

# Rolling out Determine™ 4th Gen HIV Rapid Test in the Community

Thomas Knoble

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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.

# Webinar Tips

- Please do not put the phone line on HOLD during the webinar
- Please be sure your audio preference is selected – PC/Phone
- Please feel free to type comments/questions into the chat box
- Q&A – Raise your hand and we will call on folks individual



- @getSFcba
- #TestTalkSF

# 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** – Stephanie Cohen
- **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](http://www.getSFcba.org)

Email: [get.SFcba@sfdph.org](mailto:get.SFcba@sfdph.org)

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# Rolling out Determine™ 4th Gen HIV Rapid Test in the Community



## Thomas Knoble

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

# Overview

- Introduction
- Why we were looking to change
- Overview of Determine™ Combo
- The San Francisco experience
- Issues and how we addressed them
- Moving forward

# Disclosure

## Nothing to Disclose

We are not even allowed to have Reps buy us a cup of coffee

We have been in communication  
with Sales Reps from different technologies

# Reason We are Here

- Help think through if Determine™ is right for you
- Talk about issues and how to address them
- Providing technical assistance, sharing training materials, policies and procedures, and quality assurance plans



# My Professional Background

- Trainer
- Phlebotomist
- Social Worker, MSW
- Have not worked in a lab
- Test counselor for 22 years
- Work closely with HIV testing sites
- Worked in CBOs, STD clinic, jails etc.
- Oversee HIV testing in community-based settings



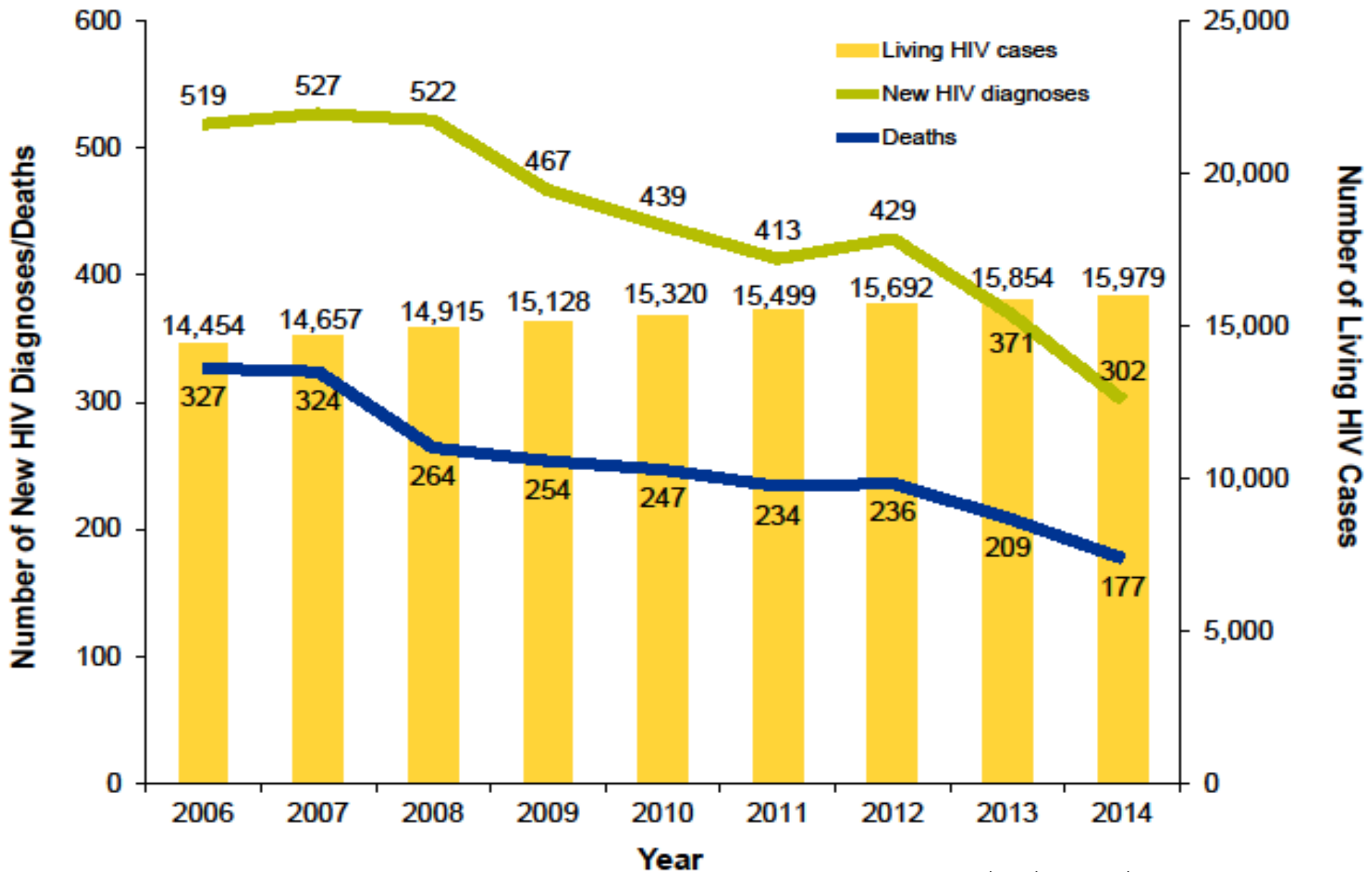
# My Personal Background

- Mixed race
  - German, Mexican
- From Sacramento
- SF since 1989
- Gay man
- Very dyslexic
- C student





