AETC AIDS Education & Training Center Program Southeast

NCHTEC North Carolina HIV Training & Education Center at the UNC School of Medicine

HIV Testing in Primary Care

LeShonda Wallace, PhD, FNP-BC, RN
Novant Health Infectious Disease Specialists

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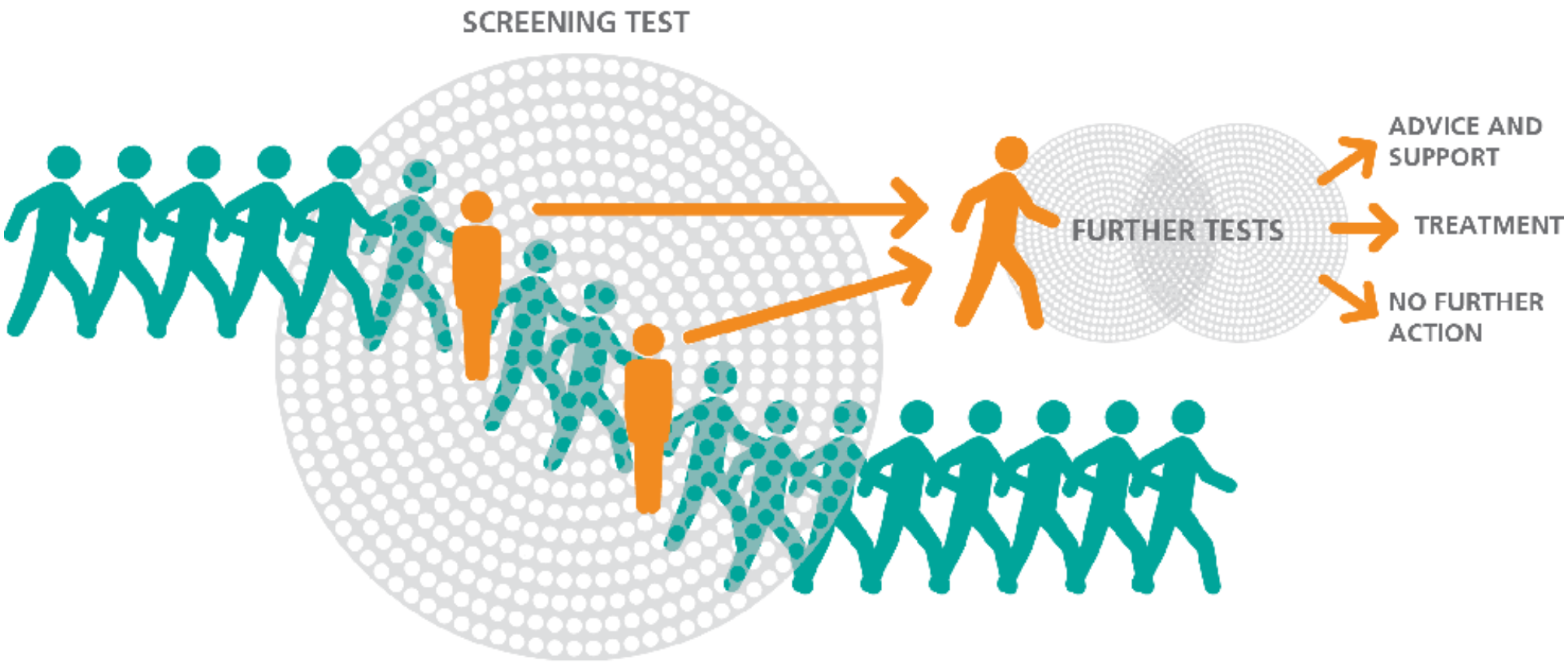
for

NORTH CAROLINA
NCCHCA
Serving Community & Migrant Health Centers
Community Health Center Association

Objectives

- Explain the difference between point-of-care (rapid) and lab-based tests for HIV screening.
- Define “preliminary positive” in the context of point-of-care (rapid) HIV testing.
- Outline an approach for disclosing test results in a structured, sensitive, and informative way.

HIV testing involves 2 steps: screening & confirmation



https://www.gov.uk/guidance/nhs-population-screening-explained

Who should be tested for HIV?

Screening	**Opt-out testing** All clinical settings (if patient [not pop] prevalence >0.1%) Ages 13-64
Special situations	Starting TB therapy Seeking STI therapy (**every** encounter) Exposures (occupational & non)
Rescreening	**At least annually** if at increased risk • IDU & sex partners • Transactional sex • >1 interim partner

Branson BM, et al. MMWR Recomm Rep. 2006;55(RR-14):1-17 Owens DK, et al. JAMA. 2019 Jun 18;321(23):2326-2336.

Who should be tested for HIV?

	CDC	U.S. Preventive Services TASK FORCE
Screening	**Opt-out testing** All clinical settings (if patient [not pop] prevalence >0.1%) Ages 13-64	Ages 15-65 Younger & older if at increased risk Pregnant women
Special situations	Starting TB therapy Seeking STI therapy (**every** encounter) Exposures (occupational & non)	(silent)
Rescreening	**At least annually** if at increased risk • IDU & sex partners • Transactional sex • >1 interim partner	**At least annually** if at increased risk

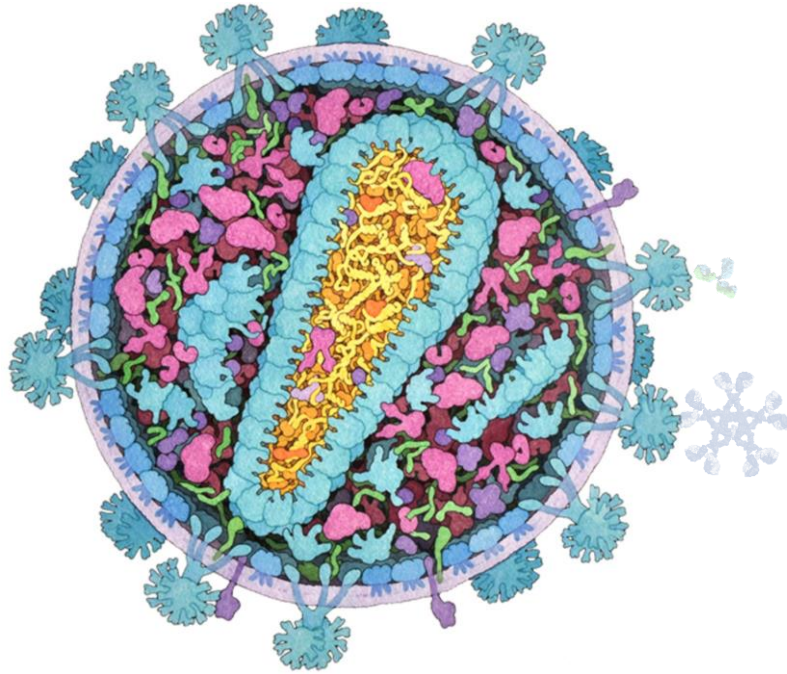
Branson BM, et al. MMWR Recomm Rep. 2006;55(RR-14):1-17 Owens DK, et al. JAMA. 2019 Jun 18;321(23):2326-2336.

Why the shift to routine testing?

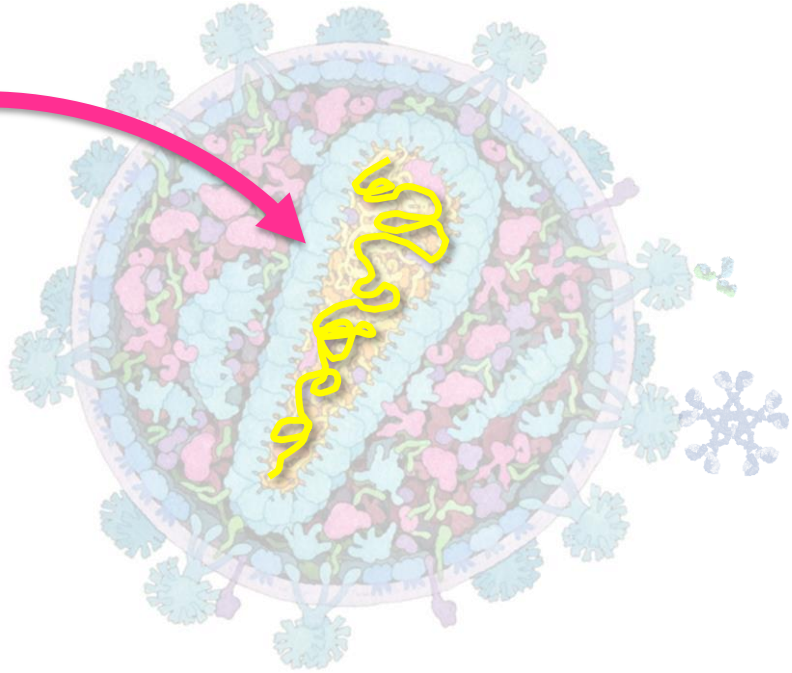
- Risk-based screening was not successful[1]
- Risk assessment is resource-intensive[1]
- Patients do not always disclose their risk – or may not be aware of it in the first place[2]
  - 39% of MSM didn't disclose to their provider[3]
  - 51% of ED-screened patients with positive rapid/POC HIV tests had no identified risk[4]

