



HIV TAC TEAM

Routine HIV Testing Community of Practice Session #2

Presenters:

Denver Prevention Training Center

Broward Community & Family Health Centers, Inc.

20 March 2016

Communities of Practice

- Routine HIV Testing CoP Series - Led by faculty from the Denver Prevention Training Center
 - Four 60 minute sessions scheduled for: February 11, March 10, April 14, and May 5 at 1:00 PM Eastern Time
- Invitation to our Electronic Medical Record CoP – March 22, 1:00 – 2:00 PM ET.



Denver
PREVENTION
TRAINING CENTER

Karen Wendel, MD, Director of STD/HIV
Prevention and Control

Objectives

- Describe the evolution of HIV testing
- Review time from HIV infection to positive testing by testing method
- Review CDC HIV testing algorithm and rationale
- Discuss limitations of 4th generation point-of-care HIV testing

Evolution of HIV Tests

- 1st generation
 - Whole viral lysate
 - Detects IgG antibody (Ab)
- 2nd generation
 - Synthetic peptides
 - Detects IgG Ab
- 3rd generation
 - Synthetic peptides
 - Detects IgM and IgG Abs
- 4th generation
 - Detects p24 antigen (Ag) allowing detection of HIV-1 infection before seroconversion
 - Detects IgM and IgG Abs

HIV Ab/Ag Tests

	1 st generation IgG Ab	2 nd generation IgG Ab	3 rd generation IgM & IgG Ab	4 th generation IgM, IgG Ab, and p24 Ag
Lab-based testing	Enzyme Immunoassay (EIA), Immuno-fluorescent assay (IFA), GS HIV-1 Western Blot*, Cambridge Biotech HIV-1 Western Blot*	Multispot, Chembio DPP, Avioq HIV-1 Microelisa System*, MedMira Reveal G2 Rapid HIV-1*, Geenius	Bio-Rad GS HIV-1/2 Plus O, Siemens ADVIA Centaur, Enhanced Ortho Vitros	Bio-Rad GS Ag/Ab Combo, Siemens ADVIA Centaur Ag/Ab Combo, Abbott Architect Ag/Ab Combo, BioPlex 2200 HIV Ag/Ab
CLIA ⁺ -waived rapid testing		INSTI HIV-1/HIV-2 [^] , UniGold Recombigen [#] , Clearview STAT-PAK, Clearview COMPLETE, OraQuick ADVANCE Rapid	INSTI HIV-1/HIV-2 [^] , UniGold Recombigen [#]	Alere Determine Combo Ag/Ab Rapid Test

- *Test for HIV-1 only; # 3rd generation test functioning as second generation test; ^Test sometimes classified 2nd gen but does detect IgM
- ⁺Clinical Laboratory Improvement Amendments of 1988 (CLIA)

http://www.cdc.gov/hiv/pdf/testing_Advantages&Disadvantages.pdf
<http://www.biolytical.com/articles/3>

HIV-1 Nucleic Acid Amplification Tests (NAT)

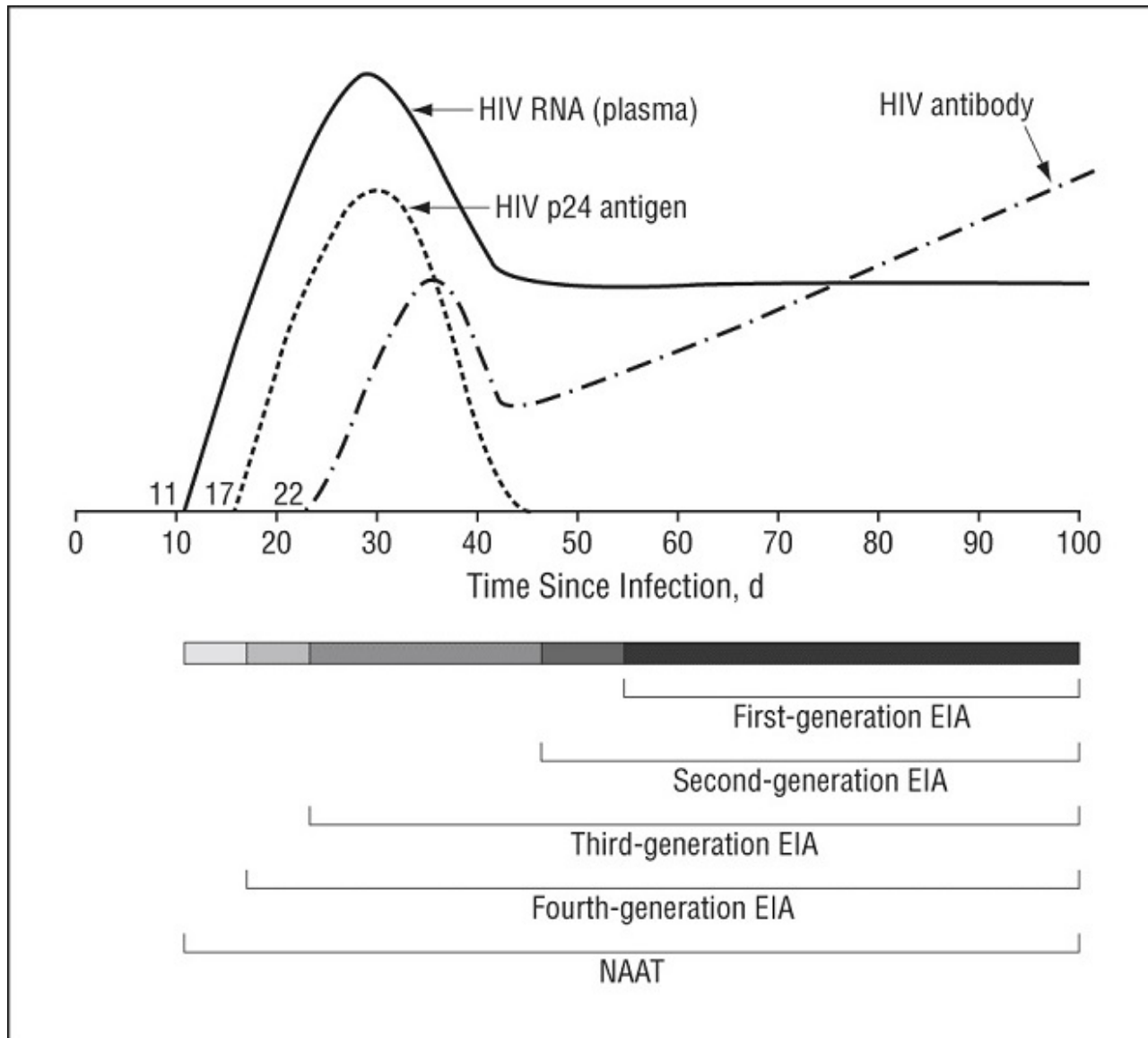
- Qualitative tests
- Quantitative tests
- Off-label use for HIV diagnosis