# New HIV Diagnoses, Deaths, and Prevalence San Francisco 2014



# Our Keys to Success

- Increase testing from 15,000 to 25,000
- Focus on gay/bi men, MSM, transgender women and intravenous drug users
- Treatment as prevention
- Community Planning
- Harm reduction
- Sex positive
- Acute testing



PrEP is looking good as well

# Overview to the Determine™ Combo Rapid Test

- Visual interpretation
- Uses blood finger stick
- Looks for HIV antibodies and HIV p 24 antigen
- Results between 20 and 30 minutes



# Basic Materials

Chase  
Buffer

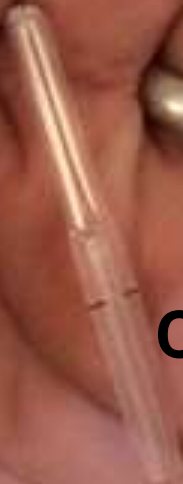


Workstation



Test Devices (card)

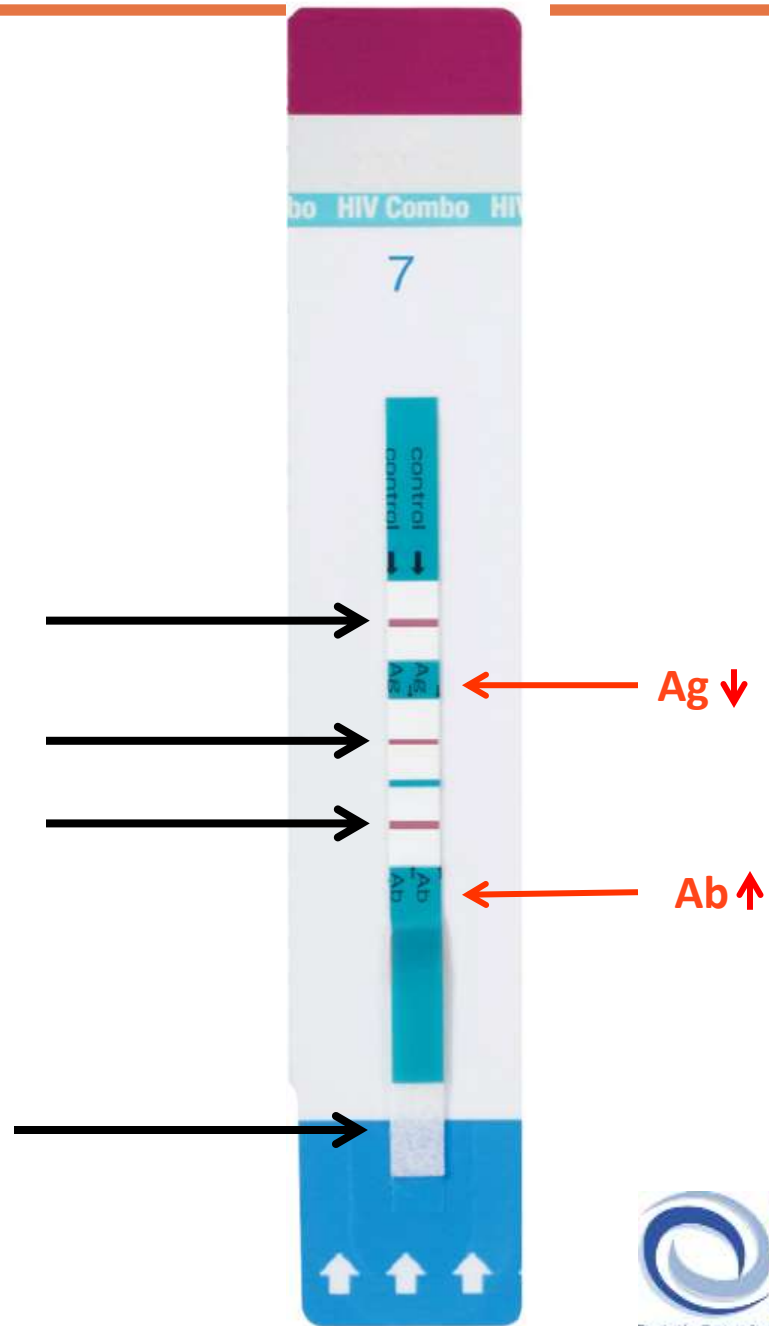
Capillary  
Tube



# Test Device

- Control area
- Antigen Ag area
- Antibody Ab area

Sample pad



# Specificity - Fingerstick

Study Population	Total Samples Tested	True Negative <sup>1</sup>	Alere Determine™ HIV-1/2 Ag/Ab Combo Nonreactive
Total	1361	1337	1335 – 99.8%

