

# Delivering HIV Test Results

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# AETC Program National Centers and HIV Curriculum

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- **National HIV Curriculum** – provides ongoing, up –to-date HIV training and information for health professionals through a free, web –based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: [www.hiv.uw.edu](http://www.hiv.uw.edu)



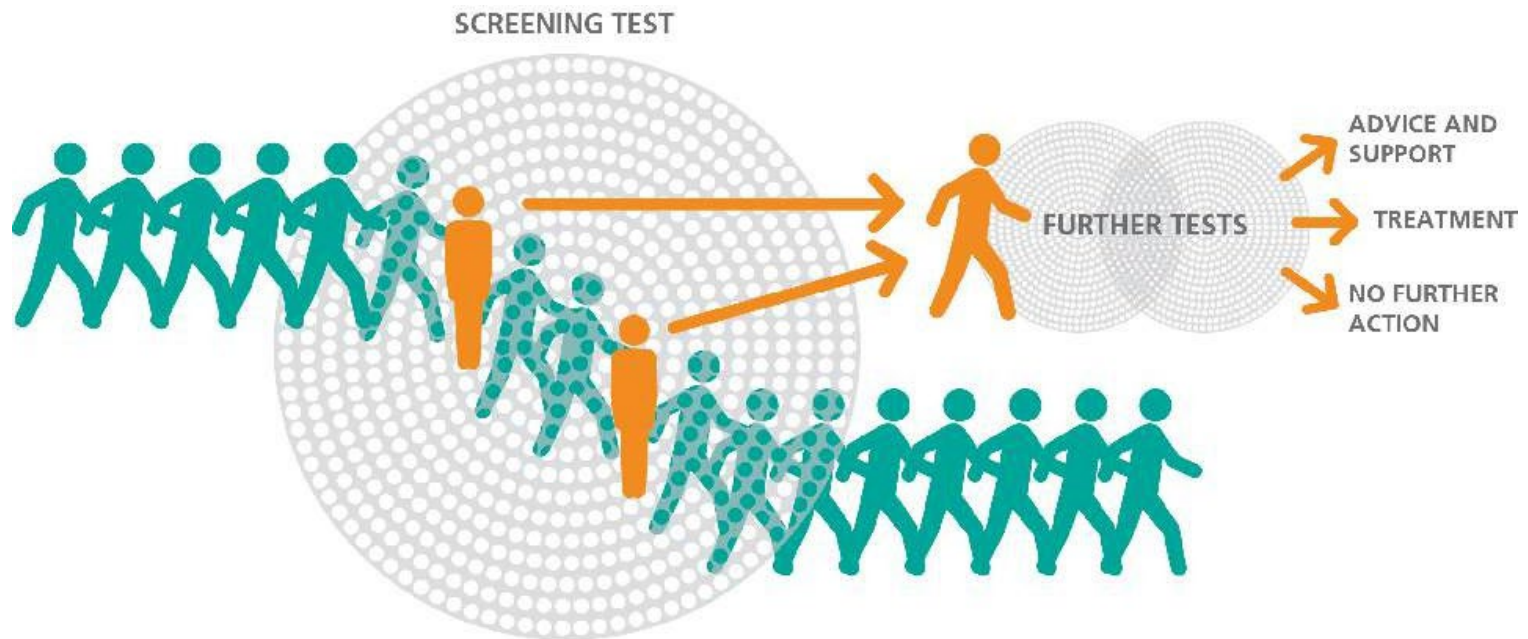
# Disclosures

- *This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling \$4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit [HRSA.gov](http://HRSA.gov).*
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# Learning Objectives

1. Explain the difference between point-of-care and lab-based tests for HIV screening
2. Define preliminary and confirmatory test results
3. Outline an approach for disclosing test results

# HIV testing involves 2 steps: screening & confirmation



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

# Who should be tested for HIV?



Screening	<b>Opt-out testing</b> All clinical settings (if patient [not pop] prevalence >0.1%) Ages 13-64
Special situations	Starting TB therapy Seeking STI therapy ( <b>every</b> encounter) Exposures (occupational & non)
Rescreening	<b>At least annually</b> if at increased risk <ul style="list-style-type: none"><li>• IDU &amp; sex partners</li><li>• Transactional sex</li><li>• &gt;1 interim partner</li></ul>



# Who should be tested for HIV?



Screening	<p><b>Opt-out testing</b></p> <p>All clinical settings (if patient [not pop] prevalence &gt;0.1%)</p> <p>Ages 13-64</p>	<p>Ages 15-65</p> <p>Younger &amp; older if at increased risk</p> <p>Pregnant women</p>
Special situations	<p>Starting TB therapy</p> <p>Seeking STI therapy (<b>every</b> encounter)</p> <p>Exposures (occupational &amp; non)</p>	<p>(silent)</p>
Rescreening	<p><b>At least annually if at increased risk</b></p> <ul style="list-style-type: none"> <li>• IDU &amp; sex partners</li> <li>• Transactional sex</li> <li>• &gt;1 interim partner</li> </ul>	<p><b>At least annually if at increased risk</b></p>



# Why the shift to routine testing?



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

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

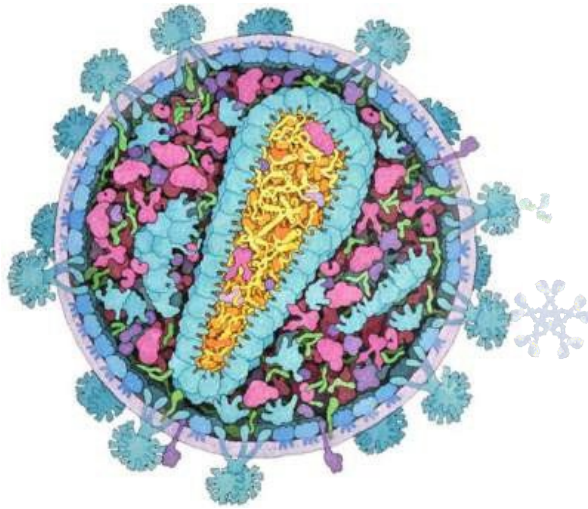
4 Lyss SB, et al. JAIDS. 2007;44(4):435-442