<http://www.hivguidelines.org/wp-content/uploads/2014/10/cdc-testing-algorithm-10-10-2014.pdf>

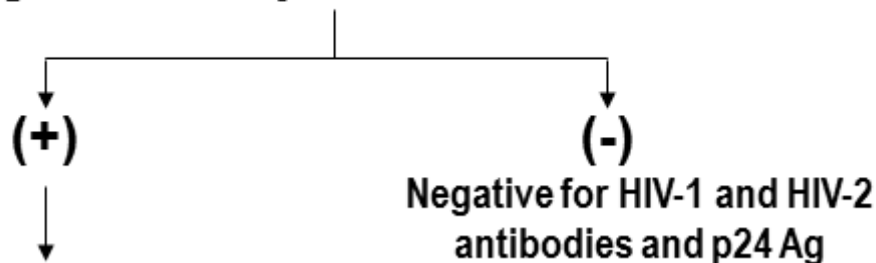
<http://www.hologic.com/products/clinical-diagnostics-and-blood-screening/assays-and-tests/aptima-hiv-1-quant-dx-assay>

HIV Testing: Time to Detection

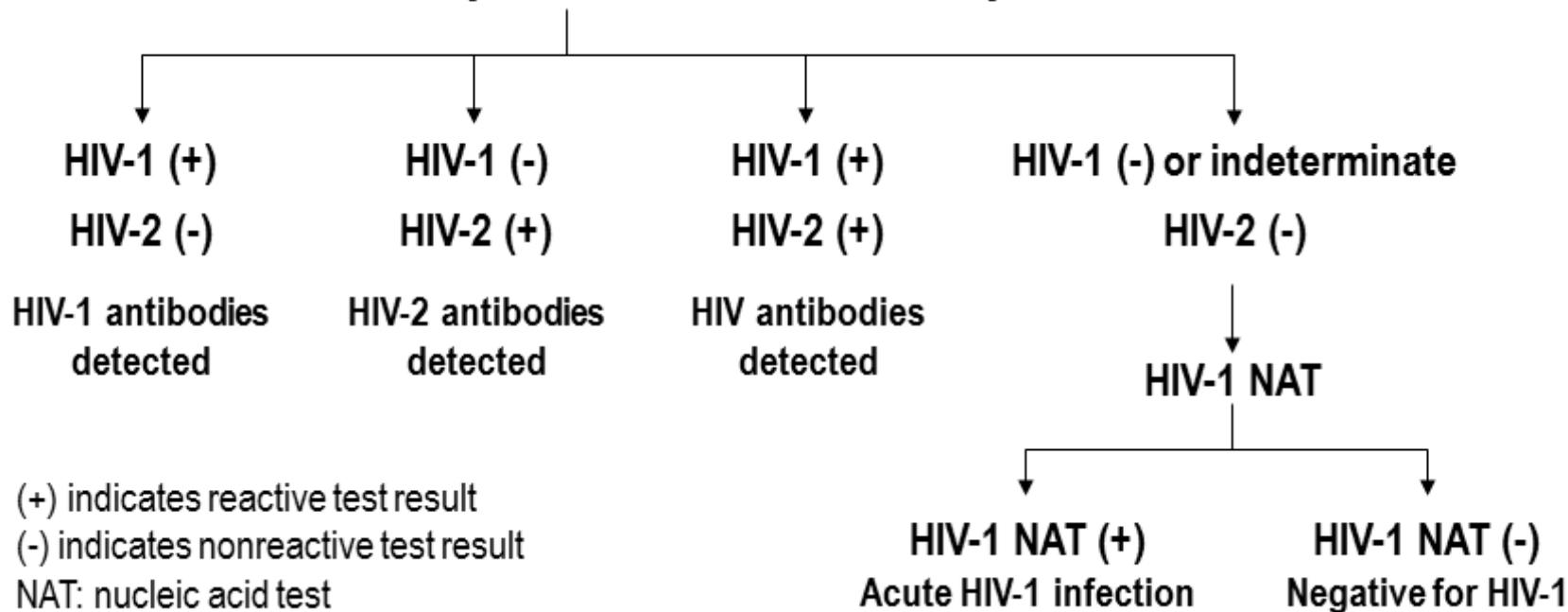


CDC algorithm for HIV testing

HIV-1/2 antigen/antibody combination immunoassay



HIV-1/HIV-2 antibody differentiation immunoassay



(+) indicates reactive test result
(-) indicates nonreactive test result
NAT: nucleic acid test

Why Use 4th Generation HIV Tests

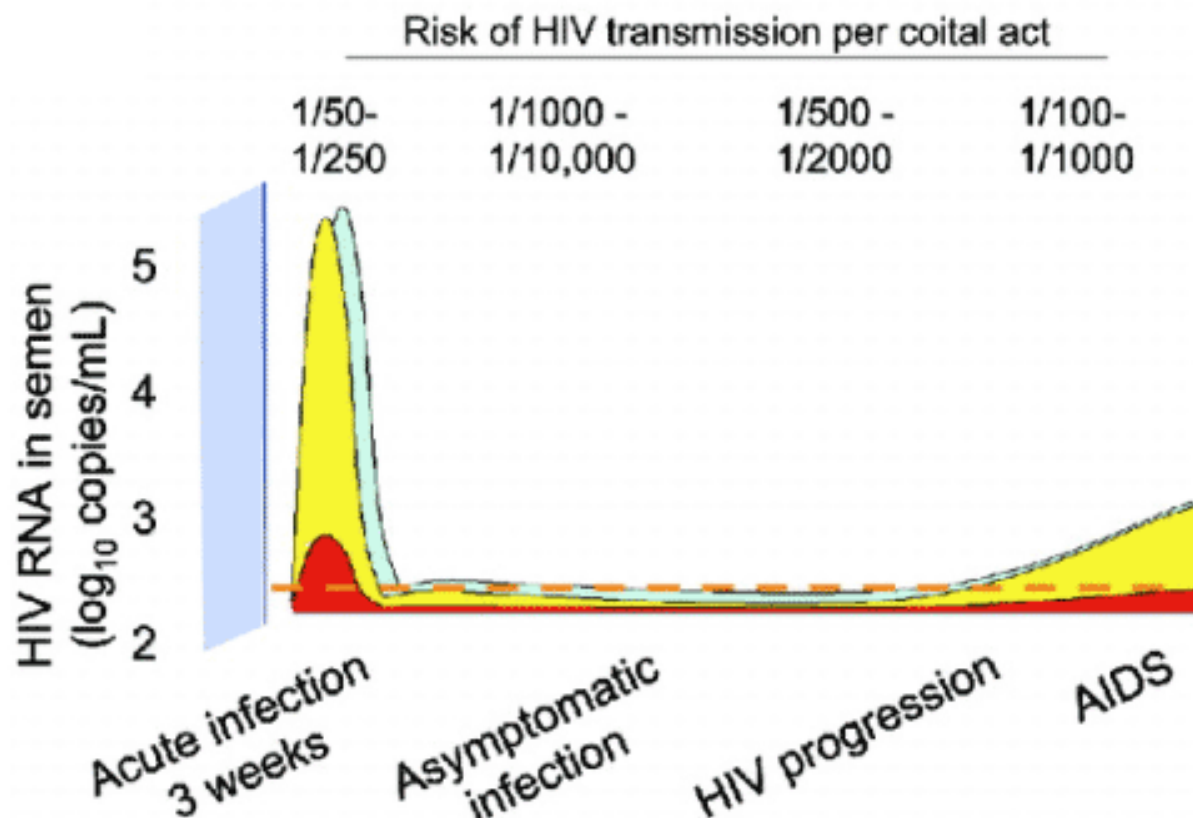
- 64 specimens from recently infected individuals
 - 35 samples with (+)HIV RNA/(-)HIV Ab including a 3rd generation HIV test
 - 28/35 (80%) were positive with 4th generation Ag/Ab combo test—Architect

- Test performance on samples from recently infected individuals

Assay	% Detected
1 st or 2 nd gen IA	12.5
OraQuick Advance	17.2
Western blot	12.5
Multi-Spot	28.1
Uni-Gold	34.4
3 rd gen IA	42.2
4 th gen IA	89.1

Gen, generation; IA, Immunoassay

Estimated Heterosexual HIV Transmission Risk



***Acute infection can account for 10%–50% of all new HIV-1 transmissions, especially in persons with multiple sex partners**