Table 14, page 17 of package insert

# Sensitivity - Fingerstick

True status	Alere Determine™ HIV-1/2 Ag/Ab Combo		
	Reactive	Nonreactive	Total
Positive	929 = 99.9% sensitivity	1 (false negative)	930 true positives

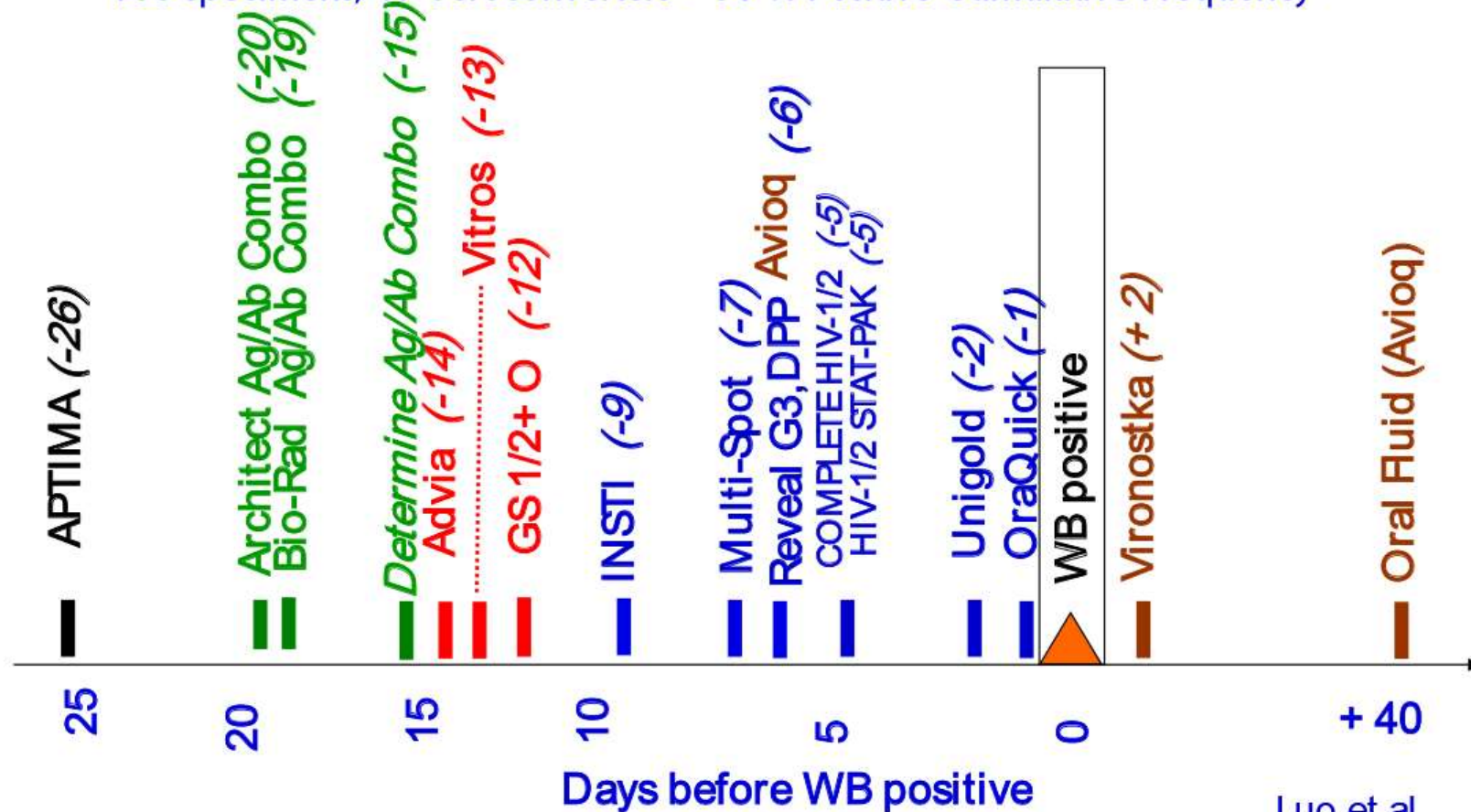
Table 9 page 14 of package insert

# Early Detection

“CDC studies compared all FDA-approved tests on the same plasma specimens collected from persons during seroconversion, and found that Determine Combo detects infection one to two weeks before other rapid tests, and one to three days before third-generation laboratory HIV antibody tests, but three to four days after fourth-generation laboratory antigen/antibody HIV tests.”