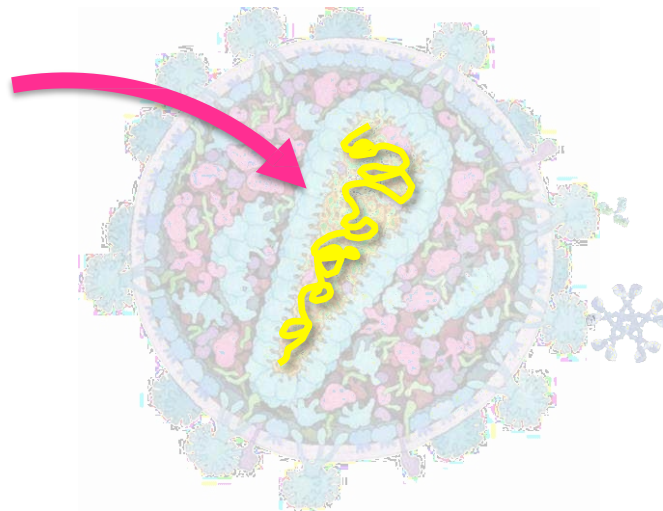


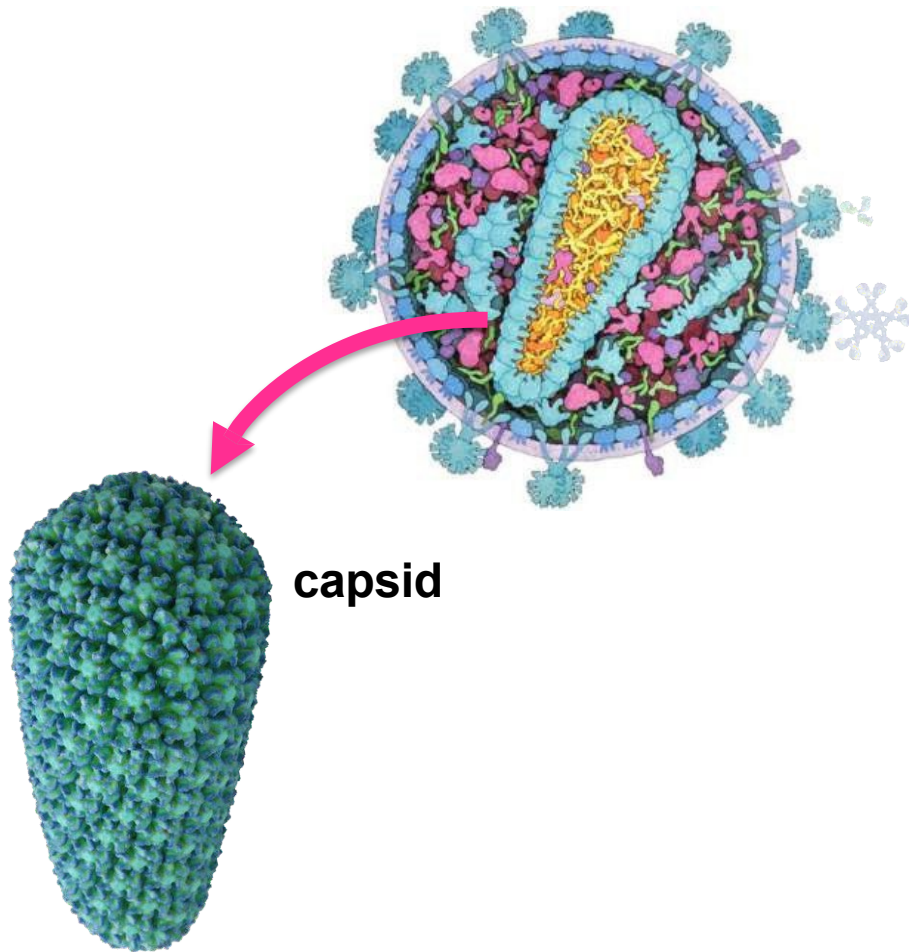


<https://palmettocare.org/>

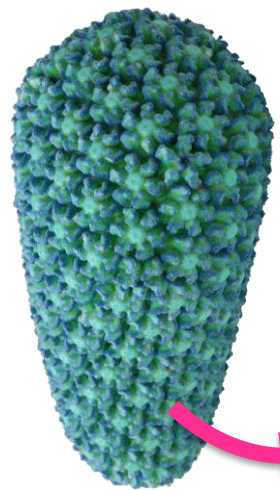
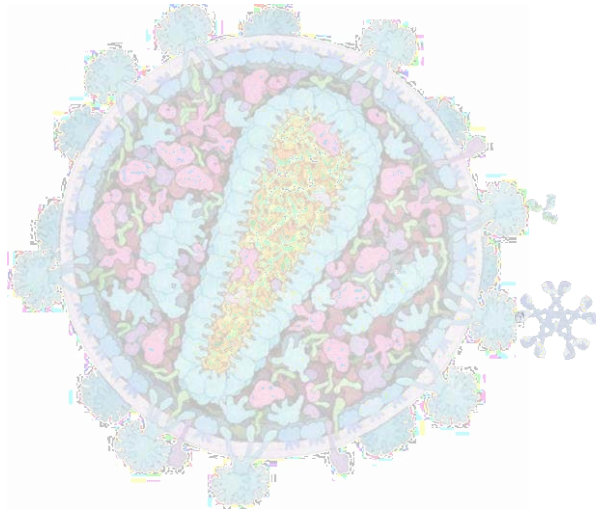