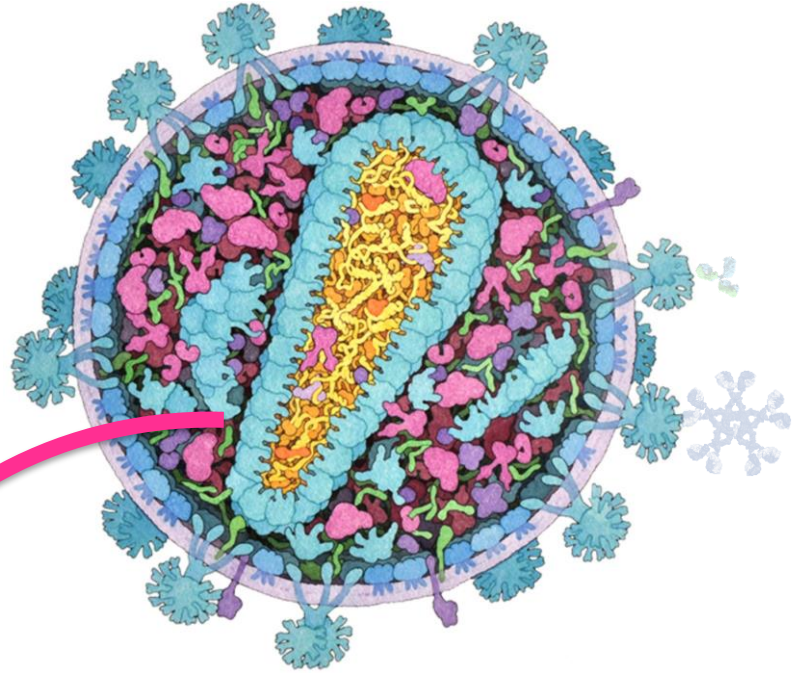
1 Branson BM, et al. MMWR Recomm Rep. 2006;55(RR-14):1-17
2 Chou R, et al. Ann Int Med. 2005;143:55-73
3 Bernstein KT, et al. Arch Int Med. 2008;168(13):1458-1464
4 Lyss SB, et al. JAIDS. 2007;44(4):435-442

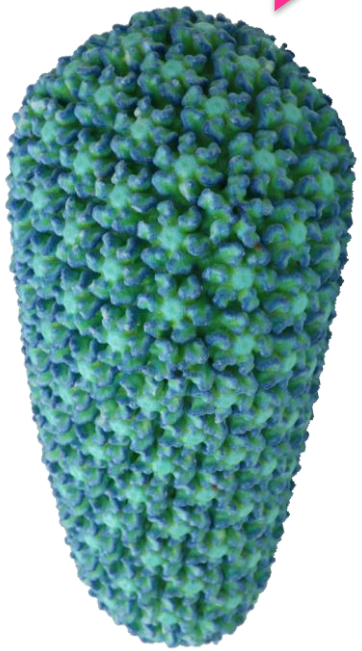

https://palmettocare.org/



HIV RNA







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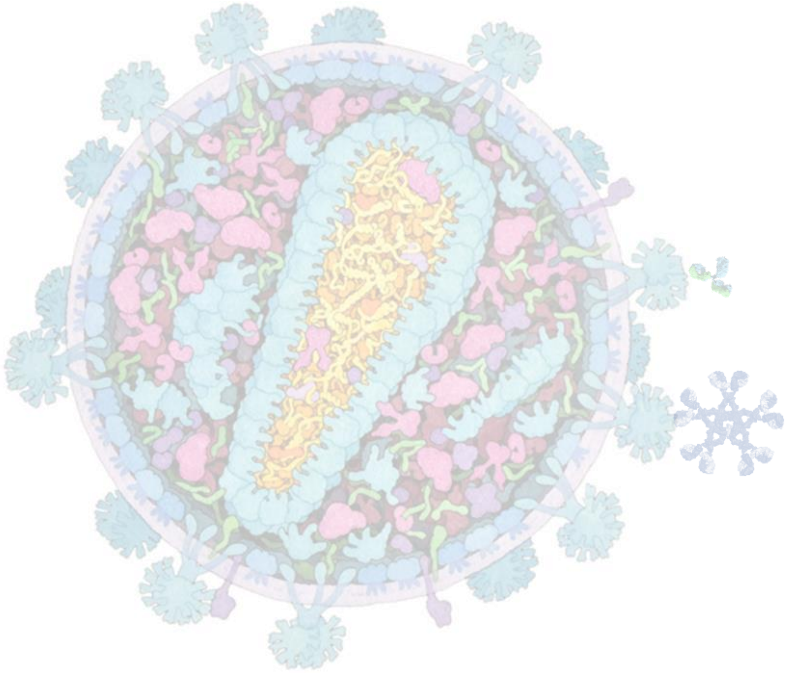
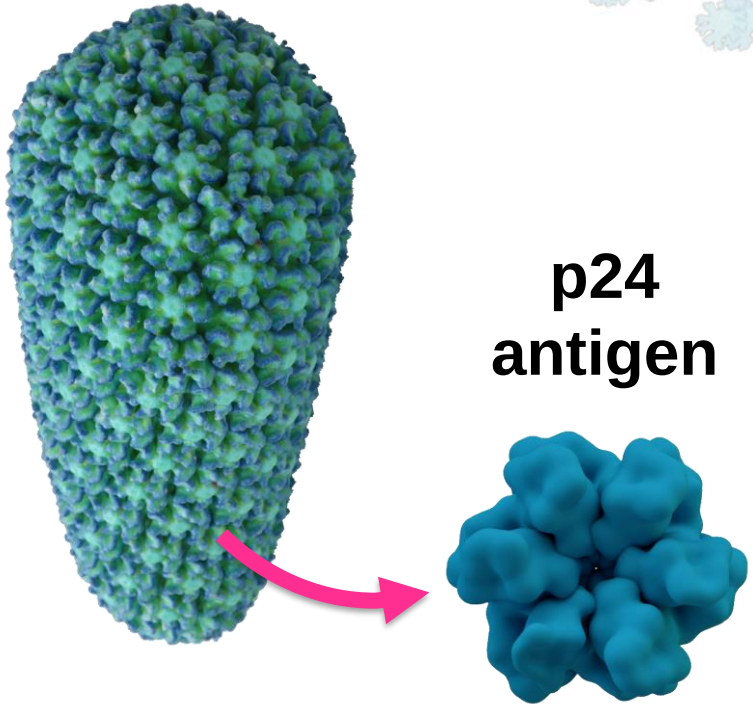
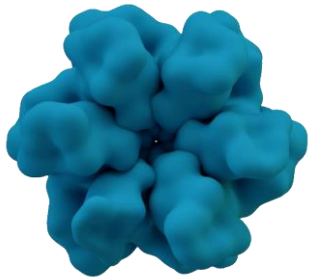
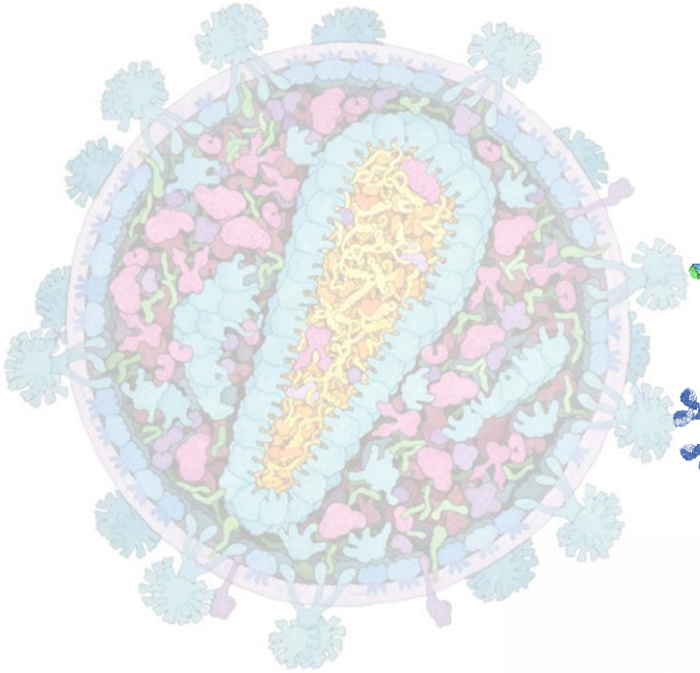