# Sequence of Test Positivity Relative to WB (plasma)

166 specimens, 17 Seroconverters - 50 % Positive Cumulative Frequency



Modified from *Masciotra et al, J Clin Virol 2011, 2013*  
and *Owen et al, J Clin Micro 2008*

Luo et al,  
J Clin Virol  
2013

Note: Not whole blood



# Determine™

- Likely decrease window by 10 to 15 days
  - We are saying 30 day from exposure
- We are estimating it will pick up 50 to 80 percent of acute HIV infections

SF will continue to run lab based pooled RNA viral load after negative point of care test

# Lab Folks Say

**“Always start with your most sensitive test”**



# Test Prices\*

▪ Determine™	\$10.00	4 <sup>th</sup> Gen
▪ OraQuick™	\$10.00	2 <sup>nd</sup> Gen
▪ INSTIs™	\$9.99	2 <sup>nd</sup> Gen
▪ Complete™	\$9.00	2 <sup>nd</sup> Gen
▪ ChemBio™	\$8.50	2 <sup>nd</sup> Gen
▪ UniGold™	\$8.00	3 <sup>rd</sup> Gen
▪ Stat-Pak™	\$5.00	2 <sup>nd</sup> Gen

**OraQuick HCV \$18.25**

**OraSure Home Test \$39.99 2<sup>nd</sup> Gen**

**\*Prices for SFDPH**

# How to Define Generation

Different Generations, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> generation, look for different proteins and have different window periods

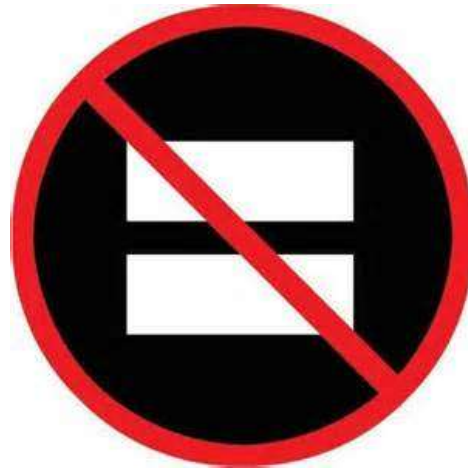


wiseGEEK



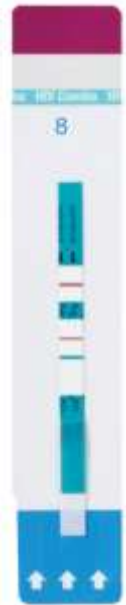
Thank you Bernie Branson

# Lab 4<sup>th</sup> Gen vs. Rapid 4<sup>th</sup> Gen



# The Platform

- Impacts how well it works
- Most are lateral flow



# What We Look for in a Test

- |               |     |                 |
|---------------|-----|-----------------|
| ▪ Easy of use | 40% | For better QA   |
| ▪ Sensitivity | 40% | Acutes          |
| ▪ Specificity | 10% | False Positives |
| ▪ Price       | 10% | Save            |



# When to Use (Acute) Rapid Tests

- With high risk groups that test often
  - 1% or higher positivity, (1 out of 100)
  - Testing every 3 to 6 months
- Non clinical settings, reaching high risk groups
  - Syringe exchanges, community base organizations, gay men's collectives, transgender services, street fairs





# Should You Go To a New Test?

- How big is your gap
  - Are you currently using 2<sup>nd</sup> gen oral fluid or individual vial load?
- What is the skill level at sites?
  - Is your site ready for a more complex test?
- How much undiagnosed HIV are you finding ?



# Roll Out Structure

Piloting with 2 sites (we have 12 county-wide)

- Confidential and anonymous testing
- CBOs, mobile, street fairs
- Offer other screenings (Hep C and Syphilis)



**FREE**  
**HIV Test**

**15-502-TEST(8378)**

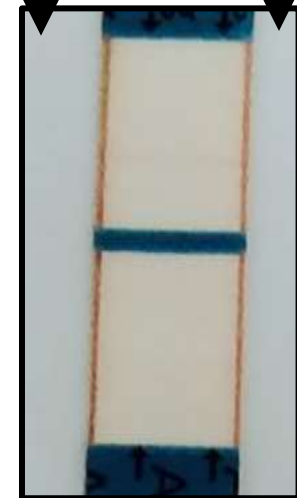


# Current Progress

- To date: approximately 800 tests (June 2015)
- 3 true antibody positives
- 3 false positives
  - 2 antigen only, 1 antibody only

# False Positive (1 of 3)

- Within first 20 tests
- Line was very faint
- No red/pink coloring
- Site took picture



# False Positive (2 of 3)

After result was given, client disclosed she often has false antibody positives due to participating in vaccine trial



# False Positive (3 of 3)

Site reported, “Antigen line was present from 20 to 30 minutes but disappeared about 30 minutes later”