HIV  
RNA

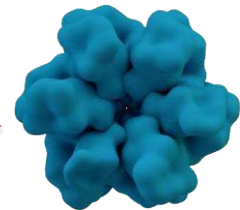


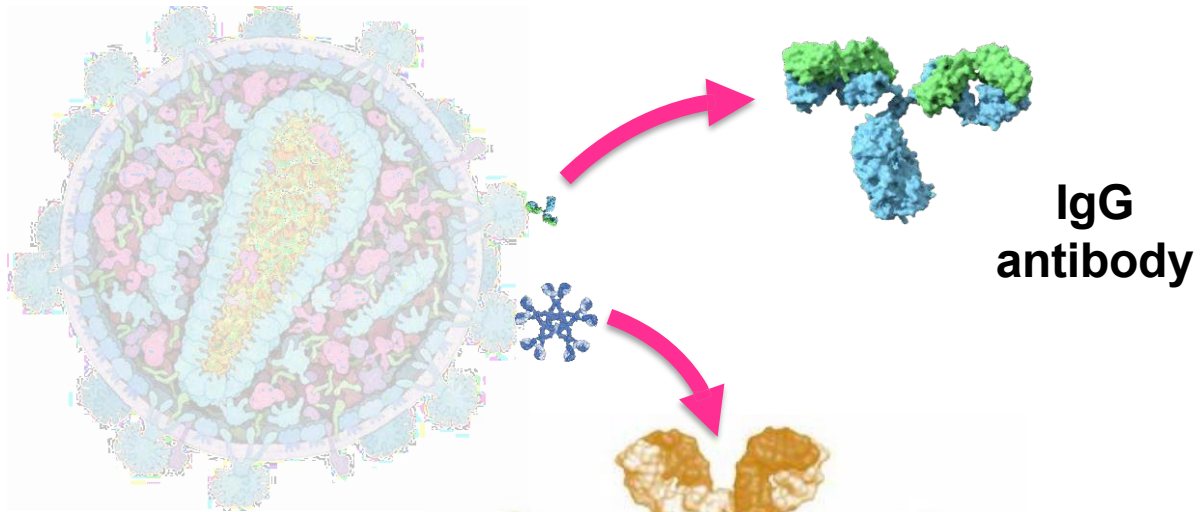


**capsid**



**p24  
antigen**

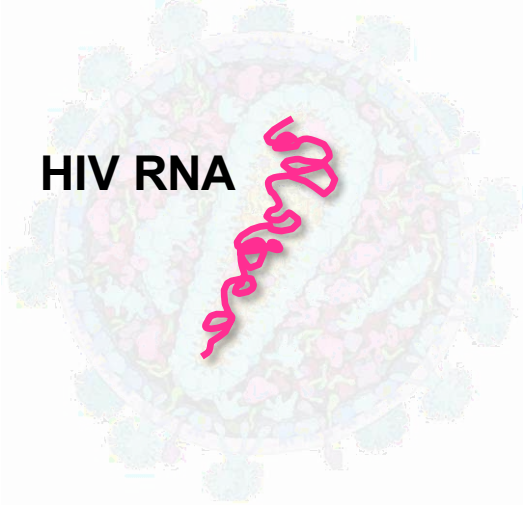




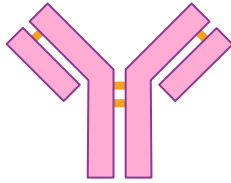
**p24  
antigen**



**IgM  
antibody**

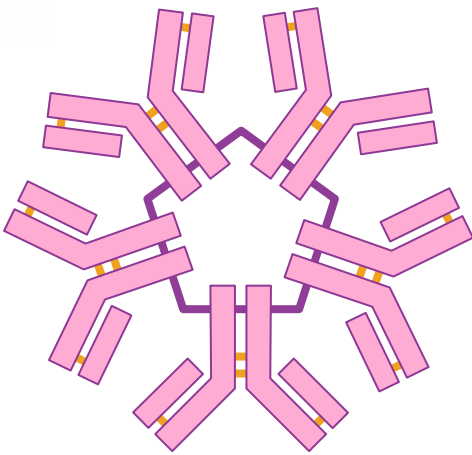
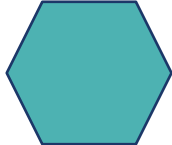


