

# Iowa Adopts New HIV Testing Algorithm

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# Objectives

At the completion of this webinar, participants will:

- Be familiar with the difference between HIV antibody, antigen, and RNA
- Have a basic understanding of the new HIV testing algorithm that will be used at the State Lab after 11/6/2012
- Understand the new “diagnostic window of detection” and possible test results for serum samples that are tested at the State Lab after 11/6/2012
- Be familiar with the advantages and disadvantages of rapid vs. conventional HIV testing
- Timeframe and processes for submitting specimens to the lab.

# Terms

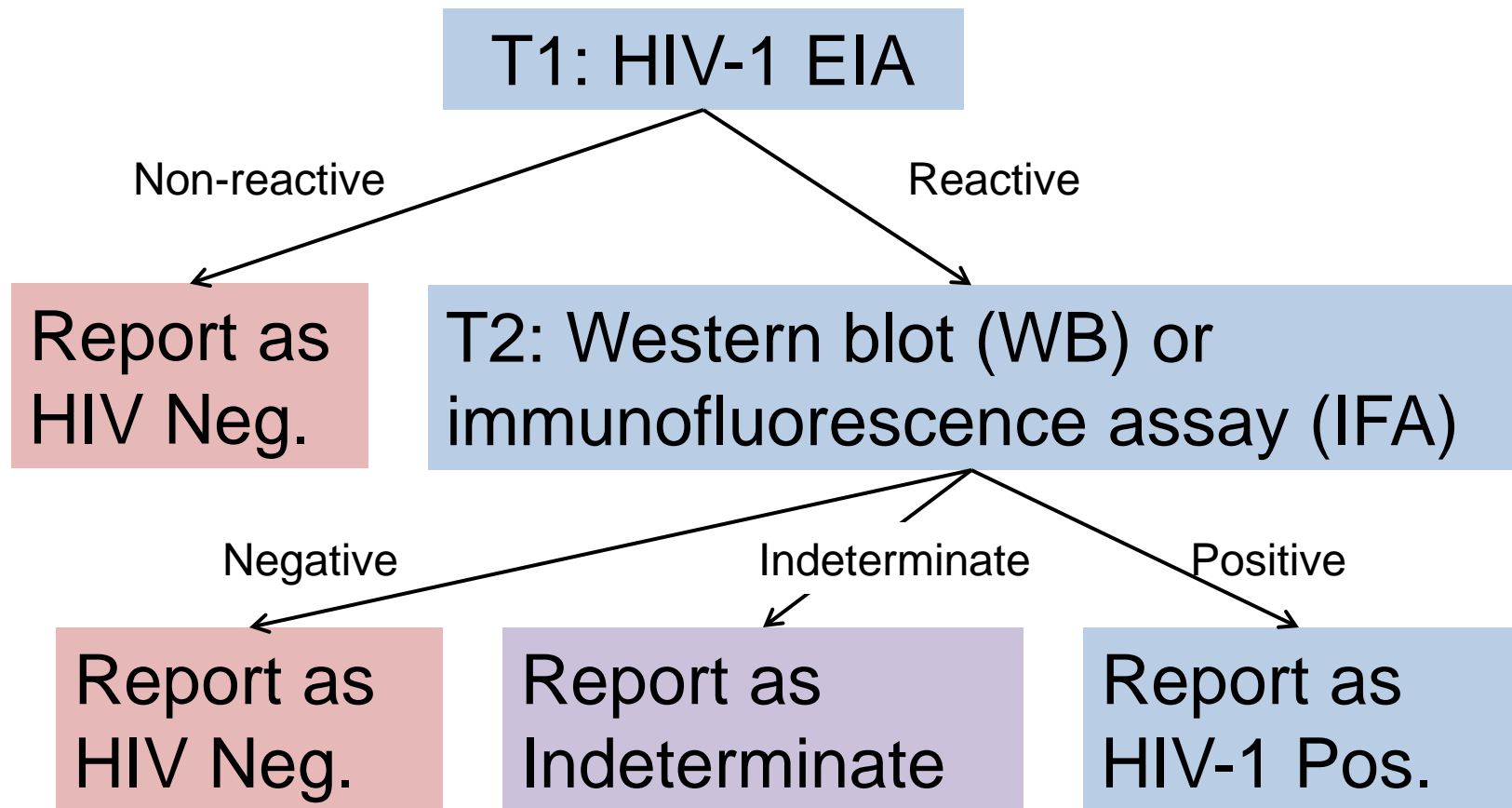
- HIV Testing Algorithm
  - Sequence in which different diagnostic tests are used to arrive at a definitive diagnosis
- Conventional HIV Test Algorithm
  - Blood (serum) sample taken from client via venipuncture; sample sent to laboratory for testing
  - Screening and supplemental tests performed at lab as necessary
  - Result sent back to provider for delivery to client
- Rapid HIV Test Algorithm
  - Blood or oral fluid sample taken from client via finger stick or oral swab; screening test performed onsite
  - Non-reactive result can be shared with client in less than 1 hour
  - Reactive result requires confirmation with conventional test as described above

