM THERE.

NJ RAPID TESTING ALGORITHM

ORTHOGONAL





3.5 → 4th Gen – Point-of-Care Test

Determine HIV-1/2 Ag/Ab Combo Whole Blood Procedure

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

1 Remove tests

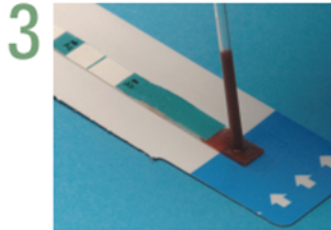


Note: Removal of the test units should start from the right side of the test card to preserve the lot number which appears on the left side of the card.

2 Remove cover



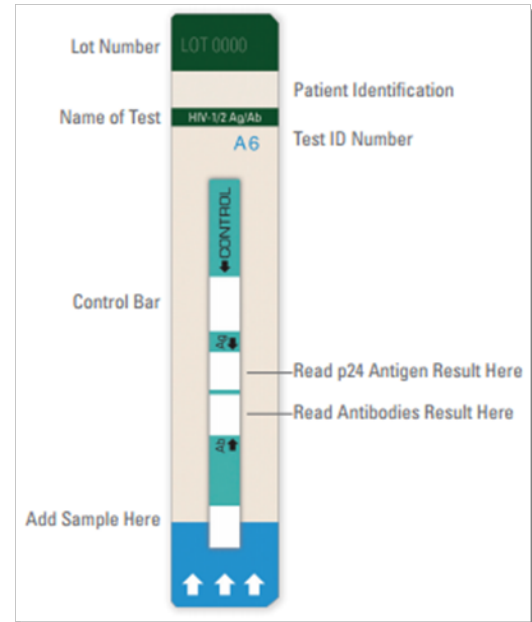
3 Add sample



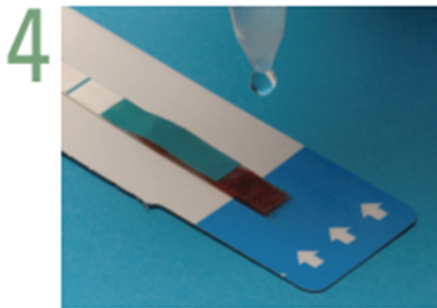
Add sample (50µl) to sample pad (finger stick or venipuncture)



Wait 1 minute



4 Add chase buffer

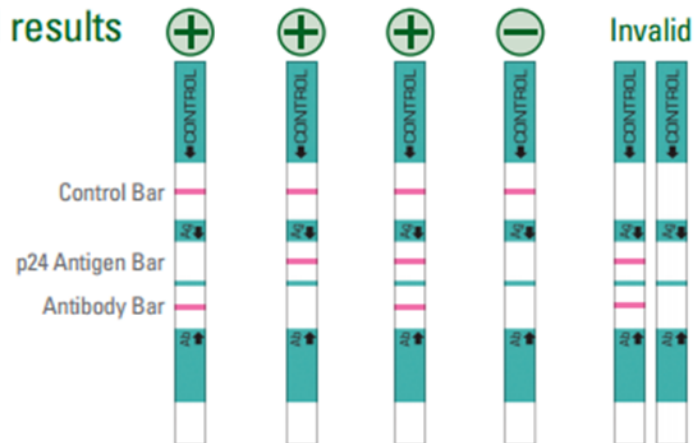


Add one drop of chase buffer



Wait 20 minutes

5 Read results



PILOT PROGRAM

NJ HIV MOBILE COUNSELOR

Person who would travel from a central office location to your sites to perform all activities related to rapid HIV testing

Expectation to increase the number of HIV tests performed

Costs supported by DMHAS through NJHIV and RWJ Medical School

Mobile HIV Counselor/Tester NJHIV

- Certified HIV counselor by DHSS/DHSTS
- Trained HIV tester by NJHIV
- Trained phlebotomist
- Based in Somerset, NJ licensed facility
 - No need to license individual sites
 - Reports to NJHIV and State DMHAS
 - Compiles statistical data for reporting
- Maintains inventory
- Quality assurance program/ quality control
- Proficiency requirements compliance
- Reporting requirements
- Bioanalytical Laboratory Director - oversees the program and can assist the site with discordant or unexpected results
 - Mobile counselor will collect blood samples if required to resolve discordant testing. No additional personnel required from the site

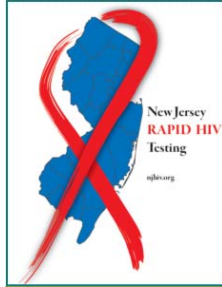
Study finds first evidence that PrEP can reduce HIV risk among people who inject drugs

Lancet, June 12, 2013

- Pre-Exposure Prophylaxis (PrEP)
- reduced the risk of HIV acquisition among people who inject drugs by 49 percent
- *“This is a significant step forward for HIV prevention. We now know that PrEP can work for all populations at increased risk for HIV,” said Jonathan Mermin, M.D., director of CDC’s Division of HIV/AIDS Prevention. “Injection drug use accounts for a substantial portion of the HIV epidemic around the world, and we are hopeful that PrEP can play a role in reducing the continued toll of HIV infection in this population.”*
- *PrEP complements other available tools, including access to new sterile needles and syringes and regular HIV testing*

Update to Interim Guidance for Preexposure Prophylaxis (PrEP) for the Prevention of HIV Infection: PrEP for Injecting Drug Users
MMWR *Weekly* June 14, 2013 / 62(23);463-465

- **CDC recommends that preexposure prophylaxis (PrEP) be considered as one of several prevention options for persons at very high risk for HIV acquisition through the injection of illicit drugs**
- In all populations, PrEP use
 - is contraindicated in persons with unknown or positive HIV status
 - should be targeted to adults at very high risk for HIV acquisition
 - should be delivered as part of a *comprehensive set of prevention services*
 - should be accompanied by quarterly monitoring of HIV status, pregnancy status, side effects, medication adherence, and risk behaviors



STATE OF NEW JERSEY

DEPARTMENT OF HUMAN SERVICES

Division of Mental Health and Addiction Services (DMHAS)

Thanks To:

RWJMS

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NJ DMHAS

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- Mollie Greene

Site coordinators and counselors throughout New Jersey