**HIV RNA**



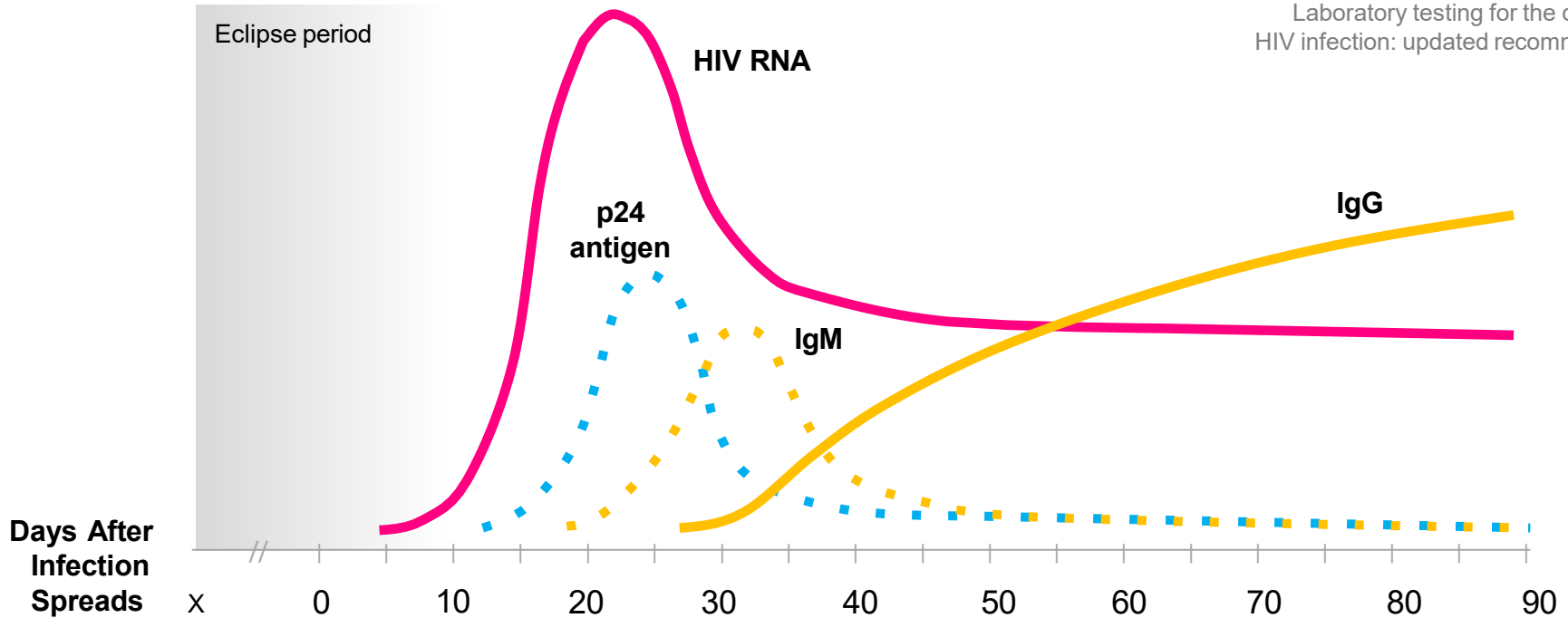
**IgG  
antibody**

**p24  
antigen**



**IgM  
antibody**

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



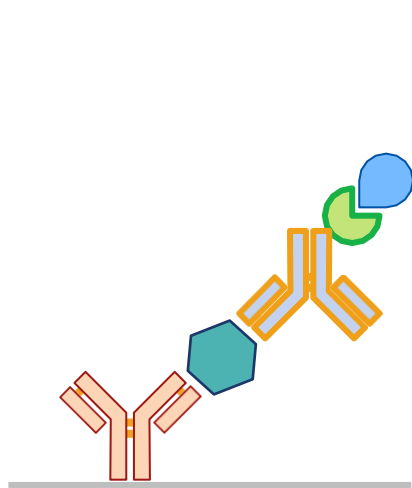
Days After Infection Spreads

x // 0 10 20 30 40 50 60 70 80 90

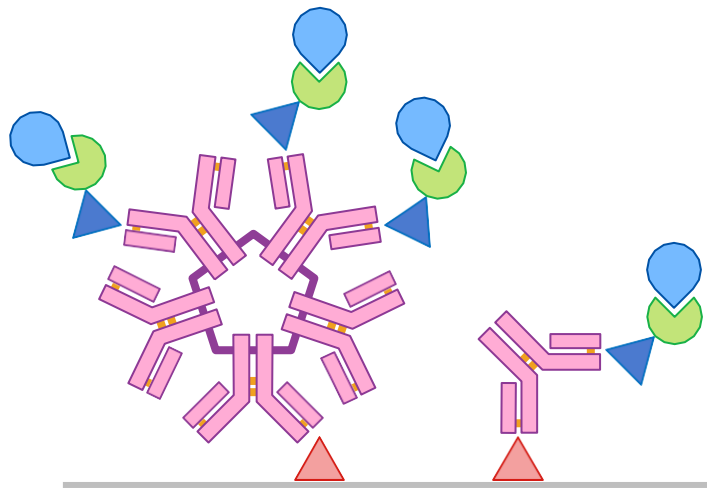
Median time to first positive result

- RNA (12d) ↑
- p24 Ag (18d) ↑
- IgM / IgG sensitive (23d) ↑
- IgG sensitive (31d) ↑
- IgG sensitive oral fluid (up to 90d) ↑

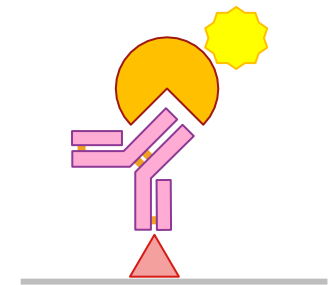




**p24 antigen detection**  
(p24 / IgM / IgG sensitive tests)



**IgM / IgG sensitive**



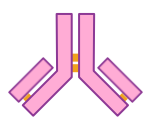
**IgG sensitive**



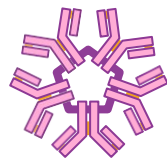
Synthetic or recombinant HIV antigens



Monoclonal anti-p24 antibody



Anti-HIV IgG (from patient)



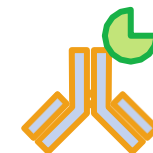
Anti-HIV IgM (from patient)



Protein A-linked colloidal gold



p24 antigen (from patient)