After talking with staff, I believe it was the issues you see in picture



This picture is from the package insert

# Our “Investigation”

- What are the odds we hit false positive in the first 20 tests?
- We suspect test was not read correctly
- We used known negative blood on 25 tests
- Learned a few things





# 1<sup>st</sup> Thing We Learned

- Old Training Message
  - “A line is a line is a line”
- New Training Message
  - “A line has to be **red/pink**”



# 2<sup>nd</sup> Thing We Learned

## Watch Pot Effect

- The process of over studying a test by watching it develop
- More likely to “over read”
- Happens when something is new



We used to have a lot of false positives



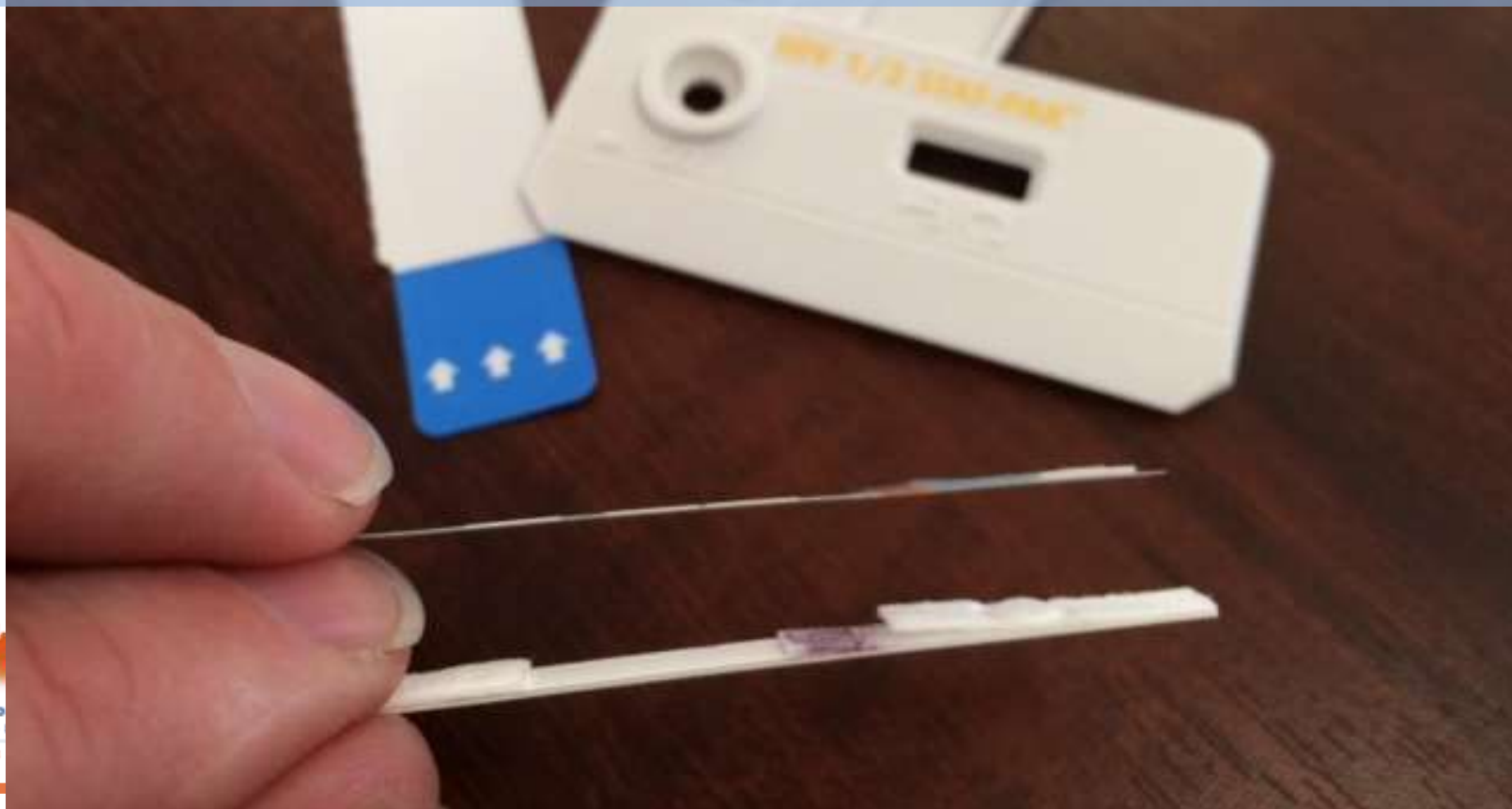
# Flash back to 2003/4

- False positive were happening, for years
- 2007/8 SF had 52 false positive out of 13,134 (4%)
- In 2014 less than 10 out of 25,000



# Dam”b” Issues

- Determine™ product is thin
- Fluid build up around the lines acting like a dam. Therefore... you must look for true color in lines



# Remember All Negatives !!

- Shorter window period

## Case Study:

Client # 3: Woman, 40s, found out 30 days ago husband was shooting drug and having sex with others.