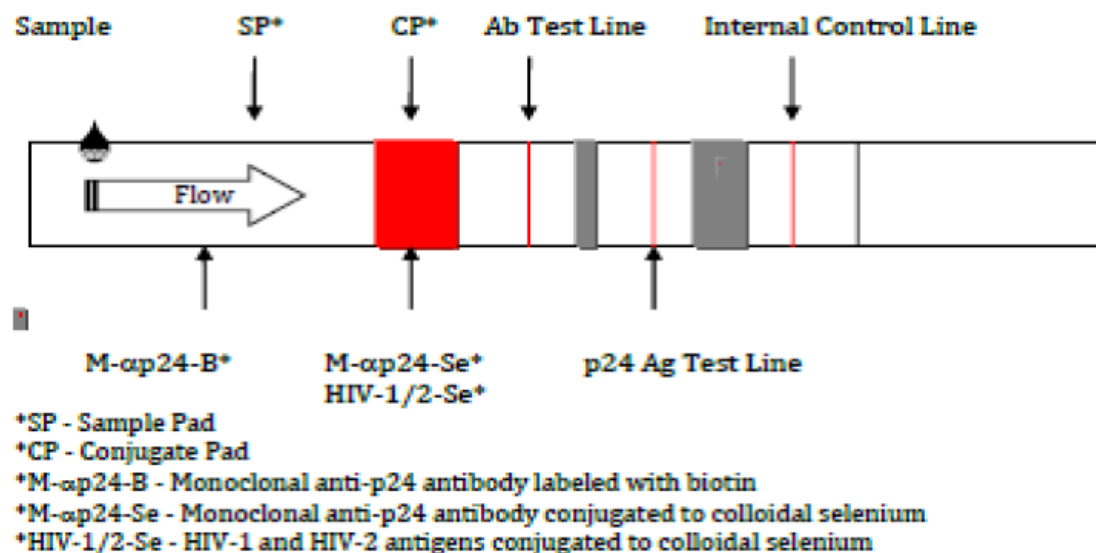
Cohen M. JID. 2005;191:1391–3; Koopman JS et al. J Acquir Immune Defic Syndr Hum Retrovirol. 1997; 14(3):249-58; Brenner BG et al. J Infect Dis. 2007; 195 (7): 951-9.; Prabhu VS et al. AIDS.2009;23(13):1792-4.; Jacquez et al. J Acquir Immune Defic Syndr.1994;7(11):1169-84

HIV-1/2 Antibody Differentiation Immunoassay

- Faster lab turn around than the Western blot
- Distinguishes between HIV-1 and HIV-2 more reliably than the Western blot
- Able to detect disease earlier after infection than the Western blot
- Current differentiation assay is Multispot
- New differentiation assay to replace Multispot in December 2016 is Geenius

4th Generation Point-of-Care HIV Testing

- Determine HIV -1/2 Ag/Ab Combo
 - Separate results for HIV p24 antigen and HIV antibody result



<http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM364701.pdf>

Determine HIV-1/2 Ag/Ab Combo

- Package insert
 - Sensitivity 99.9% with serum, plasma, and whole blood
 - Specificity 98.9-100% with serum, plasma, and whole blood
- In CDC studies on **plasma** specimens collected during seroconversion, Determine Combo detected infection:
 - 1-2 weeks before other rapid tests
 - 1-3 days before 3rd generation laboratory tests
 - 3-4 days after 4th generation laboratory tests
- There are limited data on the sensitivity of rapid HIV tests when used with **whole blood** specimens.

Systematic Review: Determine HIV-1/2 Ag/Ab Combo Test

- Review of 4 studies with 17,381 participants
- Studies sites: Australia, Swaziland, United Kingdom, and Malawi
- Analysis of cases of acute infection
 - p24 component evaluated in all 4 studies
 - 26 acute infections were missed—0% sensitivity
 - 35 false positive HIV-1 p24 results—0% positive predictive value
 - Antibody component evaluated in 2 studies
 - In one study, 0 of 3 cases of acute HIV detected
 - In one study, 2 of 8 cases of acute HIV detected

Point-of-Care HIV Testing

- Confirmation of a positive result
 - Standard algorithm
- Data are insufficient to recommend the use of the Determine Combo as the initial assay in the laboratory algorithm.

Case 1: Non-CDC Algorithm Testing

- 35 year old man with a positive point-of-care Determine HIV-1/2 Ag/Ab Combo test result in outreach is sent to a primary care provider.
- Further testing ordered
 - HIV viral load (NAT)
 - CD4 count
- Results
 - HIV viral load: Not detected
 - CD4: 350

Case 1: How do You Proceed

- What do you tell the patient?
 - A. It looks like you don't have HIV. The point-of-care test was wrong
 - B. We need to do more HIV testing to clarify your HIV status
 - C. I believe you have HIV based on your point-of-care HIV test and cd4 count. Let's repeat your viral load.
- What do you order next?
 - Repeat HIV viral load
 - Lab-based 4th generation HIV test
 - HIV genotype
 - Repeat HIV point-of-care test

Case 2

- Results:
 - HIV -1/2 Ag/Ab Combo test positive
 - HIV-1/HIV-2 antibody differentiation immunoassay negative
 - HIV-1 viral load 345,000
- Diagnosis
 - A) False negative antibody differentiation immunoassay
 - B) Acute HIV infection
 - C) Chronic HIV infection



Broward Community & Family Health Centers, Inc.