# HIV Testing Processes Then and Now

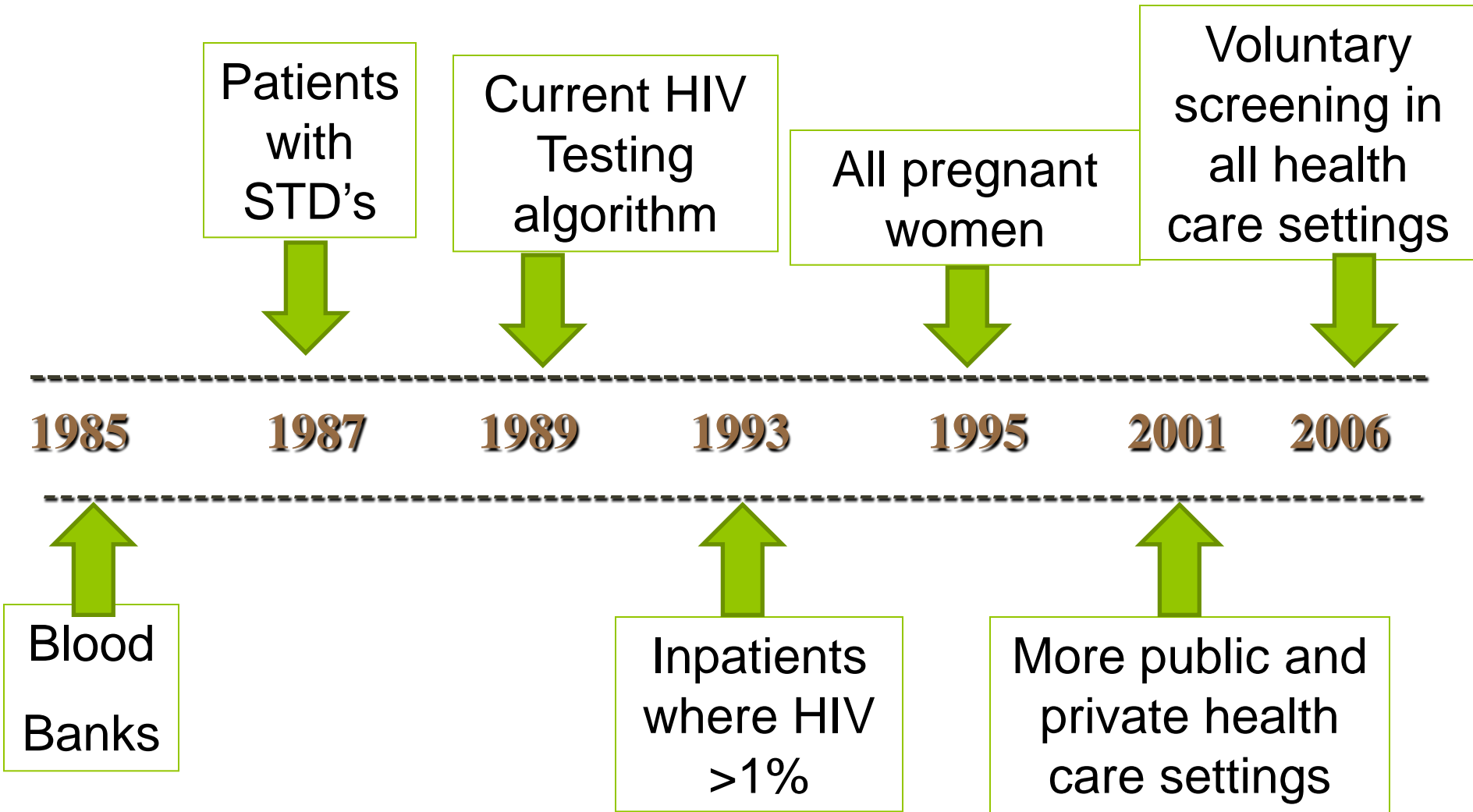
# HIV Antibody Testing

- Antibodies are proteins produced by the immune system to neutralize infections or malignant cells
- Most people develop detectable HIV antibodies 2-8 weeks after infection (**average 25 days**)
- Current HIV testing algorithm used at the State Lab:
  - EIA screen (3<sup>rd</sup> Generation)
  - Confirmed by Western Blot (WB)