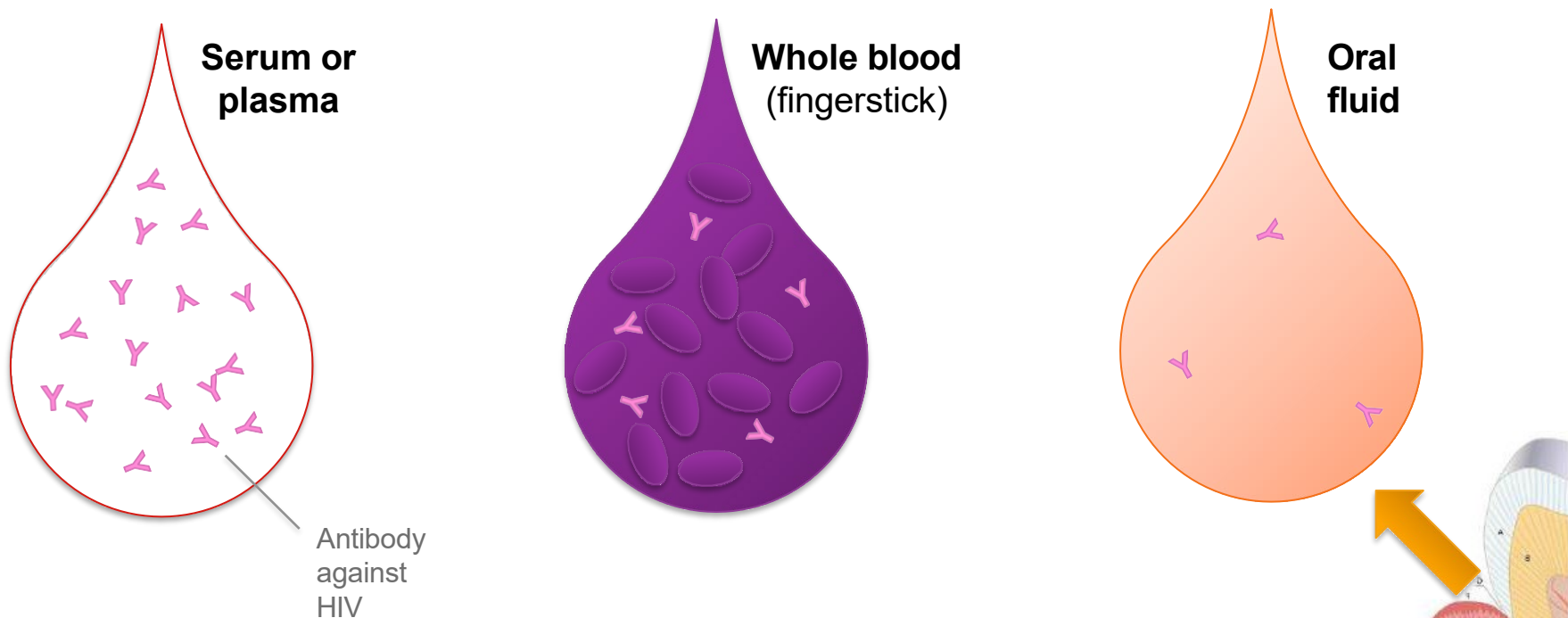


Enzyme-linked anti-p24 antibody



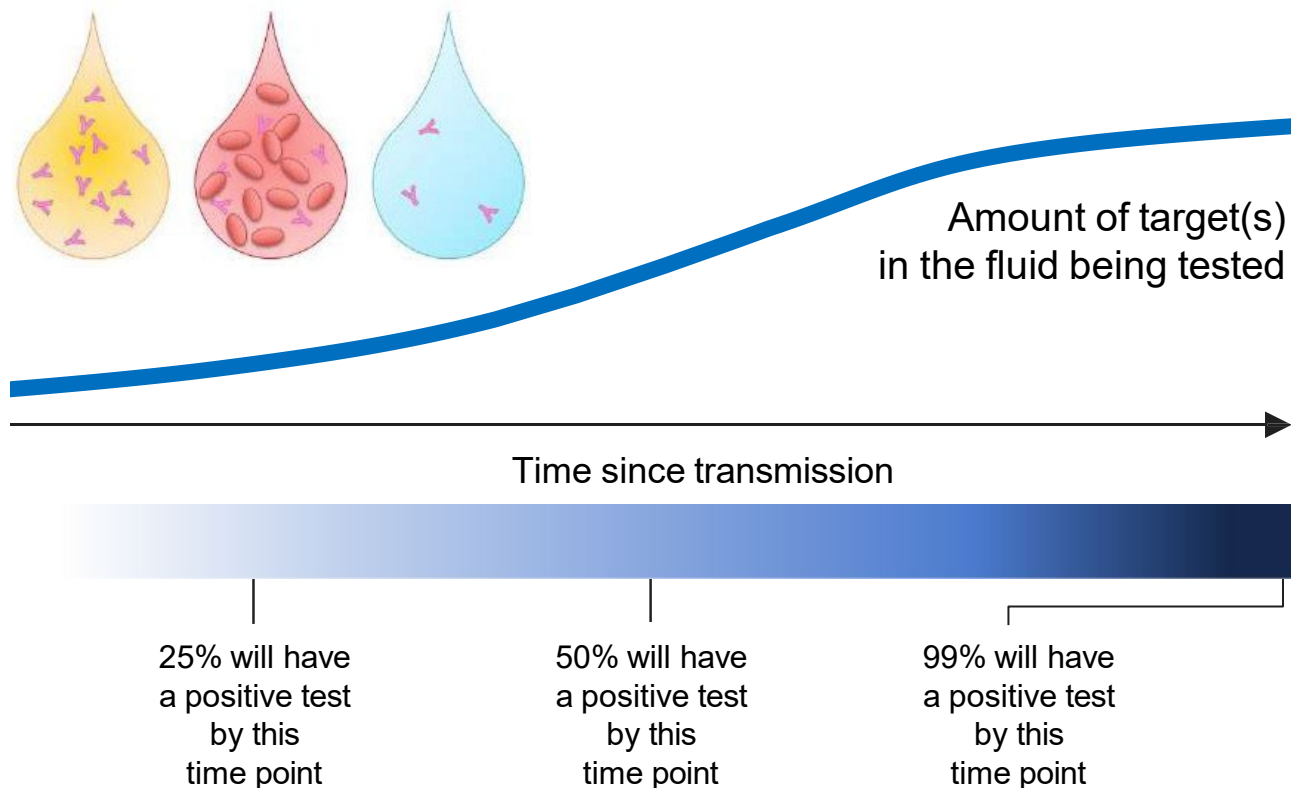
Detection reagent

# The quantity of the target depends on the specimen

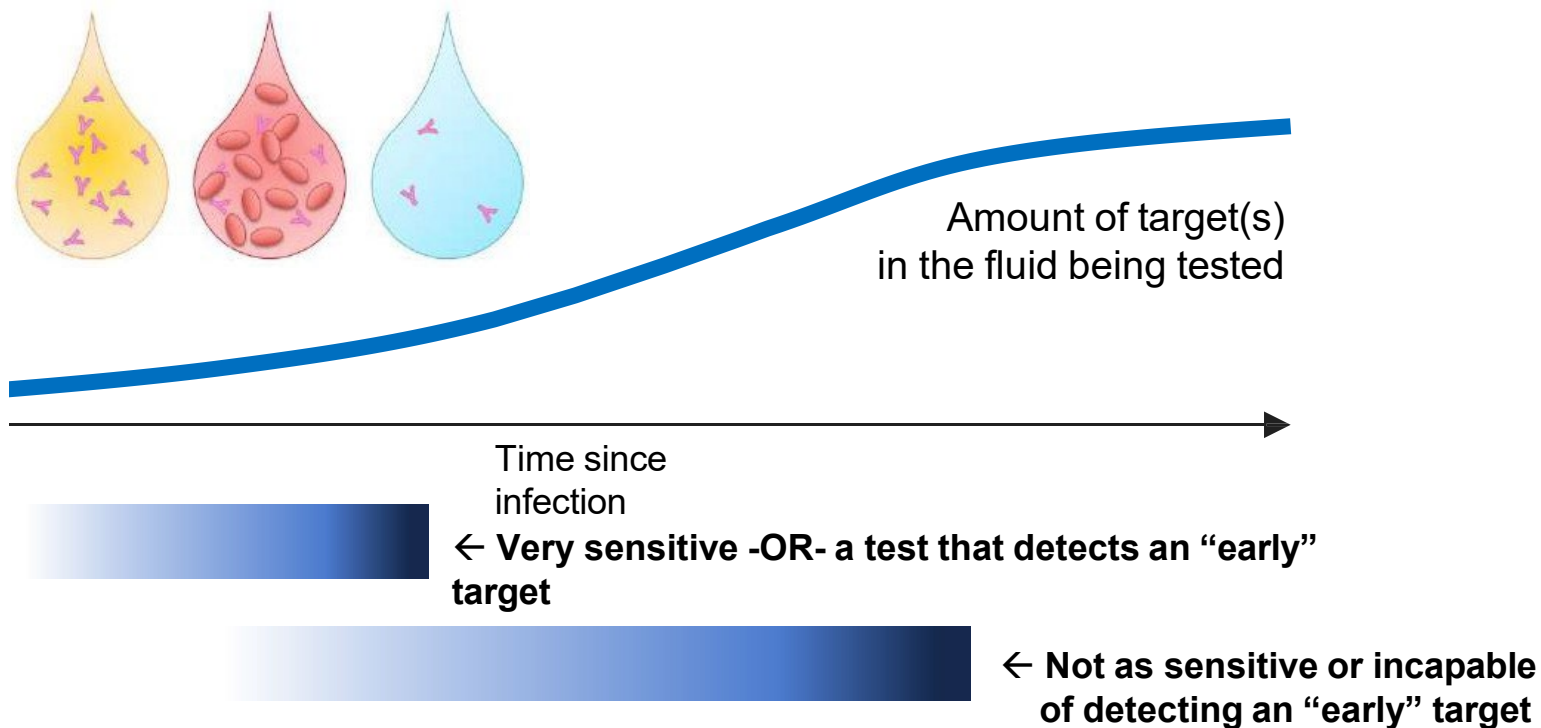


Hurt CB, et al. Sex Transm Dis. 2017 Dec;44(12):739-746

# The window period depends on the test... and time



# The window period depends on the test... and time



# 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) <sup>†</sup>	13.0	<b>17.8</b>	23.6	44.3
	p24/IgM/IgG sensitive POC test (1) <sup>‡</sup>	14.8	<b>19.2</b>	24.6	43.1
"3rd gen"	IgM/IgG sensitive laboratory tests (3) <sup>§</sup>	18.4	<b>23.1</b>	28.8	49.5