Routine HIV Testing @ BCFHC's Primary Care Centers

Andrea Brooks

*Broward Community & Family Health Centers, Inc.
Partnerships for Care (P4C) Program Lead*

March 10, 2016



Key Discussion Topics

- Overview of BCFHC
- Integration of Routine HIV Testing
- **Selecting Testing Technologies**
- BCFHC's Next Steps



Who is BCFHC?

- **Established in 1998 in Broward County, FL**
- **Mission:** *"To provide accessible comprehensive high quality primary care services to all persons with dignity and respect."*
- **4 Primary Care Centers**
- **1 Dental Center** *(Opening May 2016)*
- **88 Employees**
- **47% Federally Funded**

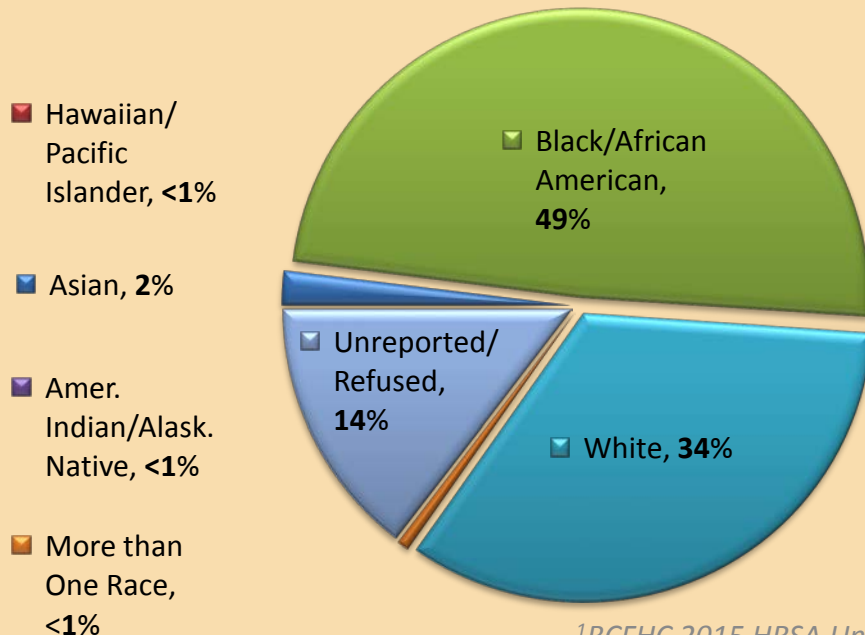


BCFHC Patients Demographics

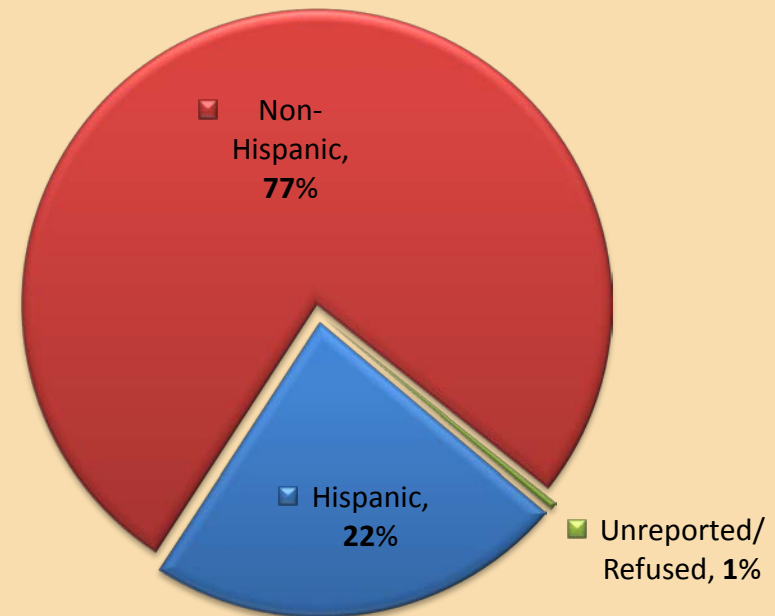
Total Patient Population¹: 8,416

PLWHA²: 327

Patients by Race



Patients by Ethnicity



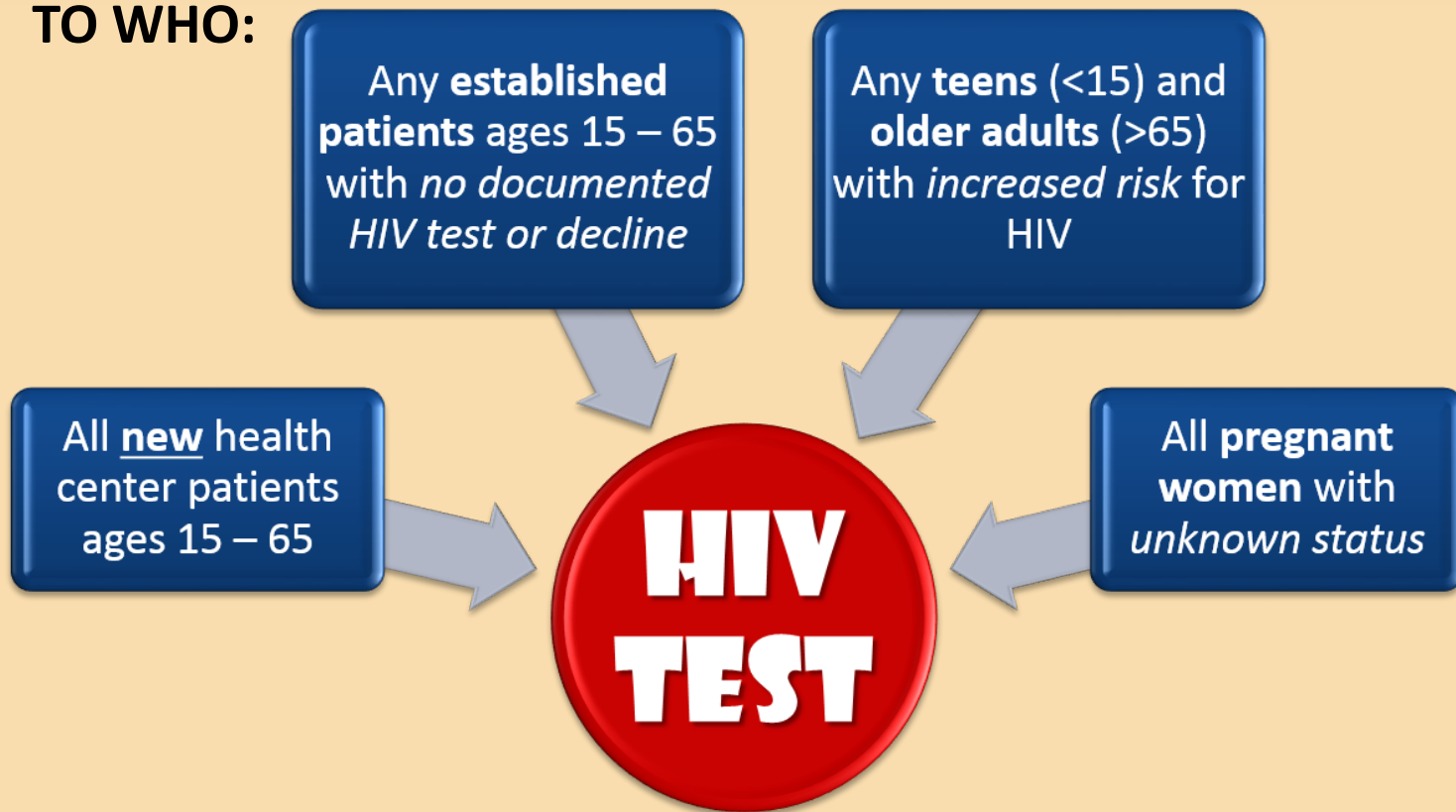
¹BCFHC 2015 HRSA Uniform Data Set (UDS) Report.

²Patient with HIV diagnosis and at least one visit between 01/01/15 and 12/31/15.



Integration of Routine HIV Testing

- Routine HIV testing introduced by Primary Care Provider
 - TO WHO:





Routine HIV Testing Diagram

Broward Community & Family Health Centers, Inc.