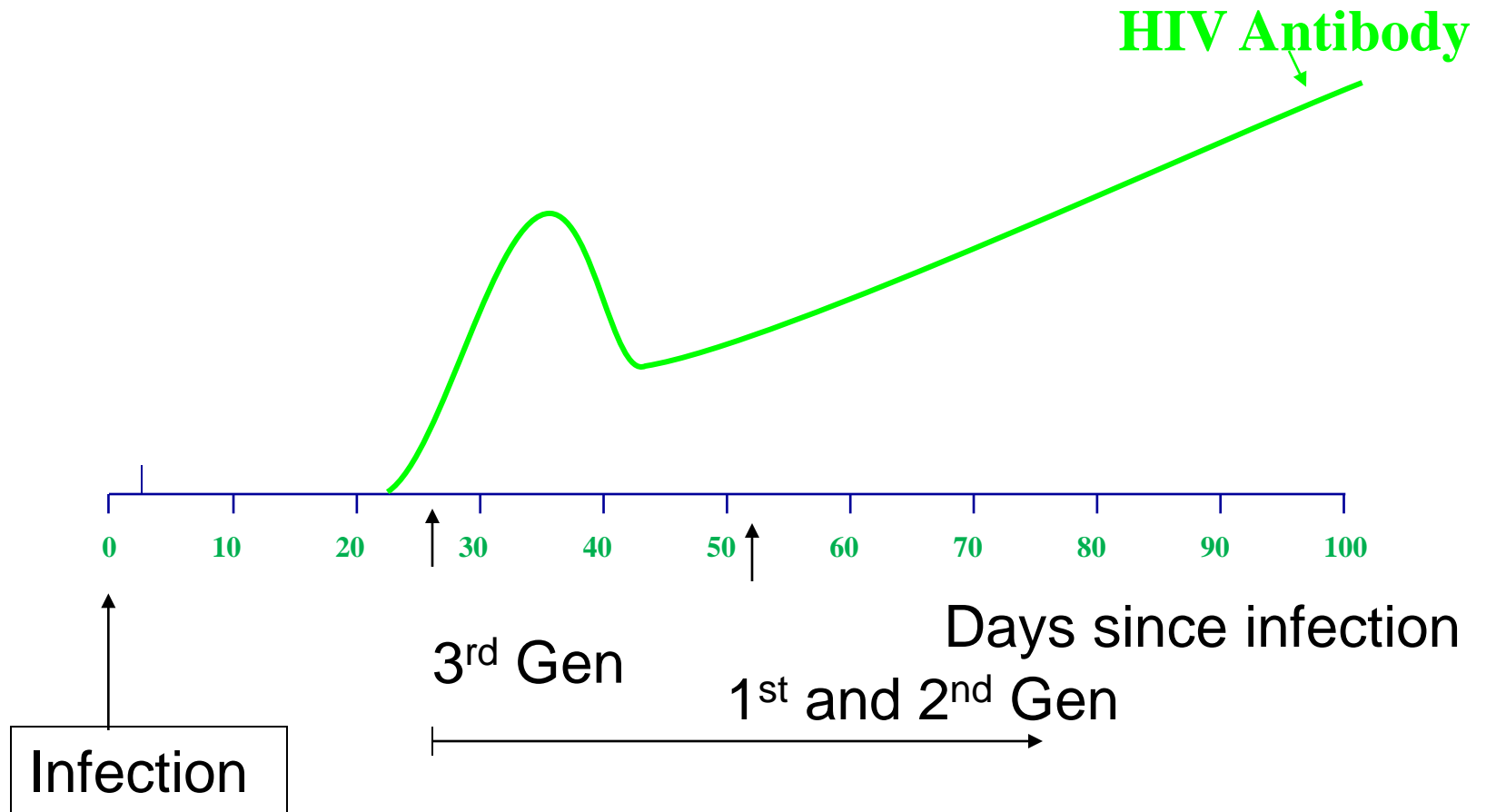
# 1989: CDC recommended two-test algorithm for HIV diagnosis