	IgM/IgG sensitive POC tests (2) <sup>  </sup>	24.2	<b>29.3</b>	35.3	57.4
"2nd gen"	IgG sensitive laboratory test (1) <sup>¶</sup>	26.5	<b>30.6</b>	35.9	54.1
	IgG sensitive POC tests (5) <sup>**</sup>	26.7	<b>31.8</b>	37.8	57.8
	IgG sensitive supplemental tests (1) <sup>††</sup>	28.2	<b>32.9</b>	38.6	57.7
"1st gen"	Western blot (1) <sup>‡‡</sup>	31.0	<b>36.5</b>	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



# Window periods of HIV tests, by category

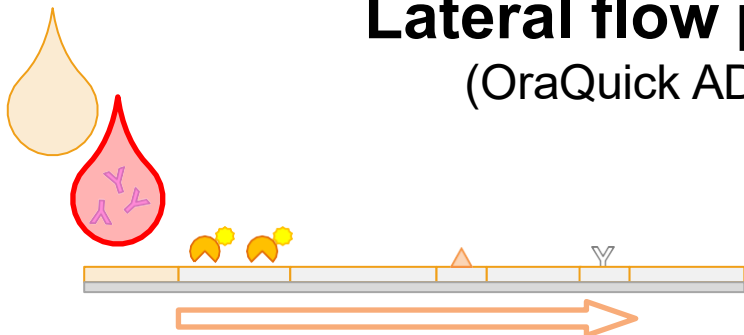
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# Lateral flow point-of-care rapid tests

(OraQuick ADVANCE IgM / IgG, ChemBio IgG)



