

Changes in the HIV Lab Testing Algorithm

Dr. Severin Gose

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Welcome!



POPULATION HEALTH DIVISION
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
CENTER FOR LEARNING & INNOVATION



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Poll Question: What type of organization do you work for?



Housekeeping

Have questions during the webinar?

- Type them in the chat box!

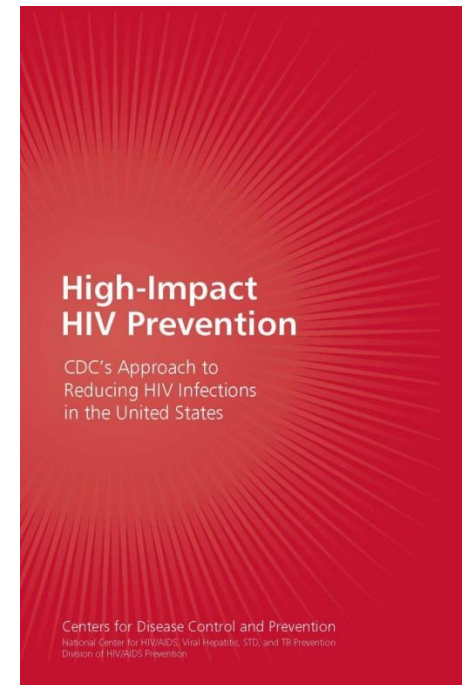
Did you have a chance to complete the HPAT?

- If not, please do so via link in chat box!
- If yes, great! Sit back and enjoy the webinar!

Please be sure to complete the evaluation at the end of the webinar! We love all feedback.

What is Capacity Building Assistance (CBA)?

CBA attempts to provide information, training, and technical assistance to the HIV prevention workforce in order to increase the adoption and implementation of high impact prevention strategies



HIV testing

- **Community-based testing** – Thomas Knoble
- **Testing in clinical settings** – Oliver Bacon, Stephanie Cohen
- **Home testing-** Hyman Scott, Oliver Bacon
- **Novel HIV testing technologies** – Severin Gose
- **Linkage/partner services-** Charles Fann
- **Internet Partner Services**– Frank Strona, Charles Fann
- **Perinatal HIV and testing** – Shannon Weber, Deb Cohan
- **Billing-** Denise Smith, Athina Kinsley

Prevention for High Risk Negative Persons

- **PrEP/PEP-** Oliver Bacon, Stephanie Cohen, Jonathan Fuchs, Albert Liu, Shannon Weber, Deb Cohan, Judy Auerbach
- **Personalized Cognitive Counseling-** Tim Matheson/Ed Wolf

Policy/Planning

- **Use of data to support HIV continuum efforts-** Data to Care: Susan Scheer, Charles Fann, Erin Antunez, Darpun Sachdev
- **Support of National HIV Behavioral Surveillance –** Henry Raymond Fisher
- **Social media to support outreach–** Frank Strona, Megan Canon (SFAF), Sapna Mysoor (AP&I WC)
- **Working with cross-sector partners –** Eileen Loughran
- **Harm Reduction Strategies with IDU –** Eileen Loughran
- **Jurisdictional Planning –** Dara Geckeler, Eileen Loughran

Ready to find out more?

Visit: www.getSFcba.org

Email: get.SFcba@sfdph.org

Call: 415.437.6226

Changes in HIV Lab Testing Algorithm



Dr. Severin Gose

Director, SFDPH Lab

Q&A Session Will Also Feature



Thomas Knoble

Capacity Building Program Coordinator,
Community Health Equity & Promotion Branch,
SFDPH

Webinar Overview

Past – Brief overview of previous HIV diagnostics

Future – New HIV diagnostics and the updated algorithm

Case Study – San Francisco's HIV testing program

Disclaimer

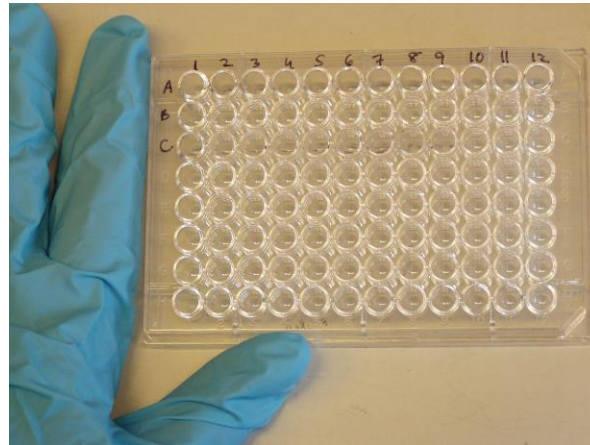
Mention of any products, tools or services is for explanatory purposes only and does not imply their endorsement.