# HIV Testing has changed over time

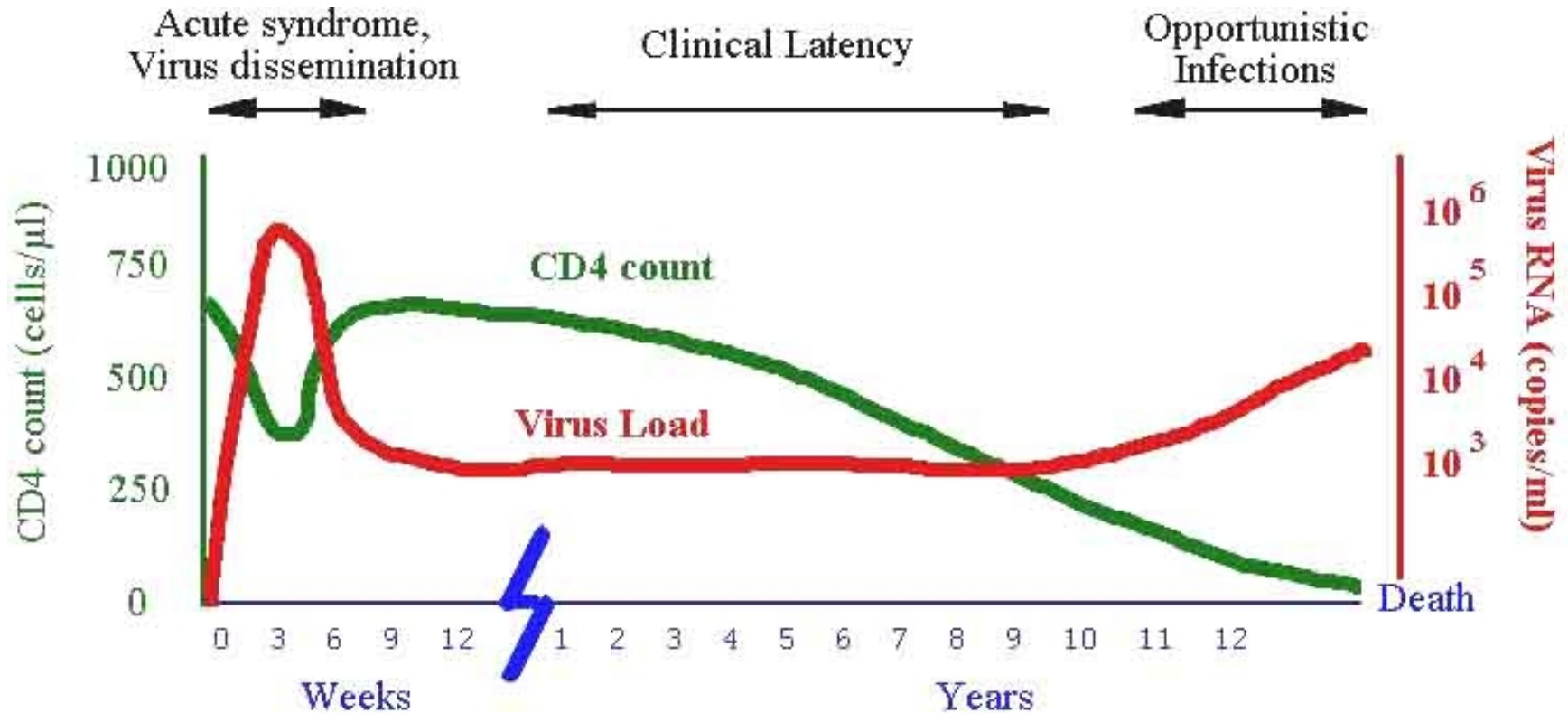


# HIV Progression and Detectable Response

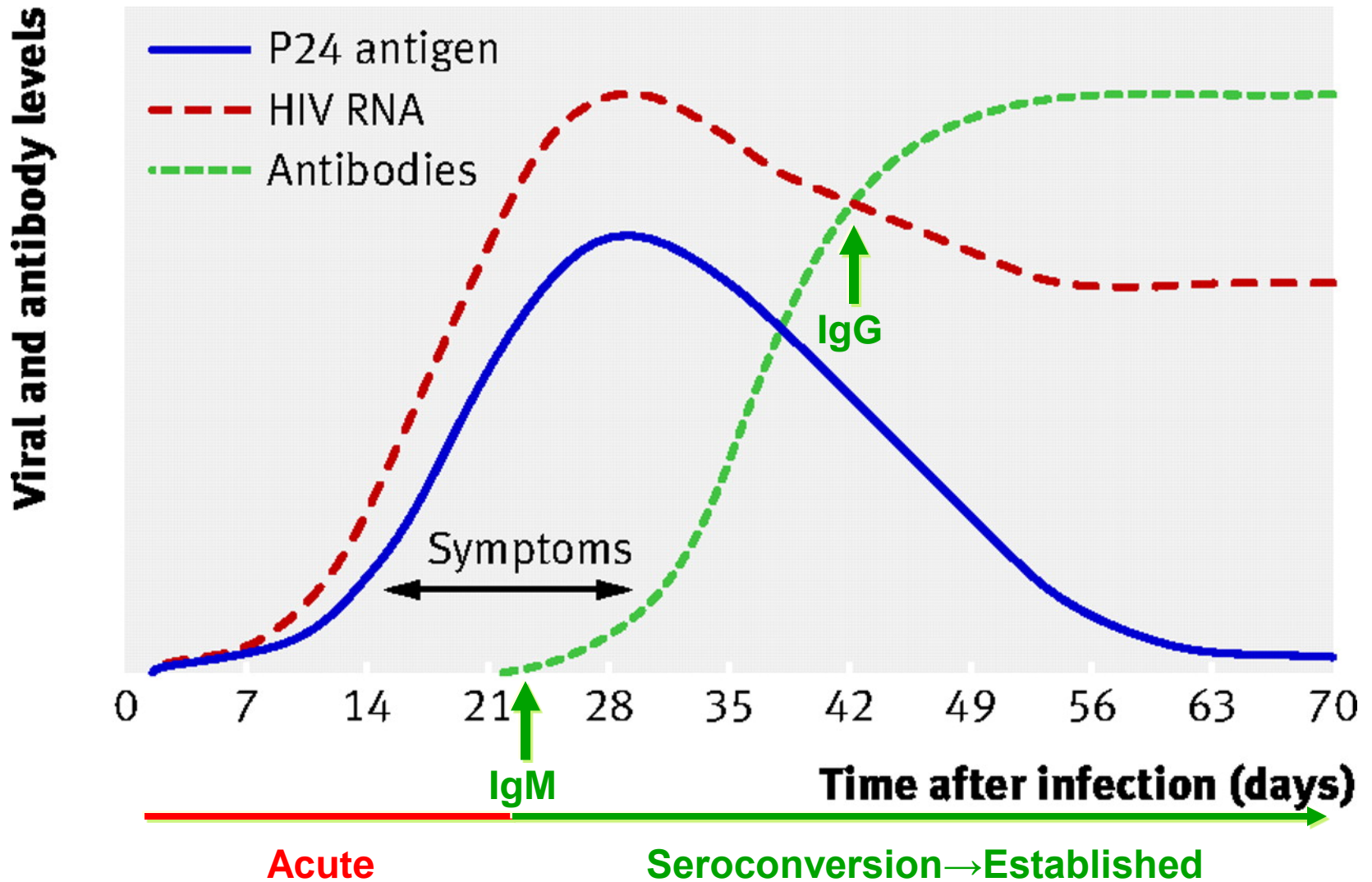




# HIV Progression and Immune Response

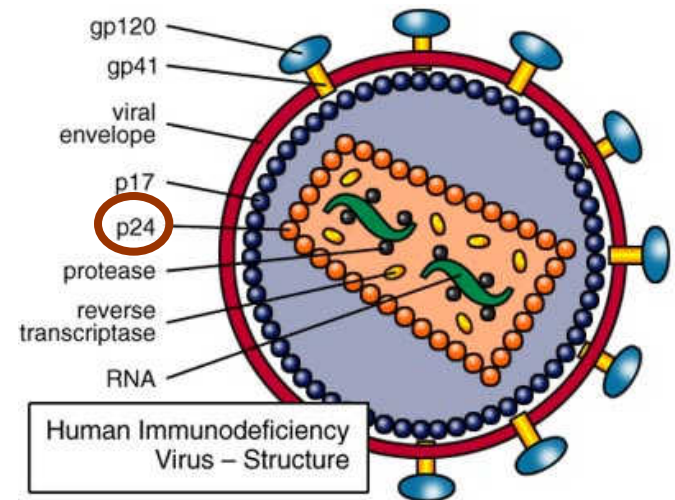


# Progression of HIV Viral Markers

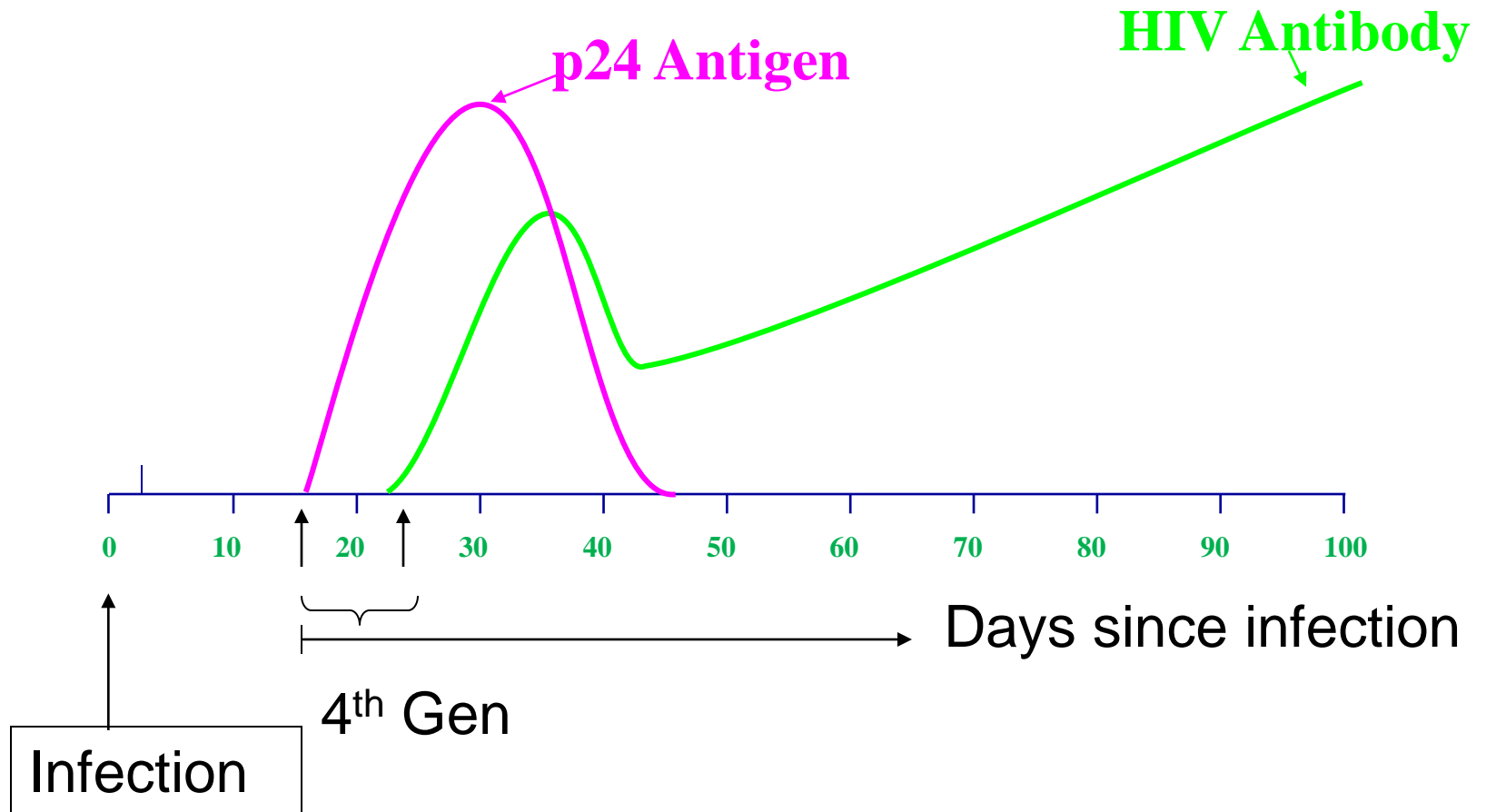


# p24 Antigen

- An antigen is a virus, part of a virus, or a foreign body that triggers the production of antibodies in the body
- p24 is the antigen on HIV-1 that most commonly provokes an antibody response
- First marker of HIV-1 infection
- Can be detected at 2 weeks from infection



# HIV Progression and Detectable Response



# 4<sup>th</sup> Generation Ag/Ab Test

- 2 FDA-approved kits available
  - ARCHITECT HIV Ag/Ab Combo (Abbott)
  - GS HIV Ag/Ab Combo EIA (Bio-Rad)
- Detects HIV-1 p24 Ag, HIV-1 and HIV-2 antibodies
- Reactive result:
  - Doesn't distinguish between Ag and Ab
  - Preliminary positive
  - Supplemental testing required