Test  
Control



Immobilized  
anti-human  
antibody



Protein A-linked  
colloidal gold



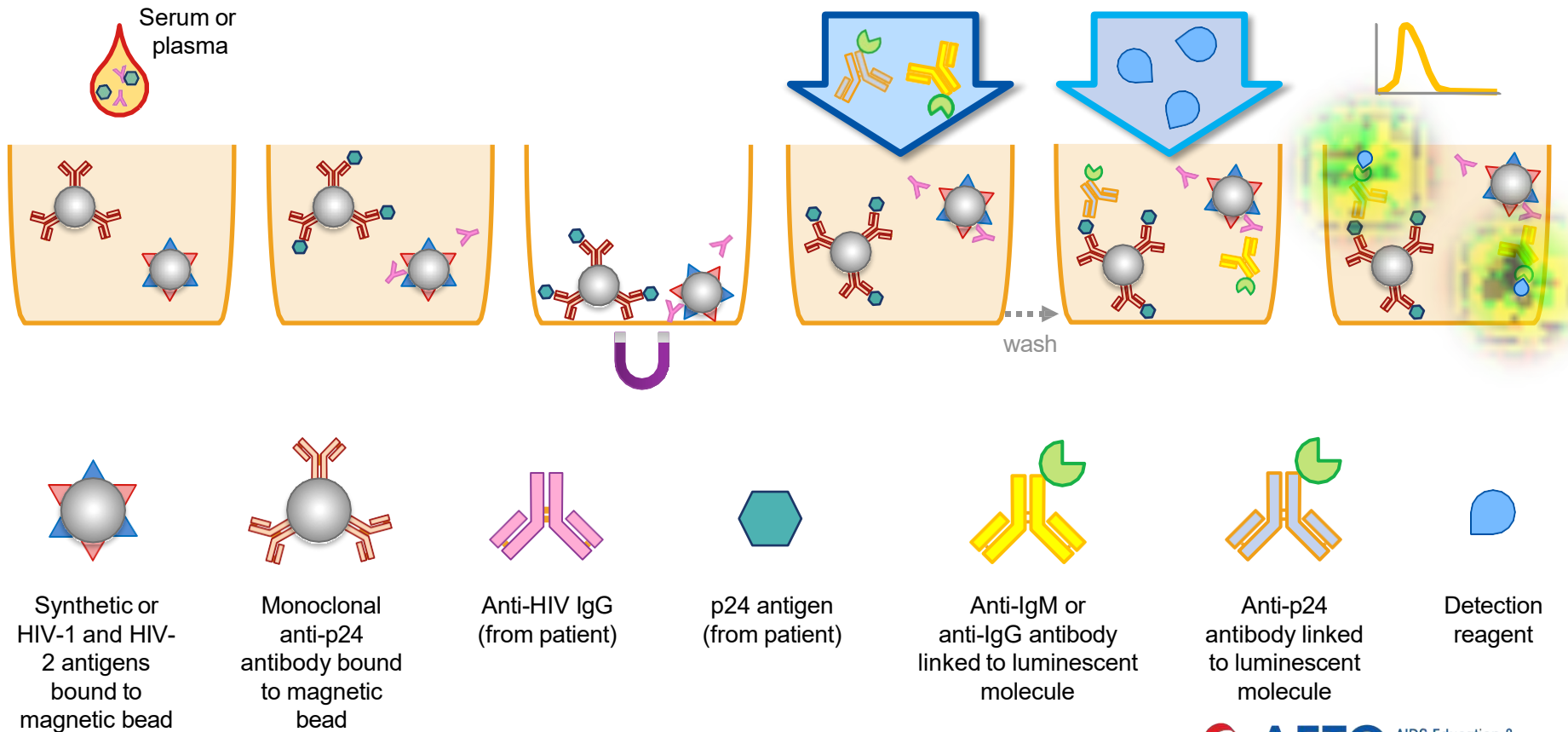
Synthetic or  
recombinant  
HIV antigens



Anti-HIV  
antibody  
(from patient)

# Lab-based, automated test platform

(Chemiluminescent microparticle immunoassay p24 / IgM / IgG)





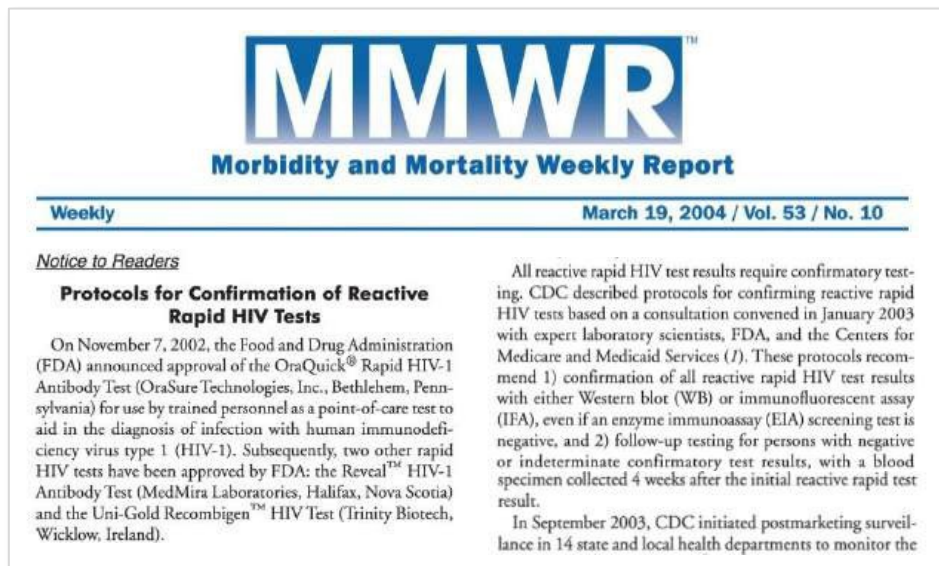
## Why are lab-based tests “better”?

- 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.