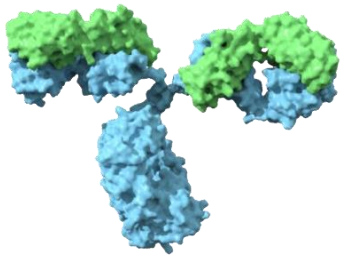


p24 antigen

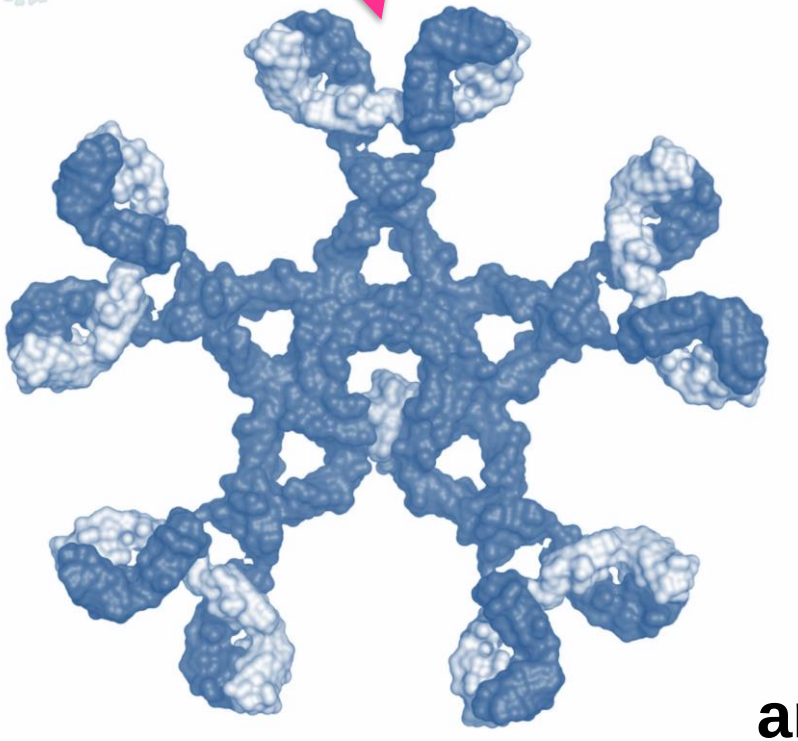
p24
antigen



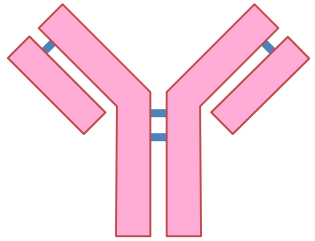




IgG
antibody

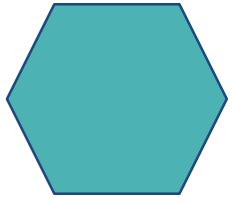


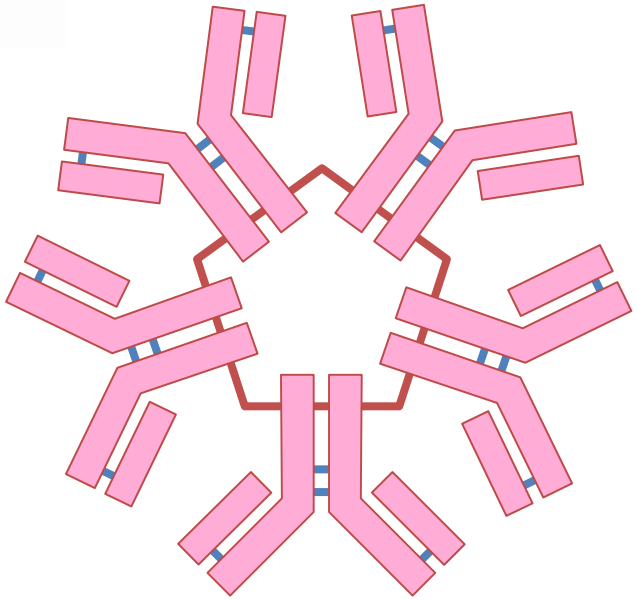
IgM
antibody



IgG
antibody

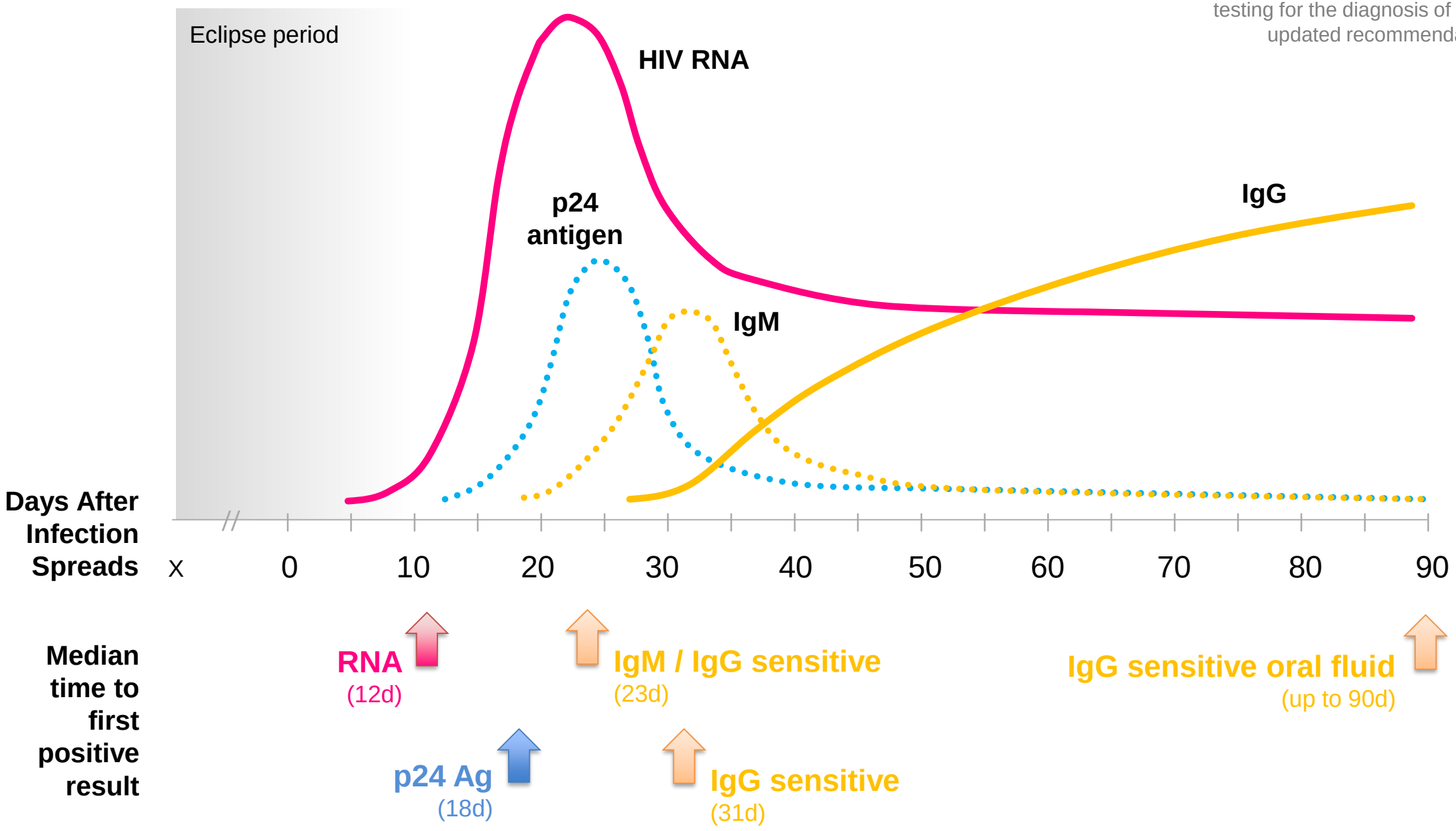
p24
antigen

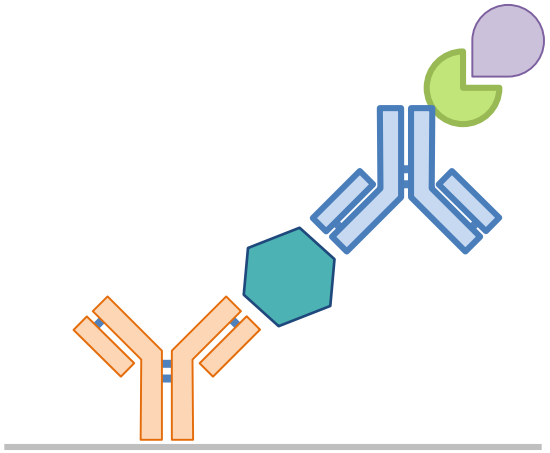




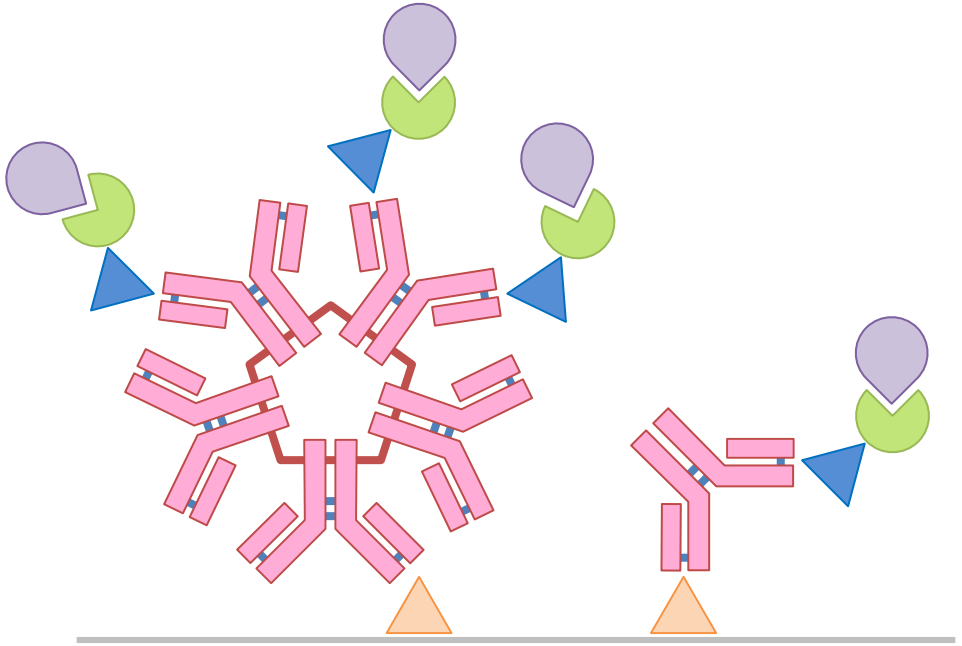
IgM
antibody

Adapted from Branson BM, et al. Laboratory testing for the diagnosis of HIV infection: updated recommendations. (2014)

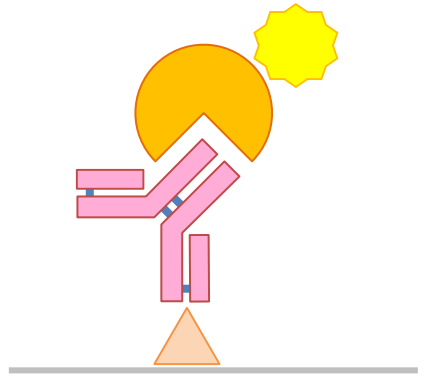




p24 antigen detection
(p24 / IgM / IgG sensitive tests)