# Why do we need new HIV testing strategies/algorithms?

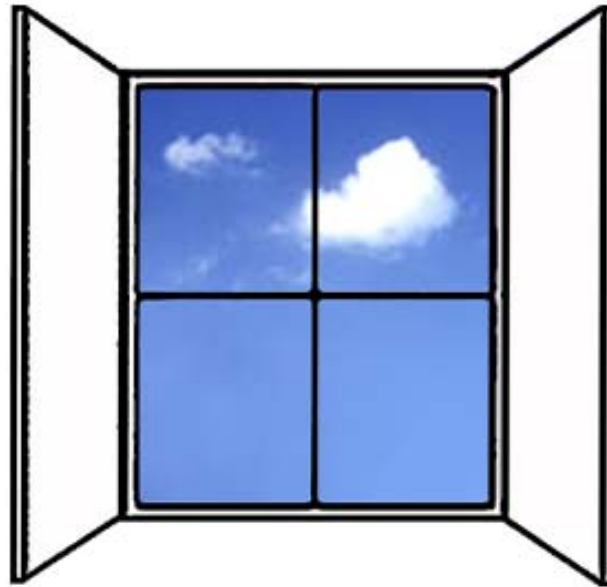
- Laboratory algorithm established by CDC and APHL (ASTPHLD) in the late 1980's
  - Over 20 years later remains largely unchanged
- More is known about the disease
  - HIV-1 and HIV-2
  - Window Period
- Evolving technology
  - Tests recently approved by FDA are not included
  - Availability of rapid tests
  - Increased sensitivity of screening assays
    - Western blot and IFA now less sensitive than some screening assays which they are intended to “confirm”

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# Diagnostic Window of Detection

- The time from infection to detection
- Varies depending on the test used





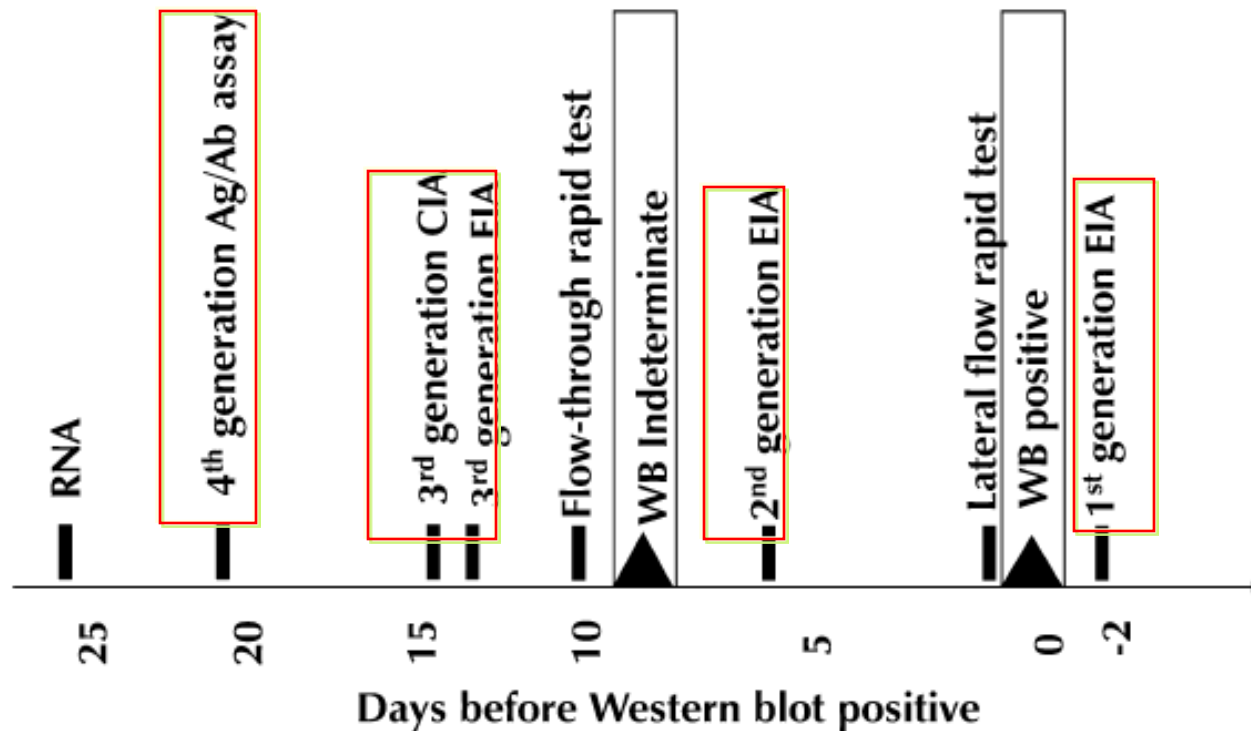
# Windows of Detection

Test	Window of Detection
<b>4<sup>th</sup> Gen:</b> <ul style="list-style-type: none"><li>• <b>Conventional</b></li></ul>	<b>2 weeks</b>
3 <sup>rd</sup> Gen: <ul style="list-style-type: none"><li>• Conventional</li><li>• Rapid HIV Test</li></ul>	2-8 weeks ( <u>avg. 25 days</u> )

# Acute HIV Infection

- The risk of transmitting HIV to others is high during acute infection. Therefore, **risk reduction measures are especially important** during this time.
- Initiating antiretroviral treatment during acute HIV infection may:
  - reduce the HIV viral setpoint and preserve key immune response functions that may slow disease progression
  - reduce the likelihood of transmission to others.
- These advantages may be outweighed by practical concerns about an individual patient's ability or readiness to take multiple medications.
- Decisions about treatment are individualized. However, with acute infections, **initiating care with an Infectious Disease clinician is crucial and very time-sensitive.**