PAST – BRIEF OVERVIEW OF HIV DIAGNOSTICS

- 2nd/3rd generation HIV diagnostics
- Western Blot

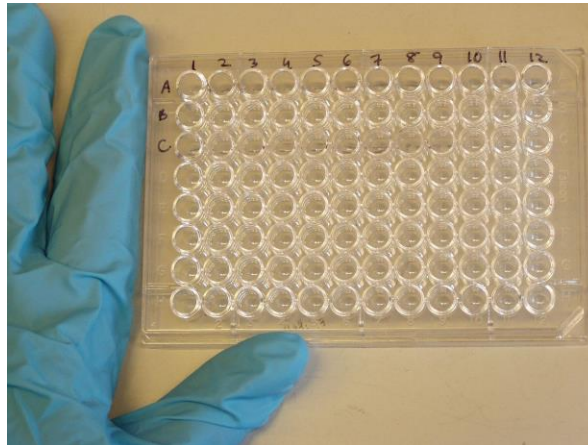
2nd Generation HIV Immunoassays

- **Platform** – Lab based
- **Method** – Enzyme Immunoassay (EIA)
- **Detection** – IgG only
- **Window period** – >30 days



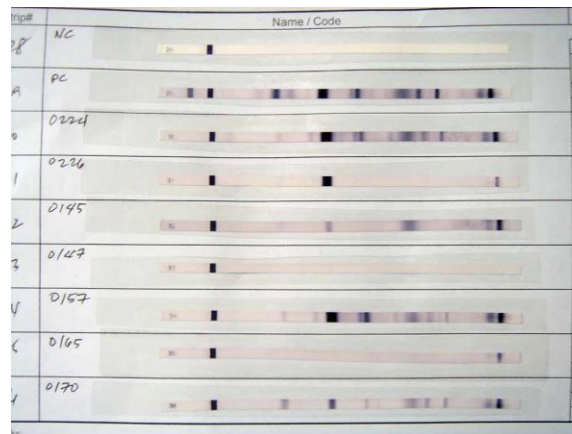
3rd Generation HIV Immunoassays

- **Platform** – Lab based or rapid
- **Method** – Enzyme Immunoassay (EIA)
- **Detection** – IgG, IgM
- **Window period** ~ 21 days



HIV Western Blot

- **Platform** – Lab based
- **Method** – Colorimetric Immunoblot
- **Detection** – IgG
- **Window period** ~ 35 days



FUTURE – NEW HIV DIAGNOSTICS AND THE UPDATED ALGORITHM

- 4th generation HIV diagnostics
- HIV-1/2 differentiation assays
- HIV viral load assays

4th Generation HIV Immunoassays

- **Platform** – Lab-based or rapid
- **Method** – Chemiluminescent Microparticle Immunoassay (CMIA)
- **Detection** - IgG, IgM, p24 (HIV antigen)
- **Window period** ~ 14 days



HIV-1/2 Differentiation Assays

- **Platform** – Lab-based (Multi-Spot)
- **Method** – Microparticle Enzyme-Linked Colorimetric Immunoassay
- **Detection** – HIV-1 gp41 (antigen), HIV-2 gp36 (antigen)
- **Window period** ~ 28 days

HIV-1 Viral Load Assays

- **Platform** – Lab-based
- **Method** – Real-time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)
- **Detection** – HIV-1 RNA



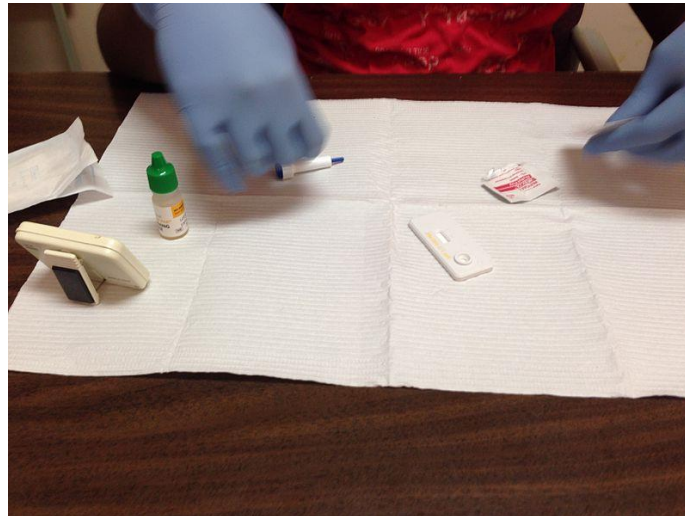
HIV-1 Viral Load Assays

- **Pooling** – similar to protocols used for blood bank testing
- **10 serum specimens** – mixed and tested together, tested individuals if pool is positive
- **Cost-effectiveness** – viral load testing is very expensive, positive are very rare



Rapid (point of care) HIV Assays

- Thomas Knoble: [Rolling out Determine™ 4th Gen HIV Rapid Test in the Community](#)
- August 13 @ 11:00 am - 12:30 pm



Clinical Laboratory Improvement Amendments

- Regulates all human diagnostic testing in the U.S.
- **Waived**
 - Rapid HIV tests
- **Moderate complexity**
 - MultiSpot, Architect 4th Gen.
- **High complexity**
 - Viral Load – not approved for diagnostic use, pooled testing validated at SF PHL.