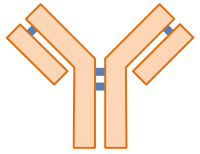


IgM / IgG sensitive

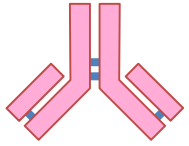


IgG sensitive

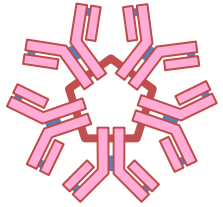
Synthetic or recombinant HIV antigens



Monoclonal anti-p24 antibody



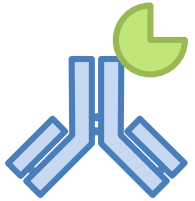
Anti-HIV IgG (from patient)



Anti-HIV IgM (from patient)

Protein A-linked colloidal gold

p24 antigen (from patient)



Enzyme-linked anti-p24 antibody

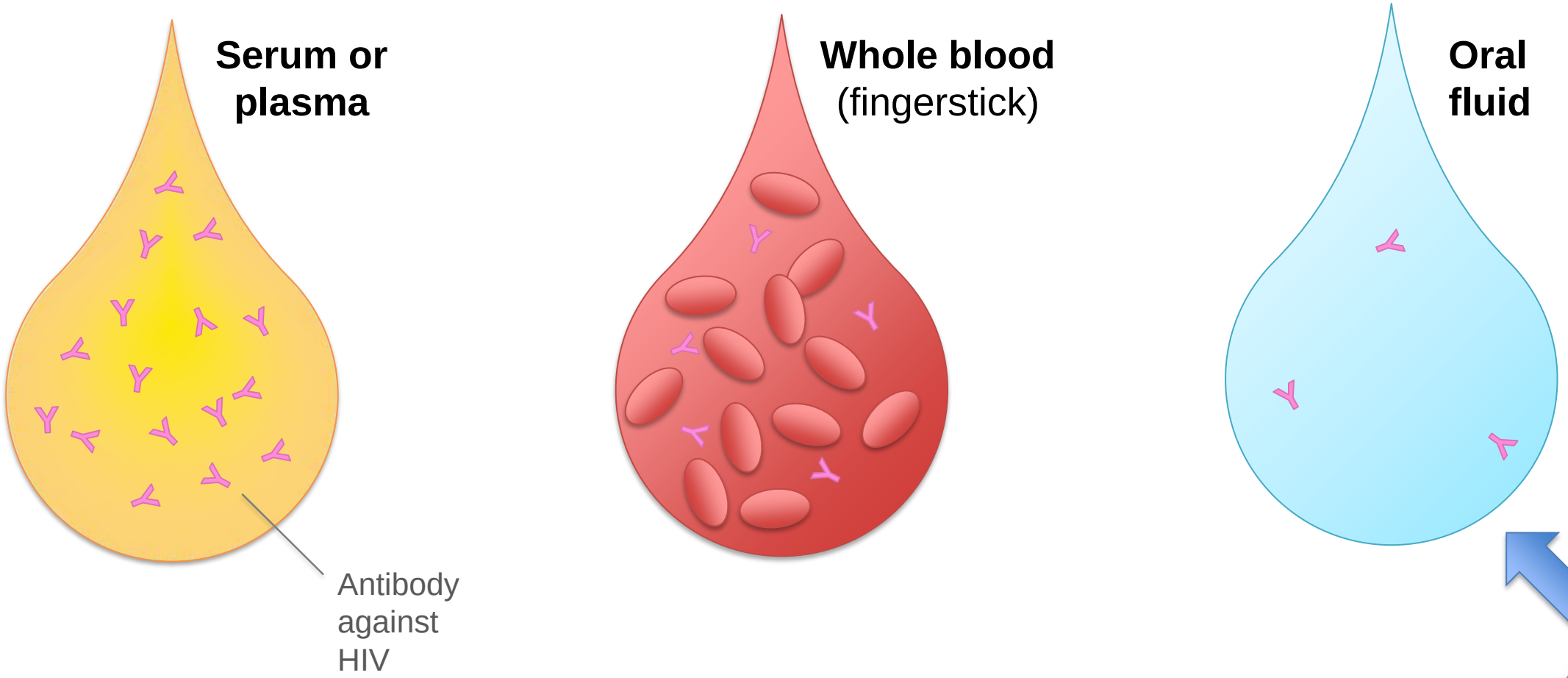
Detection reagent

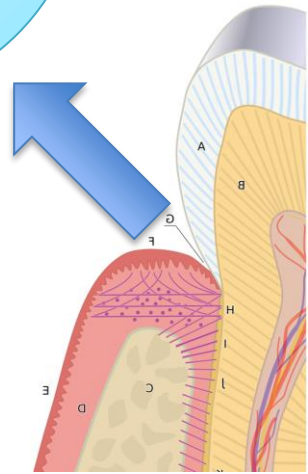
The quantity of the target depends on the specimen

Serum or plasma

Whole blood (fingerstick)