Workflow Diagram

HIV SERVICE AREAS

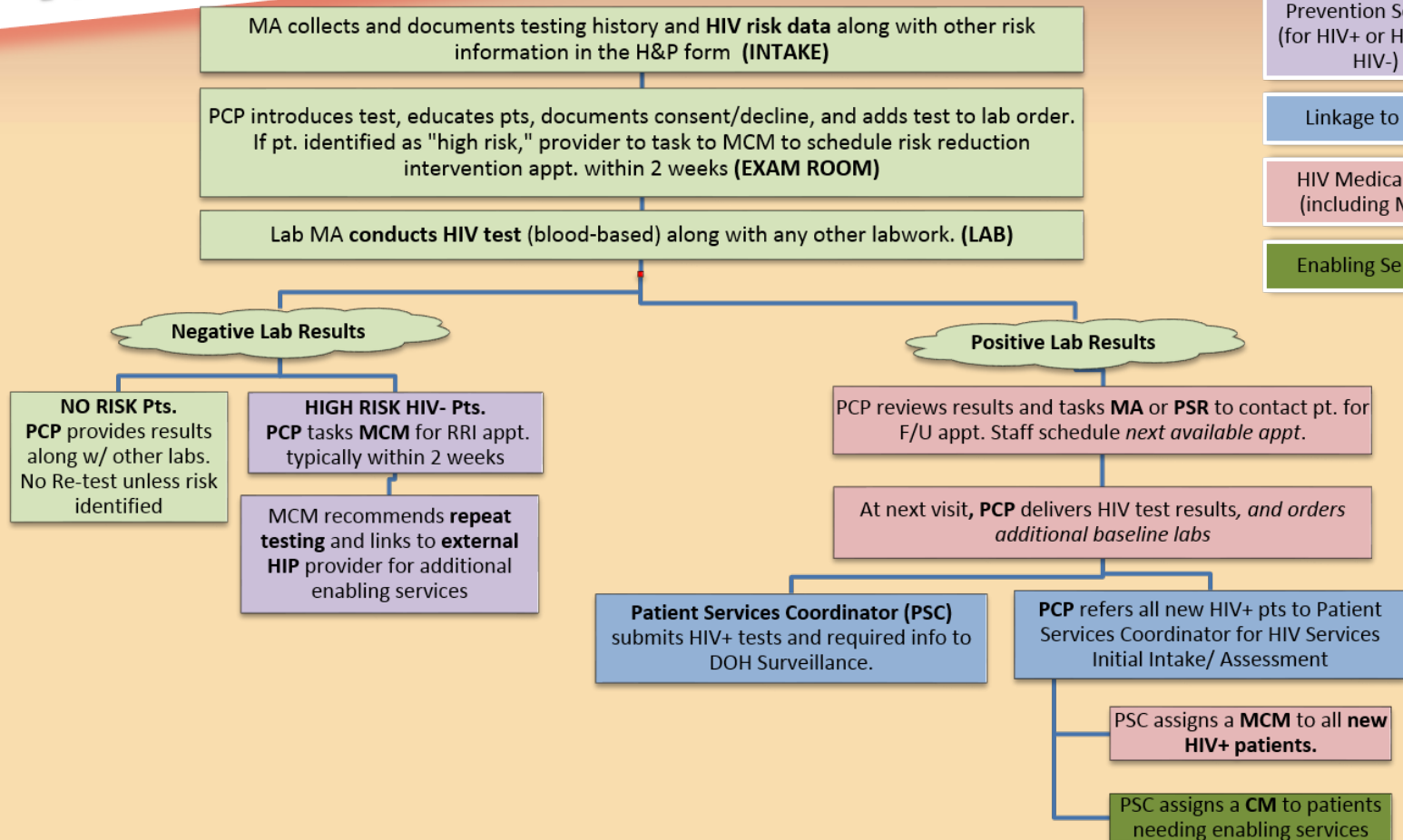
Routine HIV Testing

Prevention Services
(for HIV+ or High Risk
HIV-)

Linkage to Care

HIV Medical Care
(including MCM)

Enabling Services





Lab Based Test vs. Rapid Test

	PROS	CONS
Lab Based (HIV 1/2 antigen / antibody combination immunoassay)	<ul style="list-style-type: none">• More acceptable amongst pts when introduced by PCP• Easier to include with other labs• CDC recommended testing technology• No need for additional lab test prior to linking to care	<ul style="list-style-type: none">• Potential lost to care (pts. don't return for lab visit)• Potential delayed entry into care for HIV+• Increased lab cost for uninsured pts.• Increased organizational cost
Rapid Test (Clearview COMPLETE HIV 1/2)	<ul style="list-style-type: none">• CLEARVIEW Free of charge for patient and BCFHC• Same day result	<ul style="list-style-type: none">• Additional documentation required• Additional training required for "testers"



Lab Based Test vs. Rapid Test

- **Lab based testing for routine testing of patients**
 - Conducted by MA along with other labs
 - Lab costs for insured patients is billed to insurance
 - Lab costs for uninsured/self-pay patients currently covered by grant funding
- **Rapid testing for community members/non-patients**
 - Conducted by Certified C&T Staff (Outreach, some MAs, some Staff Nurses, HIV Care Team Staff)
 - Tests kits provided by State DOH
 - No cost to patients



Additional Training Needed

- **All Staff needed additional HIV education and training on routine testing “workflow”**
- **Rapid Testing Staff (Outreach, Medical Assistants, Staff Nurses HIV Care Team) needed additional HIV specific trainings**
 - HIV 500/501 Training through local DOH (which includes completion of in-house HIV C&T practicum)
 - CLEARVIEW Complete Training through local DOH)
 - Annual HIV 501 Update through local DOH
- **PCP need additional basic HIV care training**
- **All Staff given access to P4C trainings/webinars**