Updated HIV Algorithm

- Why make the change?
 - Better tests
 - MultiSpot is more sensitive and easier than Western Blot
 - Faster results
 - MultiSpot is faster than Western Blot
 - Lower cost
 - Multispot is cheaper than Western Blot
 - More information
 - MultiSpot differentiates between HIV-1 and HIV-2
 - PSA: these statements all have caveats

CASE STUDY – SAN FRANCISCO'S HIV TESTING PROGRAM

What makes SF unique?

- High incidence of acute HIV cases
- Intensive public health outreach and surveillance
- High-complexity laboratory resources available
- These reasons make pooled-viral load screening a viable option

Rapid test positive, indeterminate or no rapid test done

3rd/4th Gen. HIV Rapid Test
(Stat-Pak)



4th Gen. HIV Immunoassay
(Architect)



HIV-1/2 Differentiation
Immunoassay (Multi-Spot)

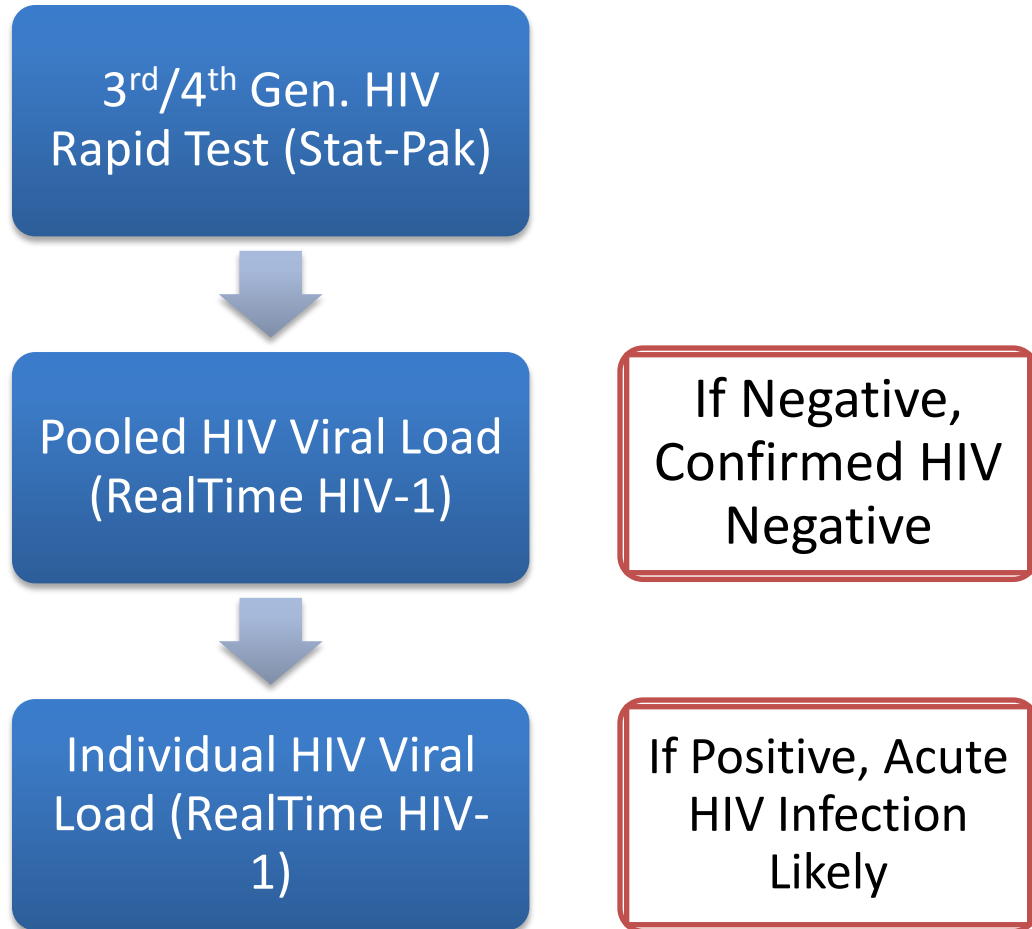
If Positive, Confirmed
HIV Positive



Individual HIV Viral Load
(RealTime HIV-1)

If Negative, False
Positive Immunoassay
Likely

Rapid test negative



Additional complexities to consider...

- Orthogonal rapid tests
 - Two rapid tests using different methodologies
- Rapid test expansion
 - Many new rapid tests coming on market, many CE certified.
- Rapid test vs. lab-based test barrier falling
- CDC guidance still in draft format (2012)
- Viral load screening is the future
- POC testing is the future

Thank you!

Please sign up for office hours!

I-on-I Q&A on 4th Generation Lab Testing

May 28 @ 10:00 am - 1:00 pm

Some ways you can use office hour time

- Discuss options of increasing detection of early HIV cases
- Talk with Severin about lab testing regulations and how they affect implementation
- Look at options for making acute screening cost effective
- Get insider knowledge on what labs care about and how to talk to your lab—a lab primer for non-lab rats!