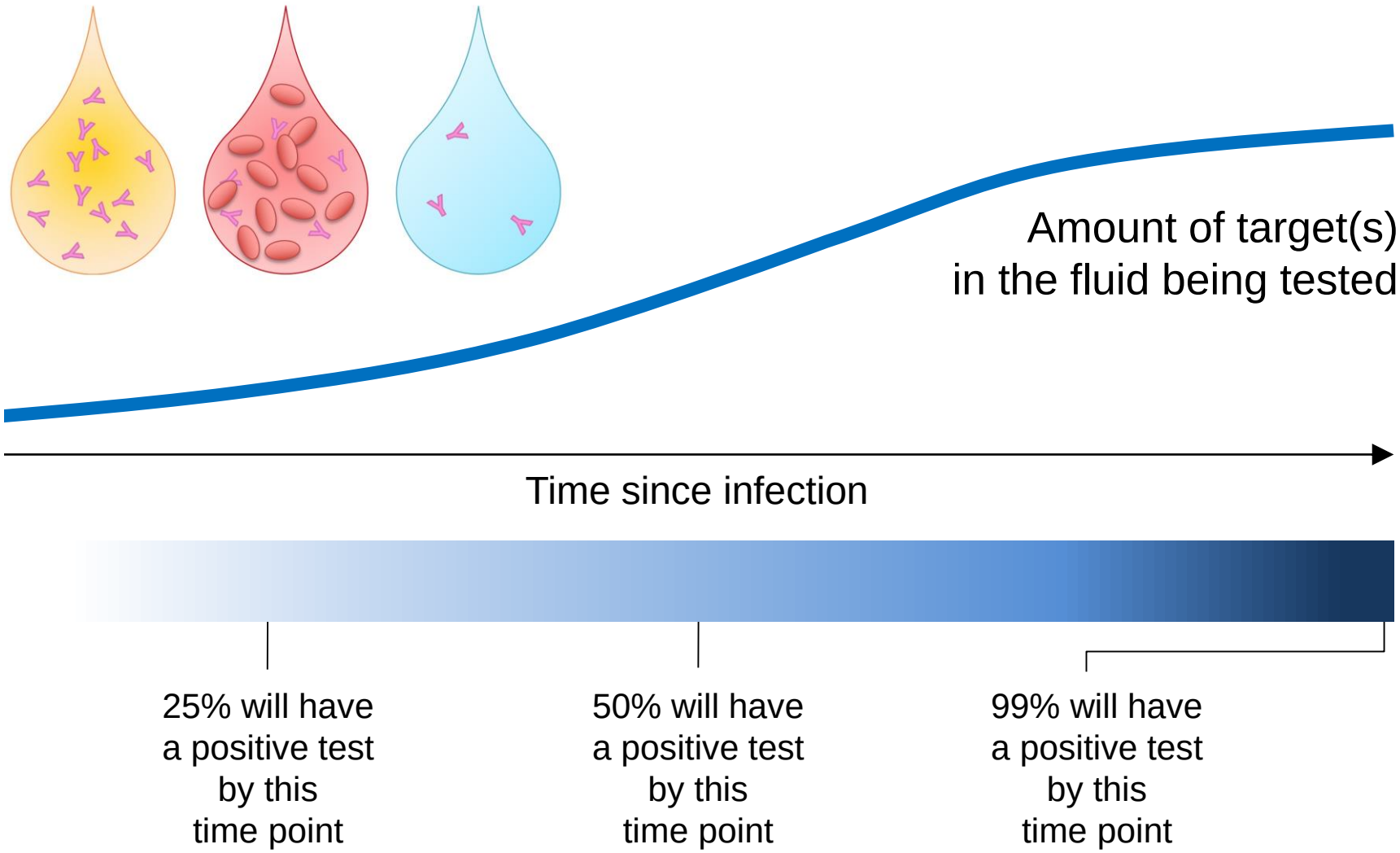
Oral fluid





Hurt CB, et al. Sex Transm Dis. 2017 Dec;44(12):739-746

The window period depends on the test… and time



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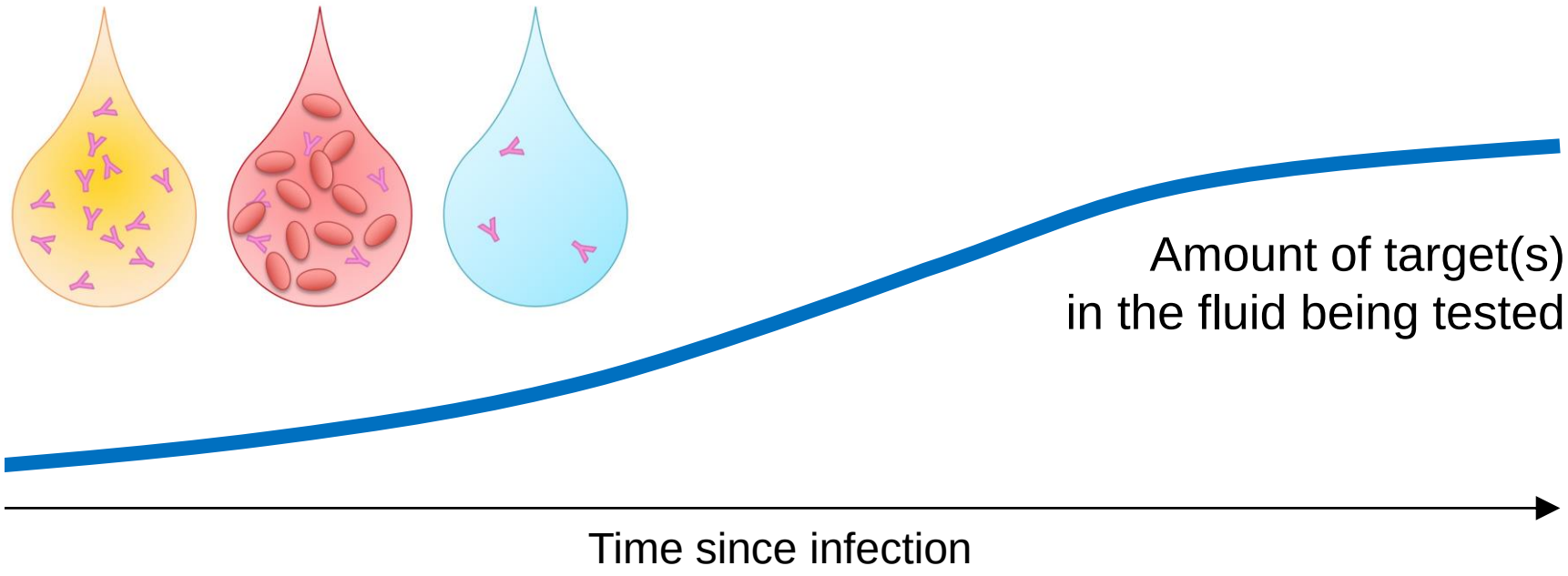

← **Very sensitive -OR- a test that detects an “early” target**

← **Not as sensitive or incapable of detecting an “early” target**

Hurt CB, et al. Sex Transm Dis. 2017 Dec;44(12):739-746

Window periods of HIV tests, by category

Category (No. of Tests Included)		25%* will have a reactive result by day	50%* will have a reactive result by day	75%* will have a reactive result by day	99%* will have a reactive result by day
"4th or 5th gen" (Ag/Ab)	p24/IgM/IgG sensitive laboratory tests (4)†	13.0	**17.8**	23.6	44.3
	p24/IgM/IgG sensitive POC test (1)‡	14.8	**19.2**	24.6	43.1
"3rd gen"	IgM/IgG sensitive laboratory tests (3)§	18.4	**23.1**	28.8	49.5
	IgM/IgG sensitive POC tests (2)‖	24.2	**29.3**	35.3	57.4
"2nd gen"	IgG sensitive laboratory test (1)¶	26.5	**30.6**	35.9	54.1
	IgG sensitive POC tests (5)**	26.7	**31.8**	37.8	57.8
	IgG sensitive supplemental tests (1)††	28.2	**32.9**	38.6	57.7
"1st gen"	Western blot (1)‡‡	31.0	**36.5**	43.2	64.8

Hurt CB, *et al*. *Sex Transm Dis* 2017;44(12):739-746
Adapted from Delaney KP, et al. *Clin Inf Dis* 2017;64(1):53-9

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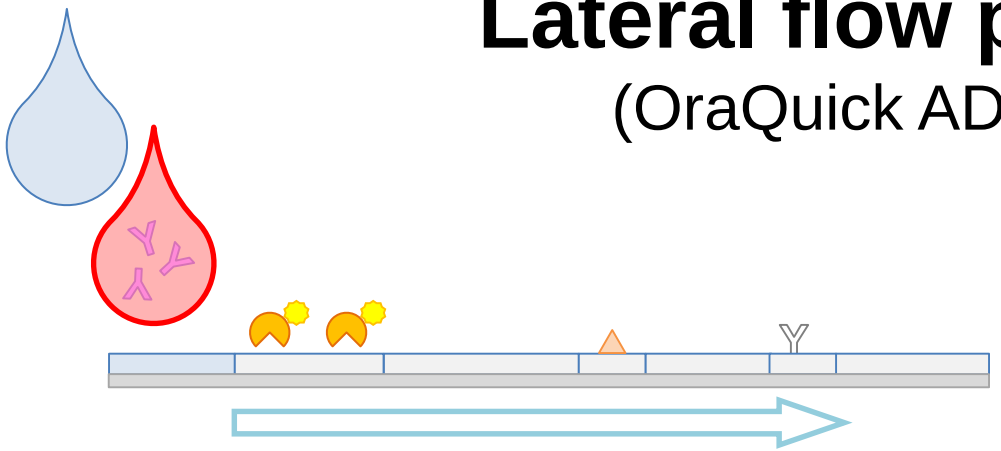
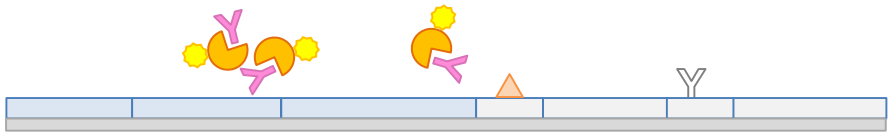
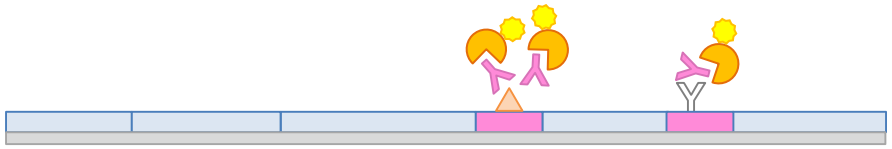
Lateral flow point-of-care rapid tests

(OraQuick ADVANCE **IgM / IgG**, ChemBio IgG)







Test Control

Immobilized anti-human antibody

Protein A-linked colloidal gold

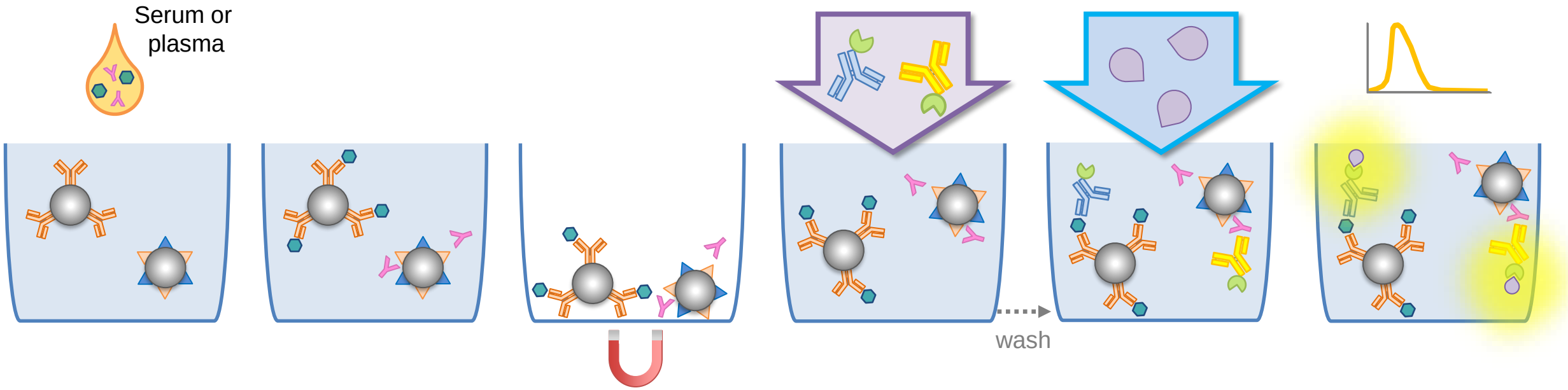
Synthetic or recombinant HIV antigens

Anti-HIV antibody (from patient)

https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf

Lab-based, automated test platform

(Chemiluminescent microparticle immunoassay p24 / IgM / IgG)



Synthetic or HIV-1 and HIV-2 antigens bound to magnetic bead

Monoclonal anti-p24 antibody bound to magnetic bead

Anti-HIV IgG (from patient)

p24 antigen (from patient)