**MUST** keep in mind mental health needs

# Issues and how we addressed them

## Anticipated

- Updating quality assurance plans
- Training on more blood, reading two lines, no buffer with controls, using pipettes
- Change is hard on people

## Not Anticipated

- False positives
- Other sales reps

# Training, Technical Assistance Products

- 4 Day Training
  - ✓ Counseling 2 to 3 days
  - ✓ Rapid Test 2 to 4 hours
  - ✓ Finger stick 2 to 4 hours
- Policies and Operations, QA Plans





# Things we trained on



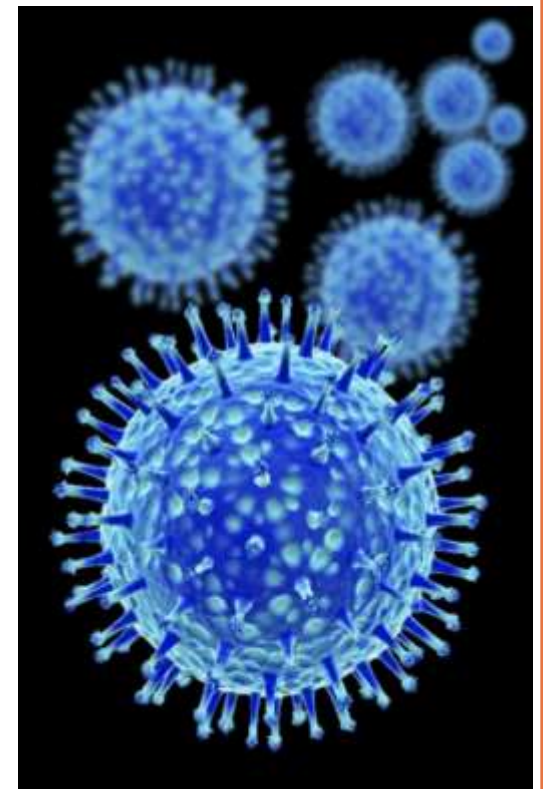
**Virus** - a small infectious agent that replicates inside cells  
(detected about 10 to 14 days)

## **Antigen - Ag**

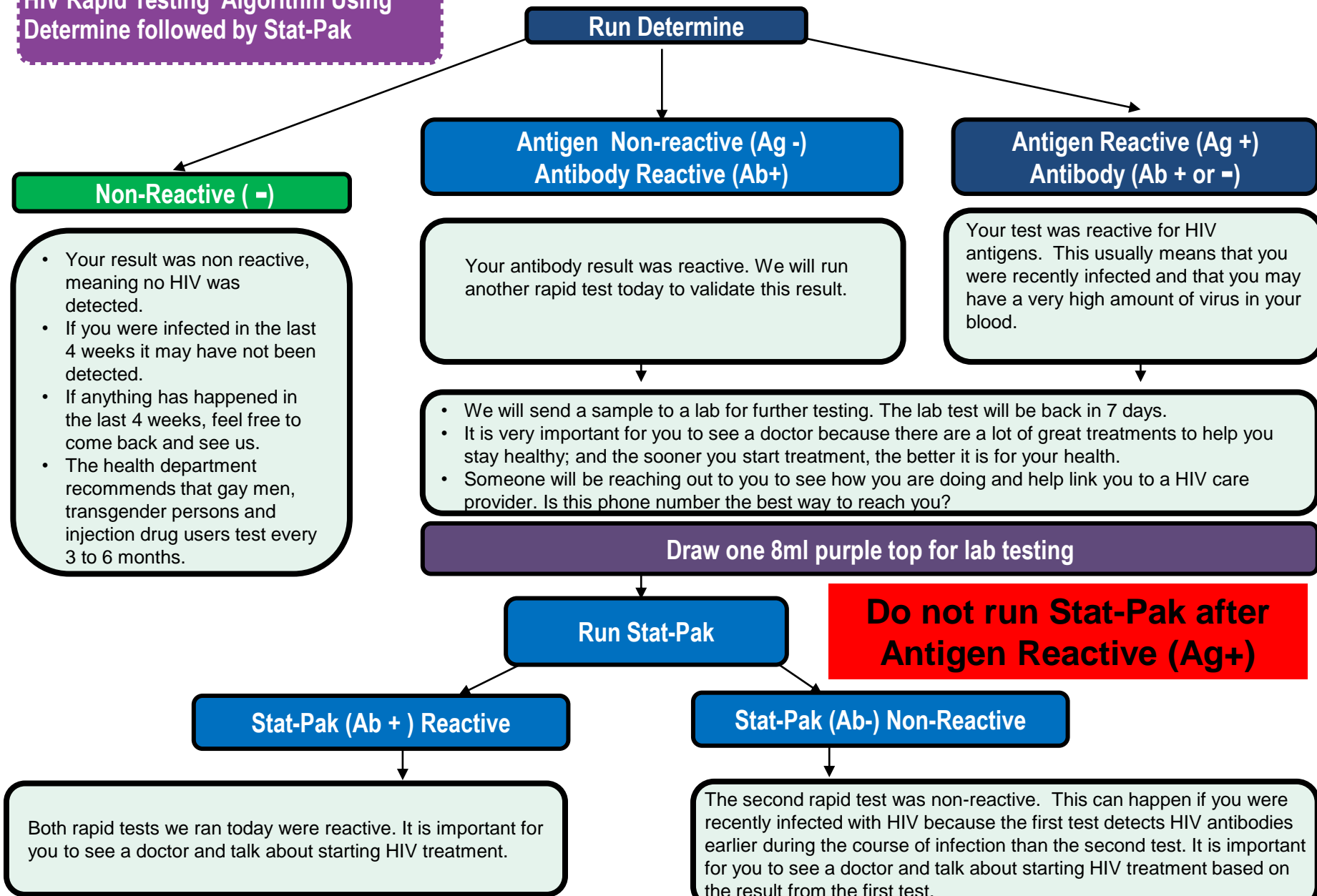
a pathogen or parts of a pathogen (virus, bacteria, fungi and parasites) that causes the body to produce antibodies  
(detected between 2 and 4 weeks)