# Relative Sensitivity of Tests



**FIGURE 2.** Reactivity of FDA-approved assays for HIV-1 compared with Western blot.

From: Branson, JAIDS, 2010, 55 (S2): S102-S105

# 4<sup>th</sup> Generation HIV Ag/Ab EIA Test

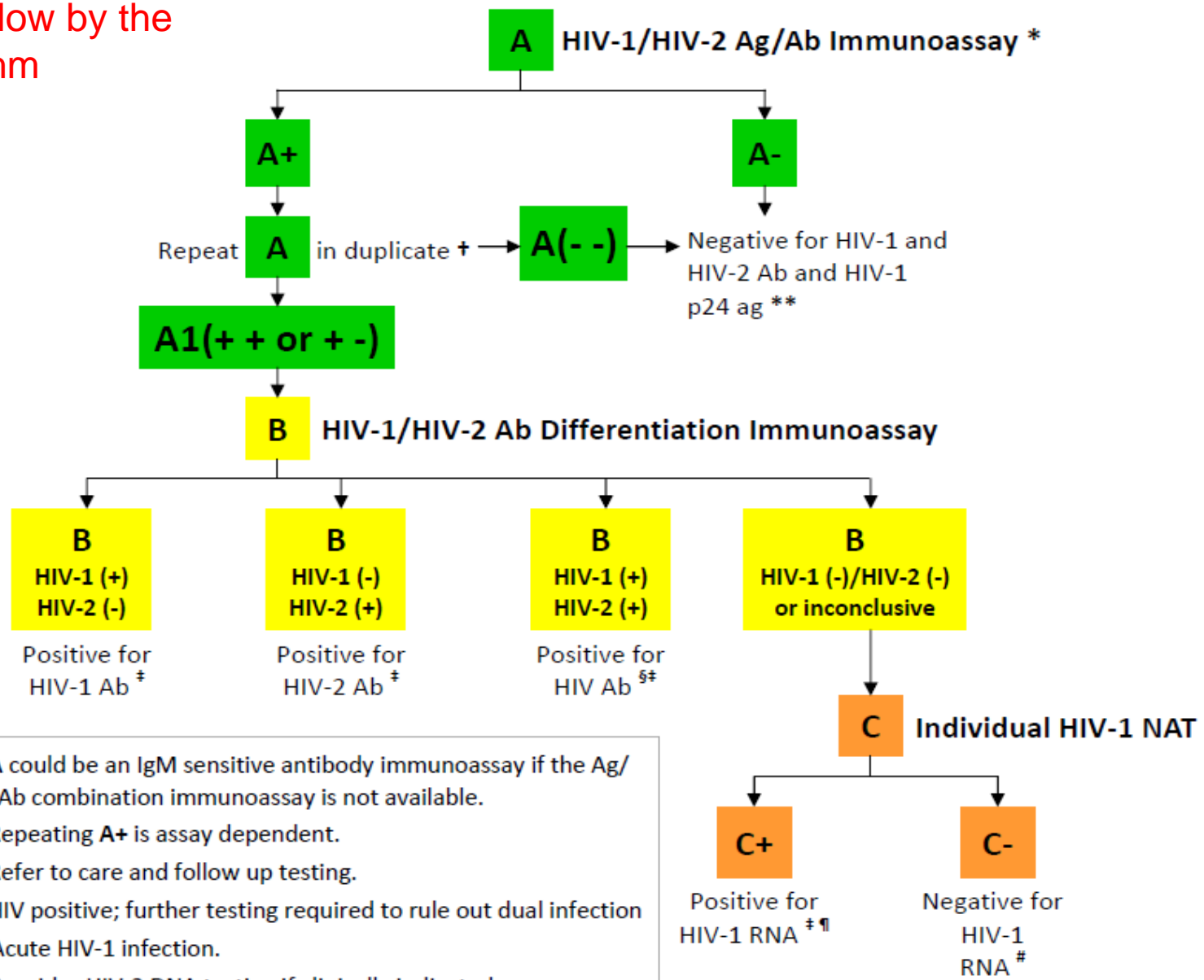
- Combined antigen/antibody test
- Can detect...
  - p24 antigen
  - HIV-1 antibodies
  - HIV-2 antibodies
- But...cannot tell them apart

# What are we looking for from these new testing strategies?

- Resolution of indeterminates
- Ability to confirm HIV-2 infections
- Increased detection of acute infection
- Use of assays as screening or confirmatory/ supplemental tests and as part of multi-test algorithms

The New (Conventional)  
HIV Testing Algorithm:  
Get to Know It!

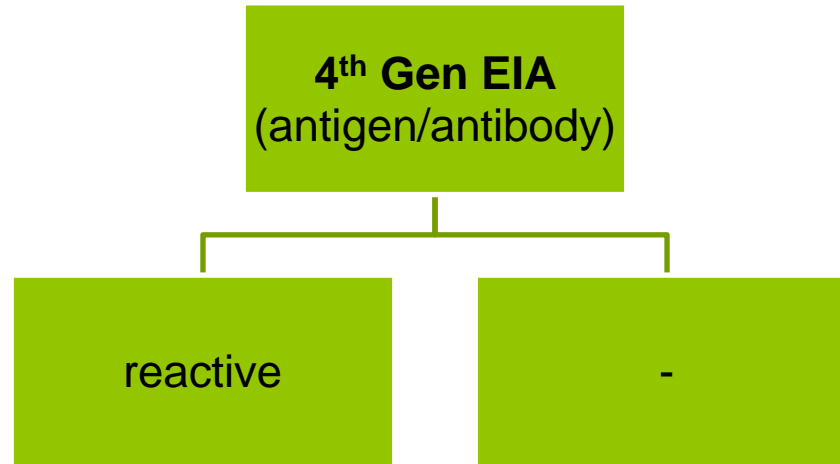
Rapid Tests Performed in the Field follow by the new Algorithm