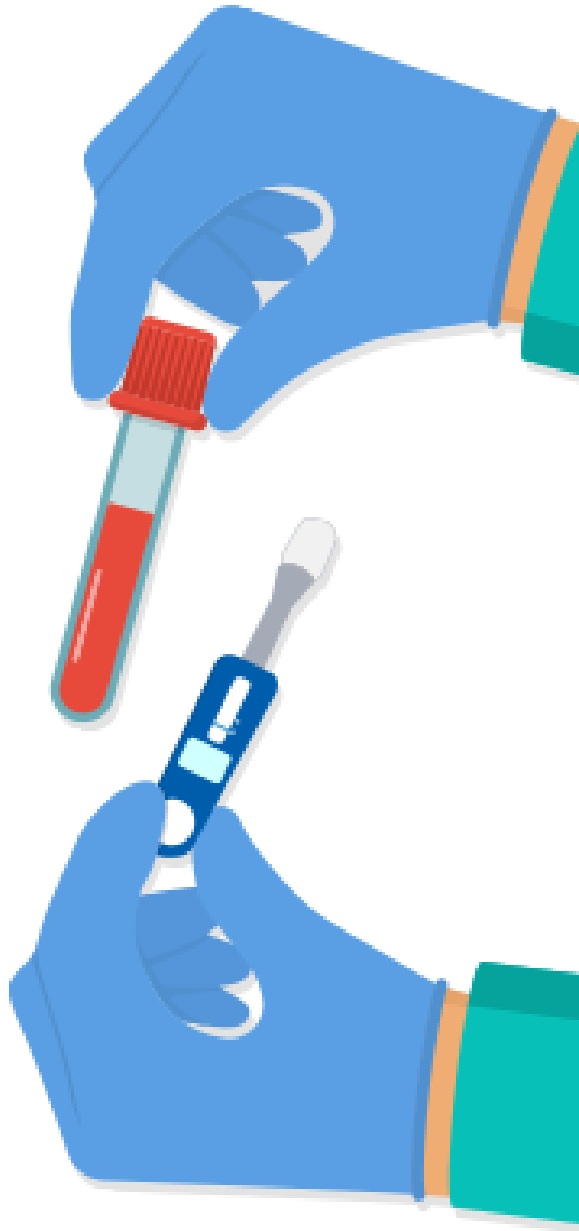
Anti-IgM or anti-IgG antibody linked to luminescent molecule

Anti-p24 antibody linked to luminescent molecule

Detection reagent

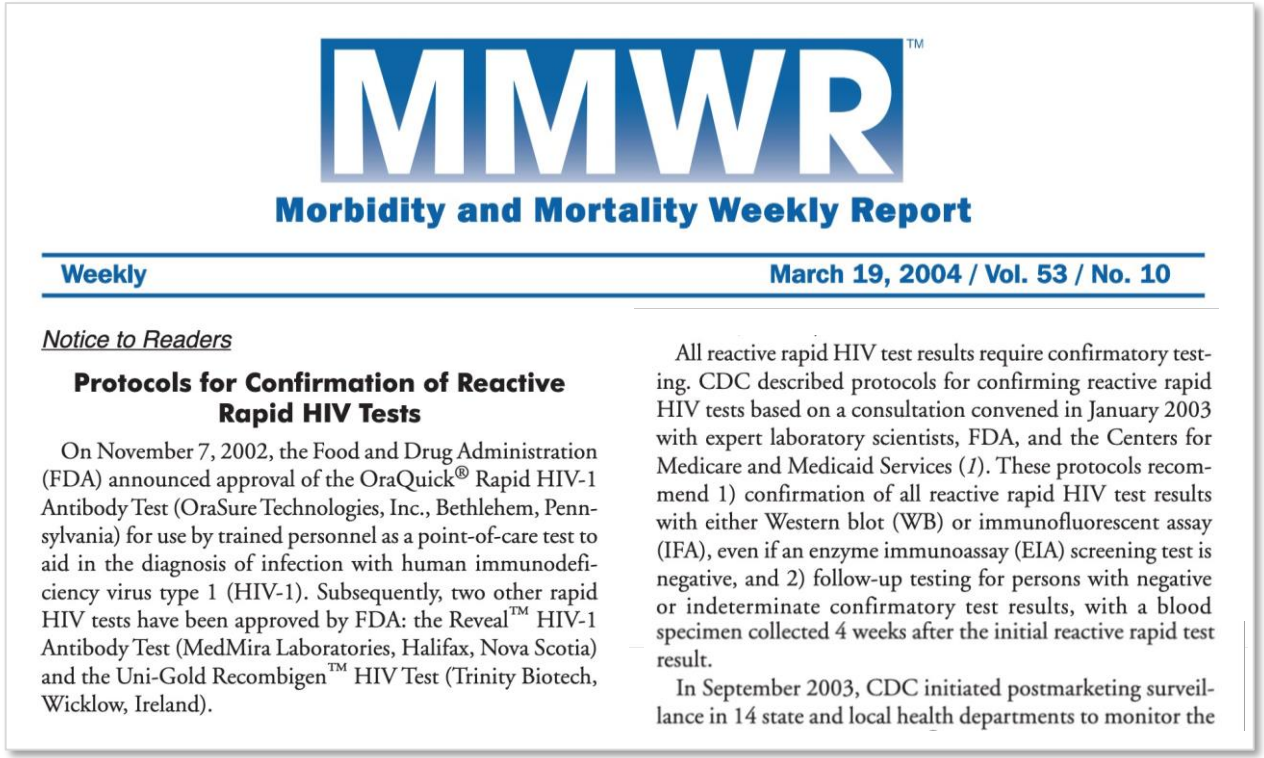
Why are lab-based tests “better”?

- Point-of-care (rapid) tests:
  - ✗ Start off with oral fluid or whole blood
  - ✗ May “lose” target(s) across the strip or via dilution
  - ✗ Detection relies on what’s visible to the eye
- Lab-based automated platforms:
  - ✓ Make use of concentrated specimens
  - ✓ Loss of target(s) is minimized
  - ✓ Highly sensitive light detection by machine



Why are point-of-care positives “preliminary”?

Because the CDC said so in 2004, after consulting testing experts.



MMWR™

Morbidity and Mortality Weekly Report

Weekly March 19, 2004 / Vol. 53 / No. 10

Notice to Readers

Protocols for Confirmation of Reactive Rapid HIV Tests

On November 7, 2002, the Food and Drug Administration (FDA) announced approval of the OraQuick® Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania) for use by trained personnel as a point-of-care test to aid in the diagnosis of infection with human immunodeficiency virus type 1 (HIV-1). Subsequently, two other rapid HIV tests have been approved by FDA: the Reveal™ HIV-1 Antibody Test (MedMira Laboratories, Halifax, Nova Scotia) and the Uni-Gold Recombigen™ HIV Test (Trinity Biotech, Wicklow, Ireland).

All reactive rapid HIV test results require confirmatory testing. CDC described protocols for confirming reactive rapid HIV tests based on a consultation convened in January 2003 with expert laboratory scientists, FDA, and the Centers for Medicare and Medicaid Services (*1*). These protocols recommend 1) confirmation of all reactive rapid HIV test results with either Western blot (WB) or immunofluorescent assay (IFA), even if an enzyme immunoassay (EIA) screening test is negative, and 2) follow-up testing for persons with negative or indeterminate confirmatory test results, with a blood specimen collected 4 weeks after the initial reactive rapid test result.

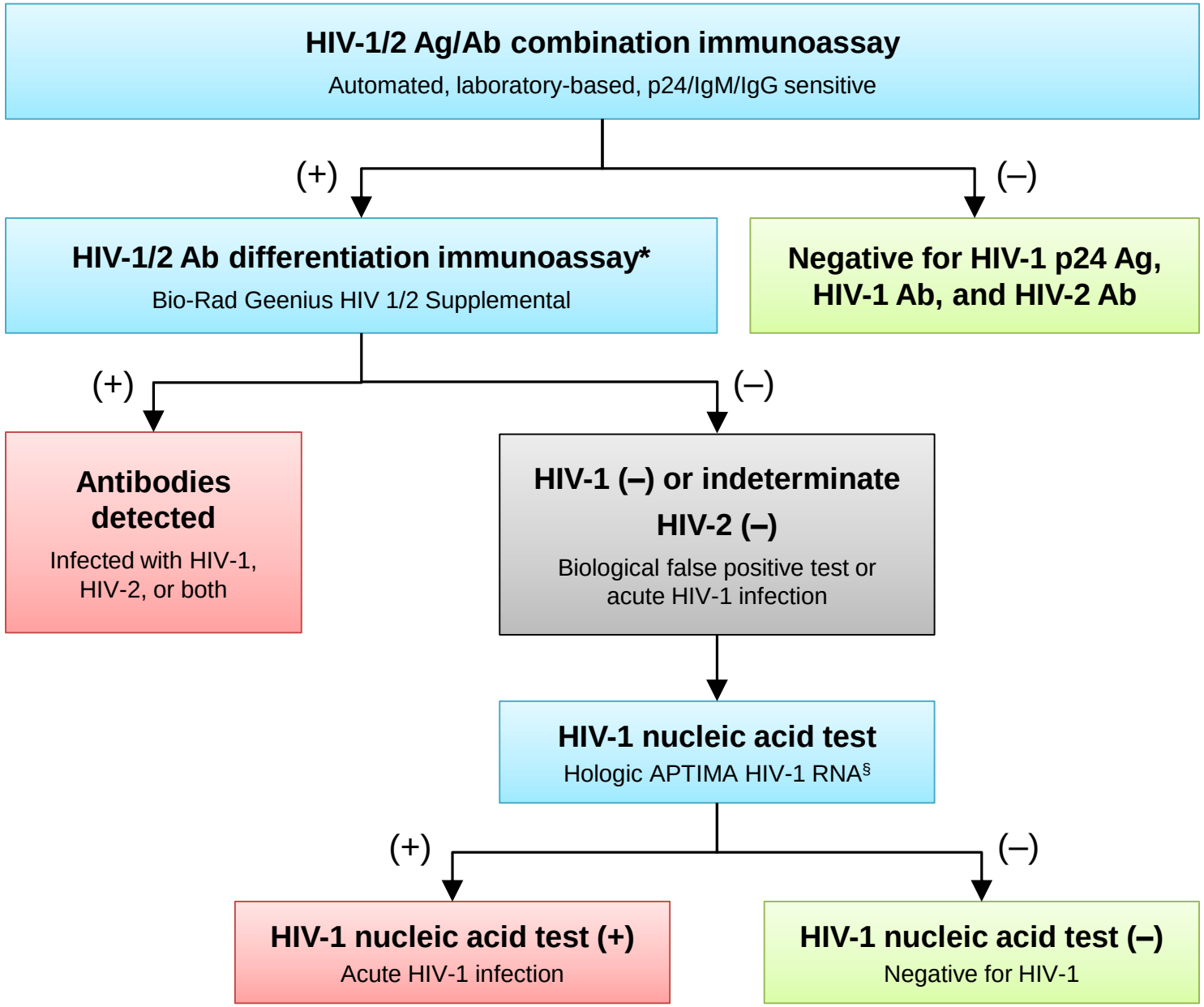
In September 2003, CDC initiated postmarketing surveillance in 14 state and local health departments to monitor the

- “All reactive rapid HIV test results require confirmatory testing.”
- Subsequent testing guideline updates (2014, 2018) do not supercede the 2004 rapid test guidance.