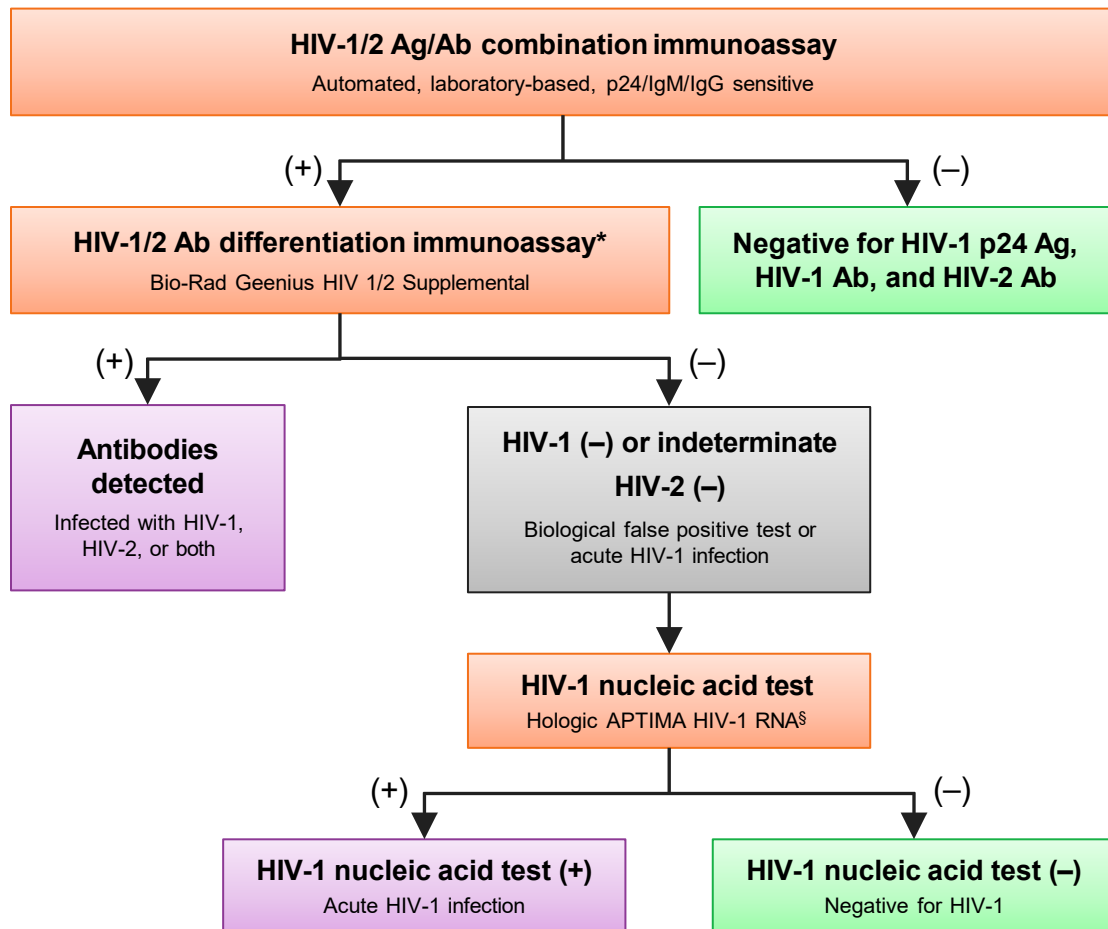
- “All reactive rapid HIV test results require confirmatory testing.”
- Subsequent testing guideline updates (2014, 2018) do not supercede the 2004 rapid test guidance.

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

- **LISTEN**... 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](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](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](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.”

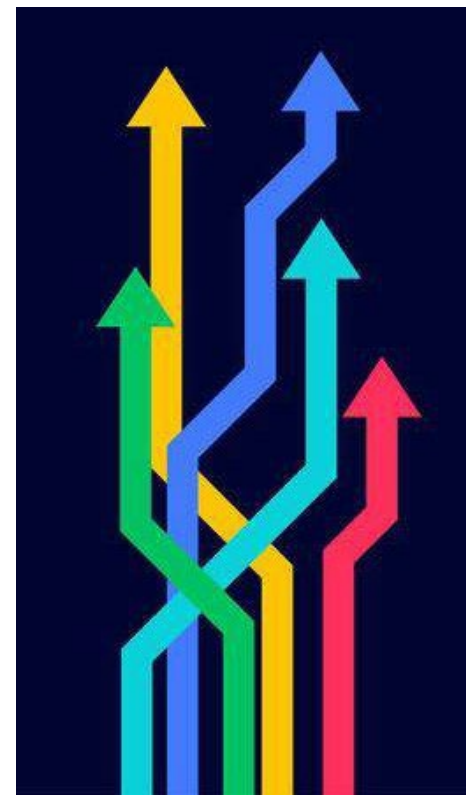


Adapted from: [https://www.cdc.gov/hiv/pdf/testing/CDC\\_HIV\\_SCRIPTS-Rapid\\_HIV\\_Testing\\_for\\_Individuals.pdf](https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_SCRIPTS-Rapid_HIV_Testing_for_Individuals.pdf) AND <https://aidsetc.org/resource/hiv-testing-and-counseling>

## 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](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>



# Delivering Positive HIV Test Results:



## Preliminary Positive – Rapid HIV Test in an Emergency Room Setting

Positive Test Results

<https://www.youtube.com/watch?v=beixuxuQNMo>

**What are your impressions  
of that encounter?**

**What did you think went well?**

**What could have been done  
or said differently?**



Delivering HIV Positive Test Results – Transgender Woman  
<https://youtu.be/sWS8cZrwsug?t=64>

**What are your impressions  
of that encounter?**

**What did you think went well?**

**What could have been done  
or said differently?**



# Resources

## 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/19XytU96ZmEljQRaRkaTvRJVsuCIXmzn/edit?usp=sharing&oid=105034987384100038938&rtpof=true&sd=true>



# Thank You

This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling \$4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please Visit [HRSA.gov](http://HRSA.gov).