## **Antibody - Ab**

a Y-shaped protein created by your body in response to antigens  
(most by 3 months, up to 6 months to be produced)



# HIV Rapid Testing Algorithm Using Determine followed by Stat-Pak



# Must Have...

## Good eye sight



## Steady hand



## Adequate lighting

- Full/bright light, task light
- Do not use a flash light



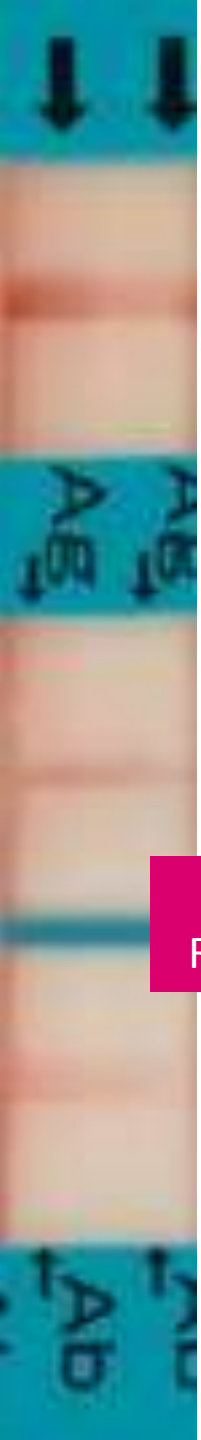
## Organizational skills



# Reading Results



Non  
Reactive



Ab/Ag  
Reactive



Ag  
Reactive



Ab  
Reactive

# Collecting the Blood Sample

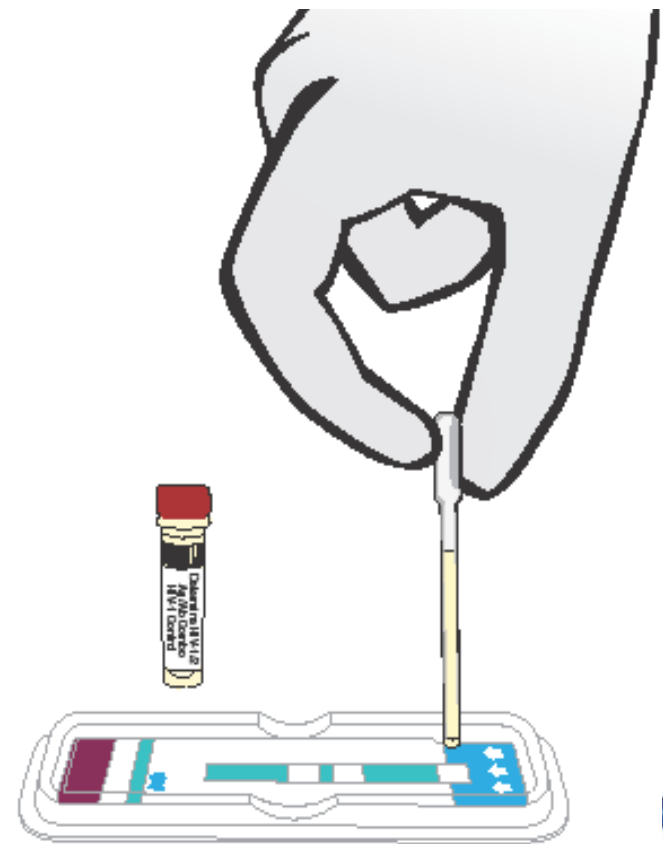
## Capillary Tube

- Milk the finger to produce the second drop of blood
- Touch capillary tube to the drop of blood AND finger at the puncture site and continue milking the finger
- Do not lift capillary tube from the site until it has collected the required volume of blood