MMWR. 2004;53(10):221-2

CDC & APHL. Laboratory Testing for the Diagnosis of HIV Infection. Published June 27, 2014

- A single rapid test still needs confirmation… so CDC was forcing/ mandating entry into conventional testing (a precursor to entering HIV care)
- In resource-limited settings, two different rapid tests can be used sequentially for diagnosis **and** confirmation.



Take home messages about HIV tests

- HIV RNA and p24 antigen are targets we can use to **directly** detect the presence of the virus in someone with infection
- IgM and IgG antibodies that bind to HIV are **indirect** ways of detecting the presence of infection
- HIV RNA and p24 antigen appear in the blood before antibodies do
- Not all HIV tests are created equal – which means a negative result isn’t always informative (or reassuring)
- A reactive result from a rapid test is **ALWAYS PRELIMINARY** and **MUST BE CONFIRMED** using a lab-based, automated test platform

Keep tabs on their temperature

- **<u>LISTEN</u>**… and pay attention to verbal and nonverbal cues
- “How are you feeling …?”

Always follow their lead

- Allow them time to process and absorb information
- “What questions do you have about … ?”

Meet them where they are

- Leave judgment at the door
- Be aware of your own biases and preconceptions
- Provide facts, not opinions

Delivering the test result

- ✓ Confirm readiness to receive result
- ✓ Avoid any kind of preamble – be **direct & neutral**

"Your test result was negative. This means the test did not detect HIV antibodies at this time."

"Your test results were positive. The tests detected the presence of the HIV virus in your body. This means you're living with HIV."

PAUSE

for however long is most appropriate for the context

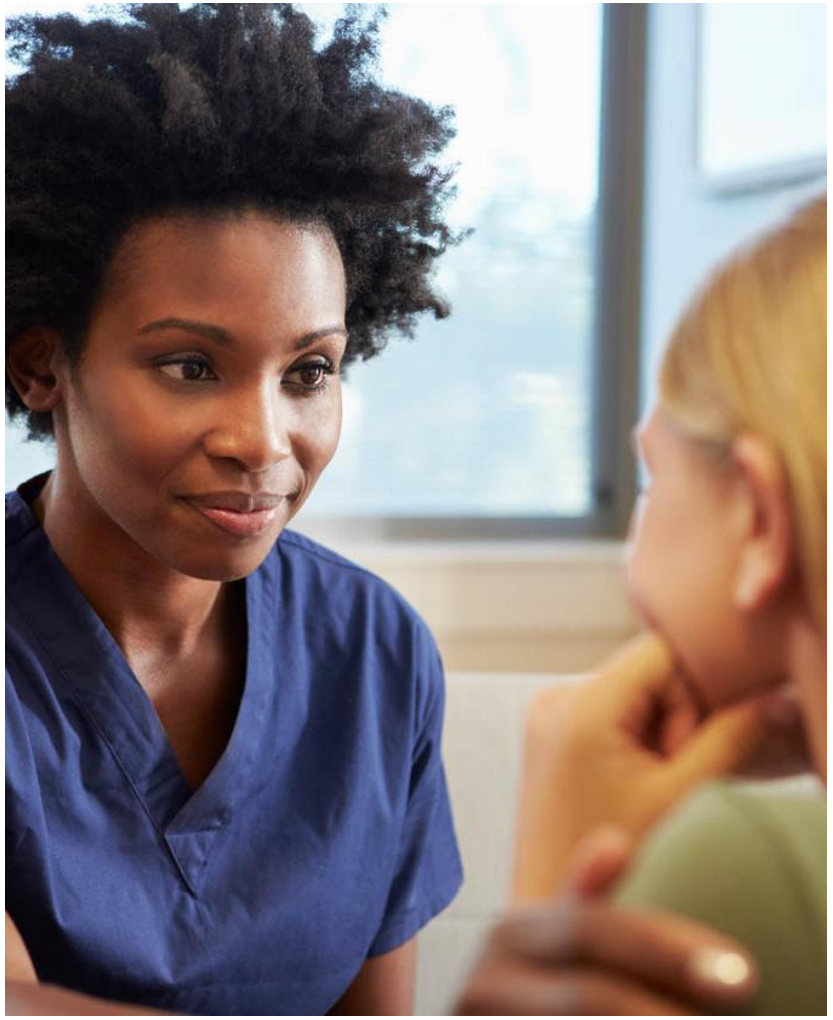
How do you feel about that result?

Adapted from: https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_SCRIPTS-Rapid_HIV_Testing_for_Individuals.pdf

Develop a plan & review next steps

- ✓ For non-reactive tests, revisit risk discussion and reinforce key messages as appropriate
- ✓ Make sure they have condoms & lube

"What's your plan for staying HIV-negative?"



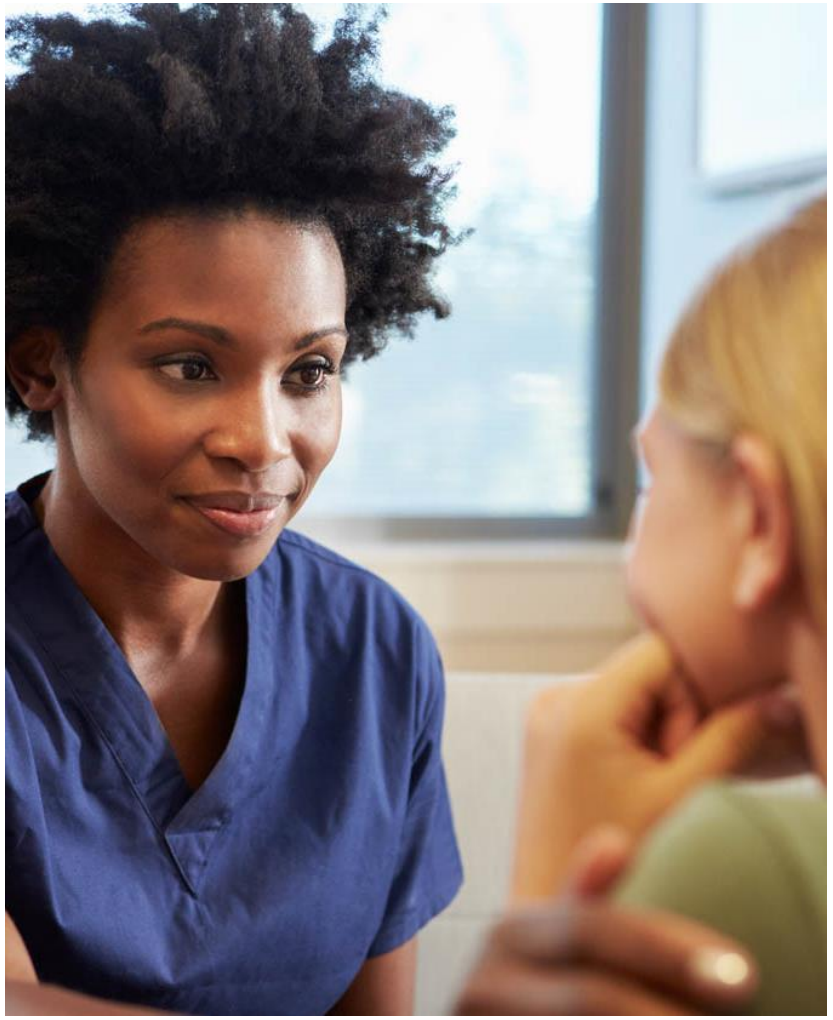
Adapted from: https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_SCRIPTS-Rapid_HIV_Testing_for_Individuals.pdf

Develop a plan & review next steps

- ✓ For reactive tests, reinforce key messages about the results
- ✓ Help them think about coping

"A preliminary positive means that we need to do additional tests to make sure the result is correct. This may take several days to come back."

"What are your plans after you leave the visit today? Is there someone you'd like to call or talk with about the positive result?"