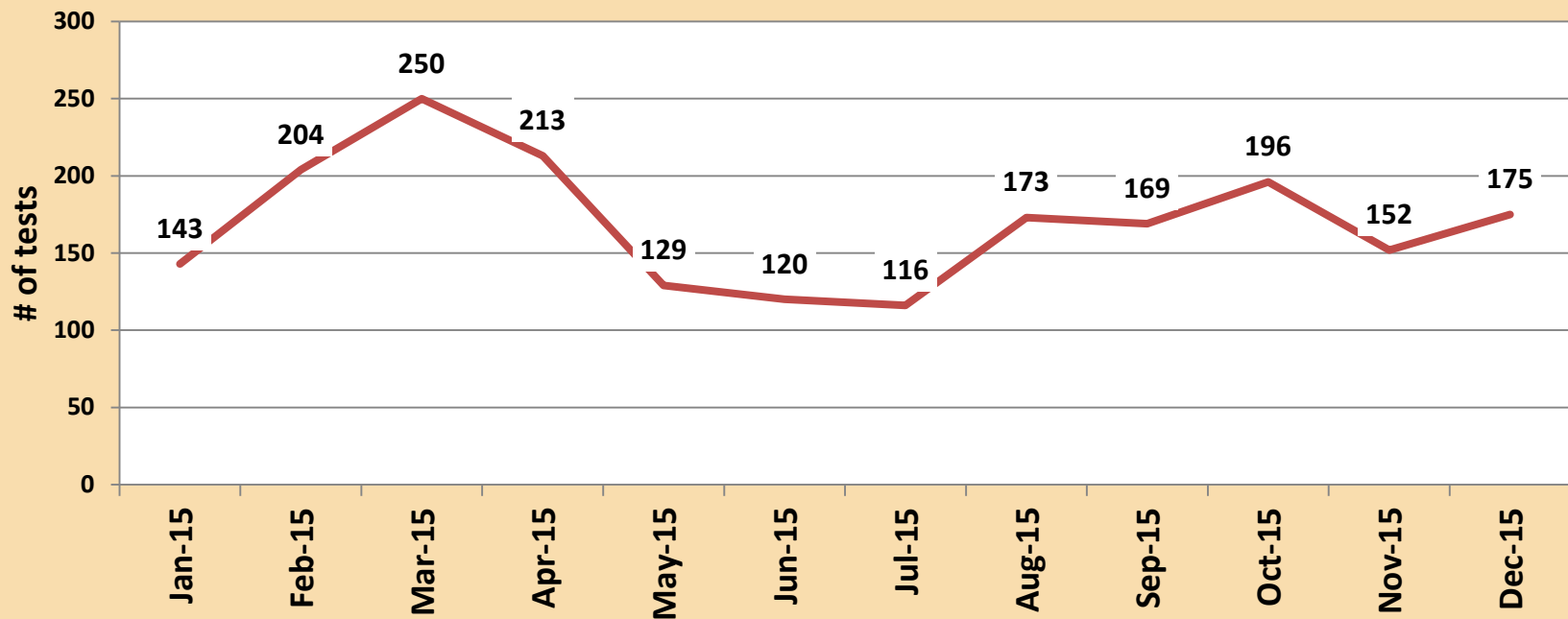
Additional Support Needed

- **Expanded documentation options in EHR**
 - Wanted to document and track “decliners”
 - Update system to reflect multiple technologies
 - Update workflow
 - Established standing orders for HIV+ patients
- **Revise Data Collection Forms**
 - Include “risk” questions in Patient H&P form



Routine HIV Testing Outcomes

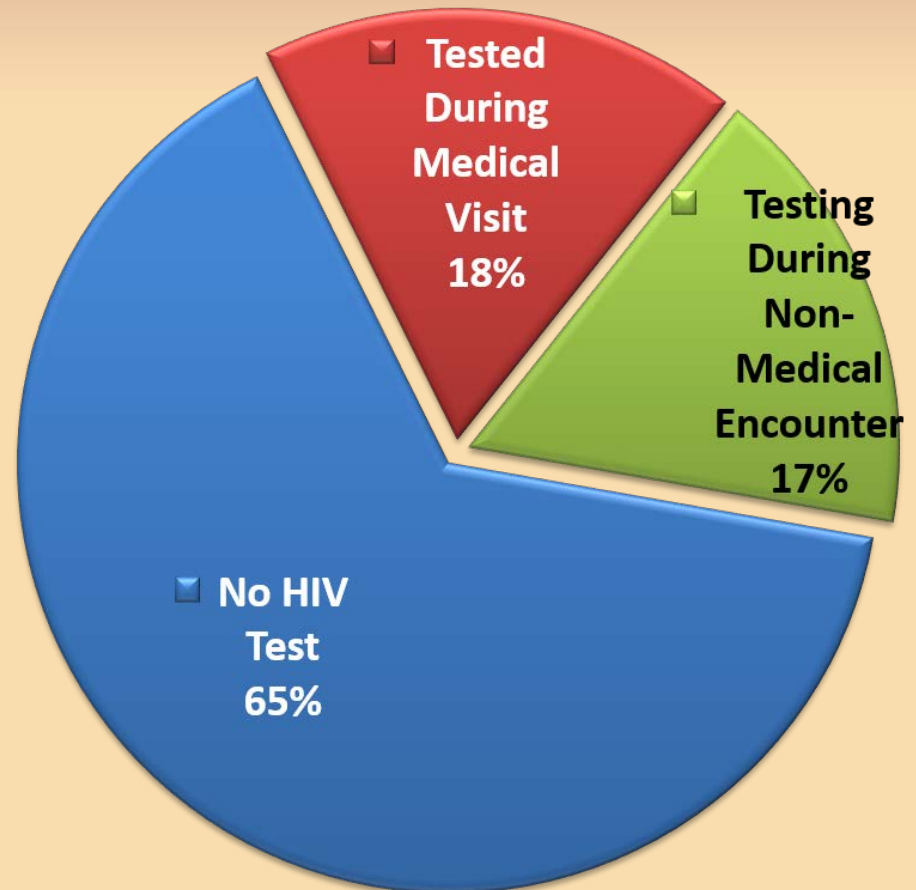
- **2,040 Routine HIV tests** conducted in 2015
- **Monthly Average: 170 tests**





Routine HIV Testing Outcomes

- **35%** of patients aged 15-65 years in need of HIV testing were tested for HIV





Next Steps

- ✓ *Increased compliance with testing workflow across sites*
- ✓ *Sustainability planning specific to lab costs for uninsured*
- ✓ *HIP for high-risk negatives*

WE NEED YOU!

Participate as Health Center co-presenter.

Contact:

Victor Ramirez,

P4C HIV TAC Collaborative Training Coordinator

vramirez@mayatech.com

Thank you for participating in this CoP webinar. We hope that you are able to find the information provided useful as you continue your P4C project. We ask that you take a few moments to complete the feedback survey you will receive in a message following this webinar.

Thank you for participating in today's CoP webinar

Please email if you have any question(s):

P4CHIVTAC@mayatech.com