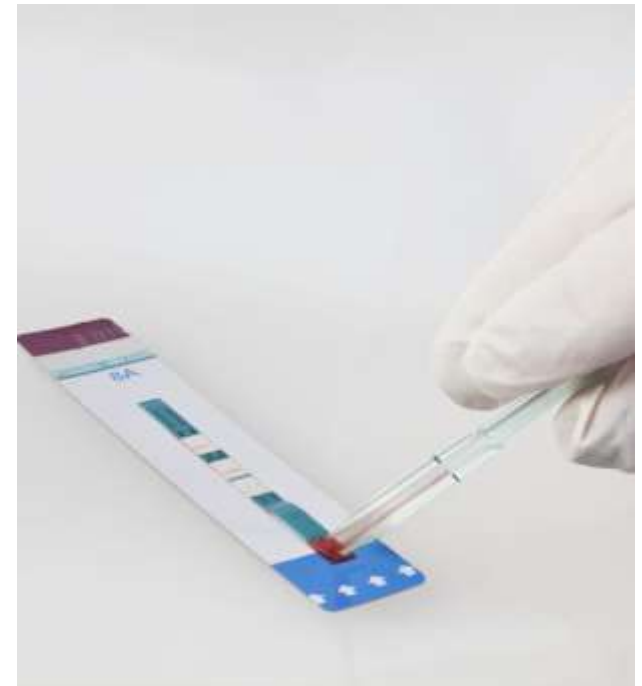
# Full Hydration with Controls

When running control you need to apply a little extra pressure to the pipette bulb



# Dispensing Sample

- Do not invert capillary tube or sample will flow into the bulb area
- Touch end of capillary tube to sample pad so pad can absorb the sample
- Do not lift capillary tube from sample pad until entire sample is dispensed
- If sample does not flow onto sample pad, cover small hole on capillary tube with gloved finger and squeeze bulb slowly as sample is absorbed
- Dispose of capillary tube





# Sales Reps

## Challenge

- “Our test is more sensitive than Determine”
- “Here is a paper showing it did not work”
- They all say the “test is easy to use”
  - but with 25,000
  - Run by 200 different users
  - In various locations, (on a van)
- “It’s a 2nd gen that acts like a 4<sup>th</sup>”
- Confusing our sites



# How We Address Sales Reps

- Meet with all of them (be polite)
  - Took no free tests from any one
  - Ask lab experts: “Always use most sensitive first”
  - Piloting, move slowly
- 
- Then ask people who are not trying to sell you something

# PrEP... Good Thing!!

# Challenge

- Game changer for High Impact Prevention
- Has a real opportunity to get us to zero new infections!!
- But has taken energy to roll out two highly effective interventions

# Tips



- Start slow
- Talk to stake holders
- Ask for help from us, willing to share QA documents, best practices, training, anything we have

# Start Up Checklist

Talk with...

- Counselor: pros and cons ?
- Clients: pros and cons ?
- Lab staff: which test ?
- Data people: how to record AG result ?
- Surveillance: is an antigen reportable ?
- Partner services: what to do if acute ?
- Clinic staff: what is window period ?

# We Still Have Questions

- Will we be able to run from venipuncture sample in the near future?
- Is the antigen sensitivity really high?
  - Client who was acutely infected with high viral load but was Determine negative
- Should we use a second test for onsite confirmation (two test algorithm)

# Future

- Tests with shorter window periods
- Test that are read by machines, removing human error as much as possible
- In a few months reporting in back with webinar

# National Leaders

- Gene Martin in New Jersey
- John Murphy in New Mexico
- Caitlin Wells in Colorado
- ????





# All Rapid Tests Have a Place



- Darpun Sachdev, MD
- Jose Luis Guzman
- Stephanie Cohen, MD
- Tracey Packer
- John Melichar
- Mehroz Baig
- Asian & Pacific Islander Wellness Center
  - Nate Cedilla
- Alliance Health Project,
- Perry Rhodes III
- California DPH Office of AIDS Staff
  - Karin Hill
  - Matthew Willis
  - Amy Kyle-Puente

# Thank You



**THANK YOU to  
Our Community!!!**

# How Can We Help!

- There a lot of things required to make it happen, but it is doable
- Your effort will stop the spread of HIV

So...THANK YOU!!!



What if today, we were just grateful for everything?

**PN**  
THE CAPACITY  
NATION'S HIV  
ON WORKFORCE

# More on Determine™

- Office Hours: 8.27.15
  - 30 min sessions for health departments to have your questions answered by me!
  - Sign up at [www.getsfcba.org/events](http://www.getsfcba.org/events)

# More on Determine™

- Supporting Clients in a Dynamic Era of HIV Treatment
  - A four-week, free e-course!
  - August 10, 2015 - September 4, 2015
  - I will talk about Determine on 8/18/15
  - Sign up here:  
<https://apiwellness.course.tc/account/login>

# Audience Q&A