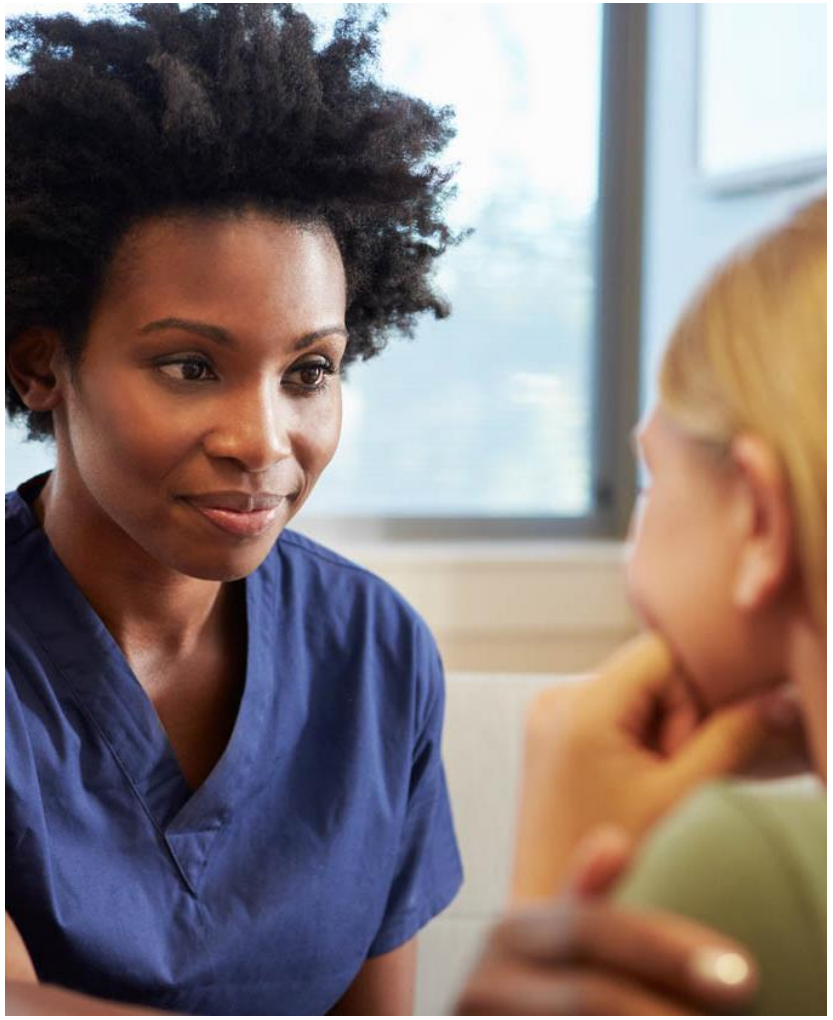


Adapted from: https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_SCRIPTS-Rapid_HIV_Testing_for_Individuals.pdf **AND** https://aidsetc.org/resource/hiv-testing-and-counseling

Develop a plan & review next steps

- ✓ Assess plans for their safety and prevention for partners
- ✓ Schedule a follow-up visit to discuss confirmatory results

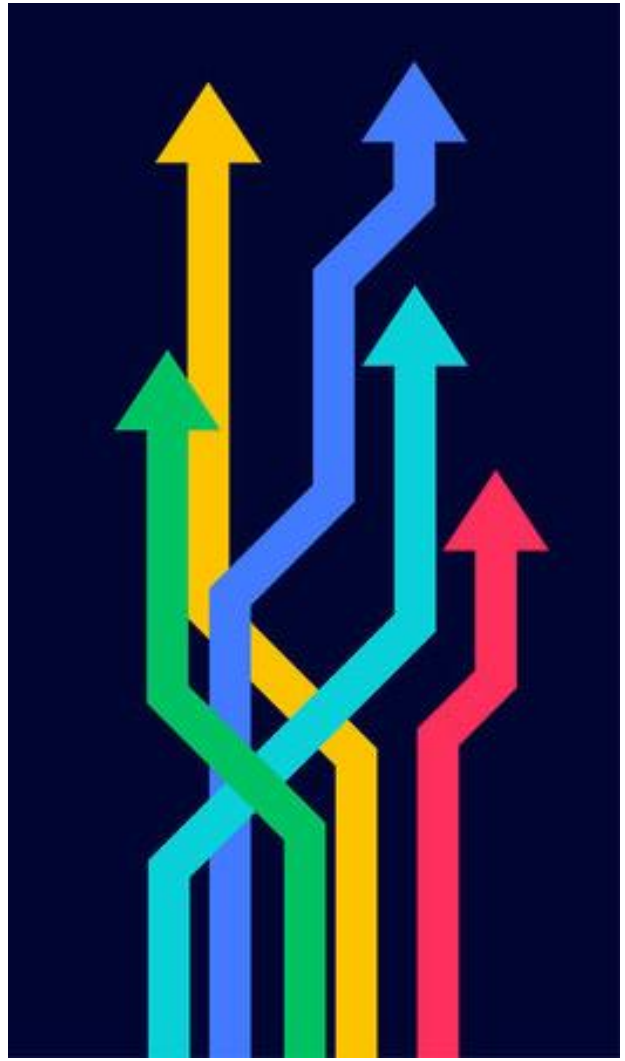
"I know this is a lot to think about, but it's also important to think about how you can reduce the risk of transmission to others, if you do have HIV."



Adapted from: https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_SCRIPTS-Rapid_HIV_Testing_for_Individuals.pdf **AND** https://aidsetc.org/resource/hiv-testing-and-counseling

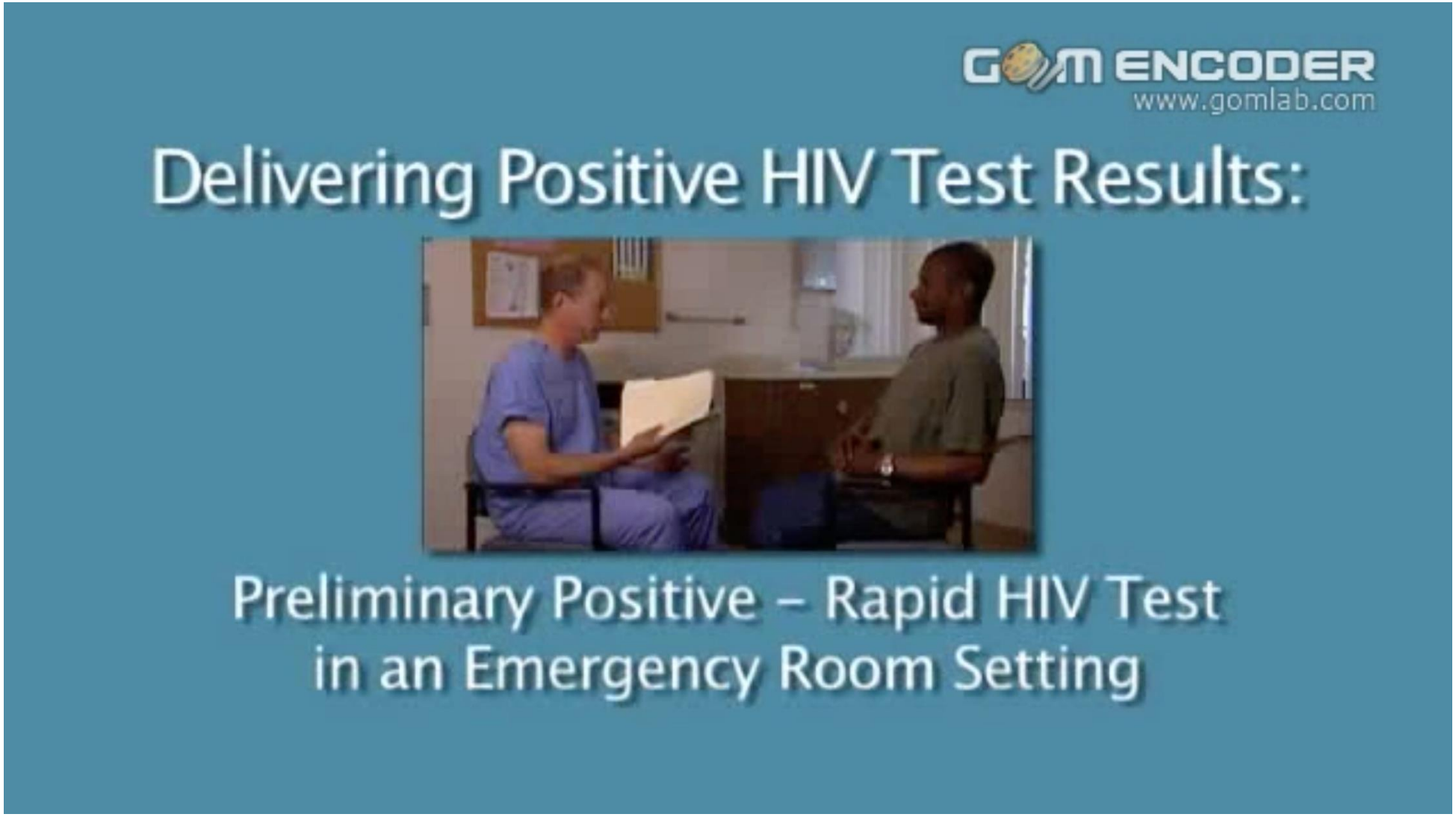
Make connections, summarize, & close

- ✓ As appropriate, consider linkages with treatment, counseling, or support
- ✓ Make sure they're aware of follow-up appointment date and time



"Do you have any questions for me?"

Adapted from: https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_SCRIPTS-Rapid_HIV_Testing_for_Individuals.pdf **AND** https://aidsetc.org/resource/hiv-testing-and-counseling


GOM ENCODER
www.gomlab.com
Delivering Positive HIV Test Results:
Preliminary Positive – Rapid HIV Test
in an Emergency Room Setting

4 minutes

https://youtu.be/0LII0_QBwDU?t=6

4 minutes

What are your impressions of that encounter?

What did you think went well?

What could have been done or said differently?

https://youtu.be/sWS8cZrwsug?t=64

7 minutes

https://youtu.be/sWS8cZrwsug?t=64

7 minutes

What are your impressions of that encounter?

What did you think went well?

What could have been done or said differently?

Follow up Questions and Resources

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North Carolina AETC - UNC
North Carolina AIDS Education & Training Center – University of North Carolina Chapel Hill

NC DHHS Programs & Services Website

NC Prevention and Care Providers List:
https://docs.google.com/spreadsheets/d/19XytU96ZmEljQRaRkaTvRJVSUcClXmzn/edit?usp=sharing&ouid=105034987384100038938&rtpof=true&sd=true

Questions?