\* A could be an IgM sensitive antibody immunoassay if the Ag/Ab combination immunoassay is not available.  
 † Repeating A+ is assay dependent.  
 ‡ Refer to care and follow up testing.  
 § HIV positive; further testing required to rule out dual infection  
 ¶ Acute HIV-1 infection.  
 # Consider HIV-2 DNA testing if clinically indicated.  
 \*\* If early acute infection is suspected, NAT can be performed

# New HIV Testing Algorithm

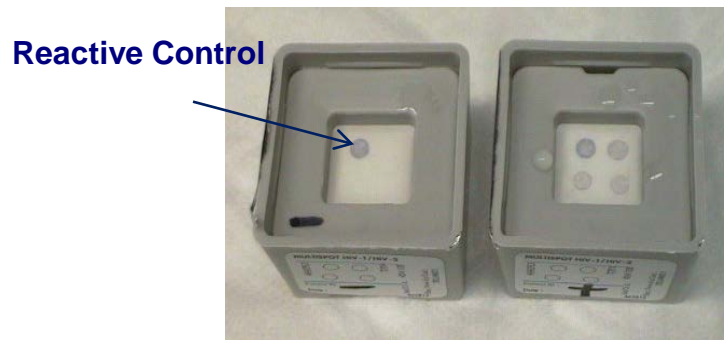
## Step 1





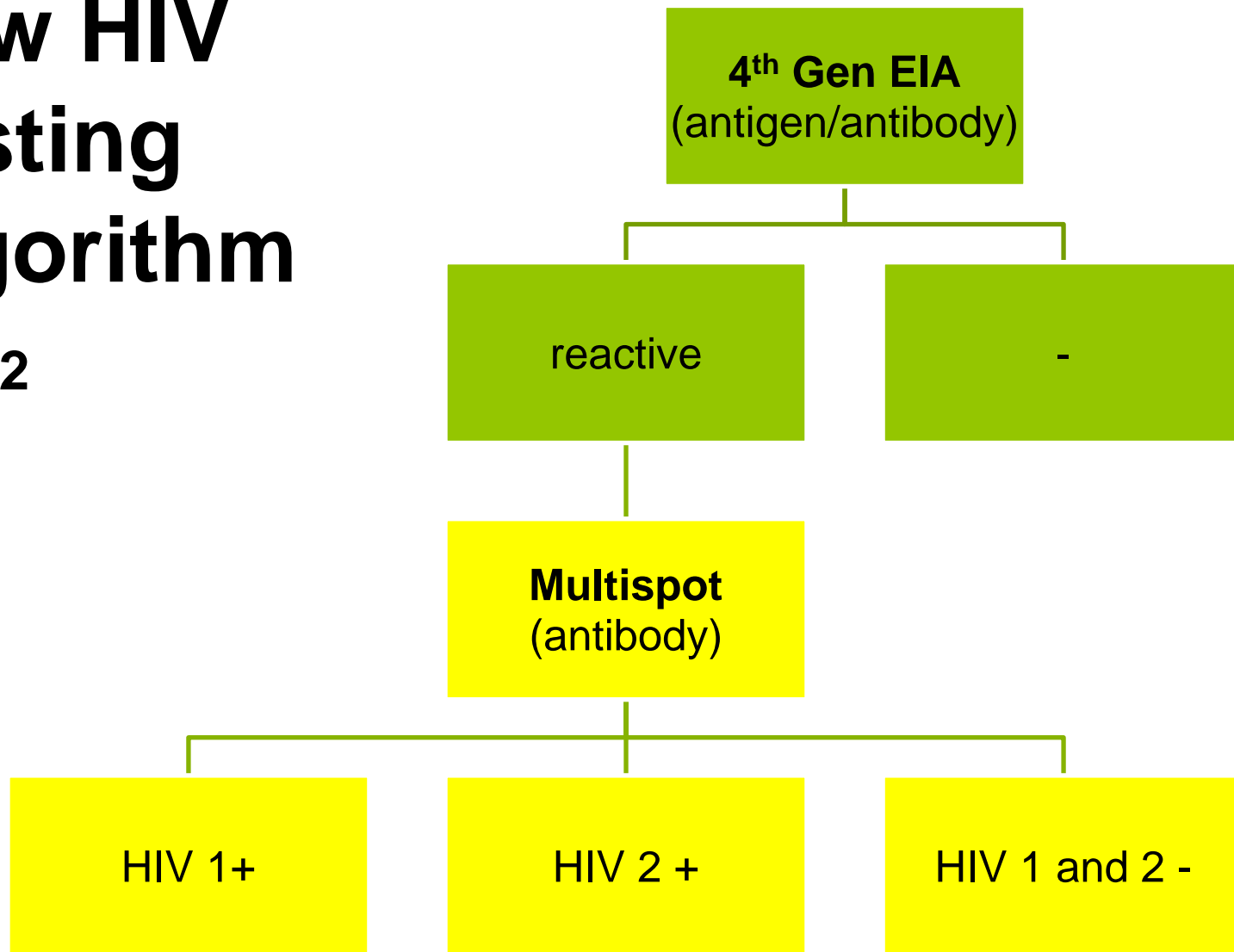
# Multispot HIV Ab Test

- Supplemental test
  - used after a reactive 4<sup>th</sup> Gen EIA
- Replaces WB
  - More sensitive and specific than WB
  - Faster and less expensive than WB
- Will differentiate HIV-1 and HIV-2



# New HIV Testing Algorithm

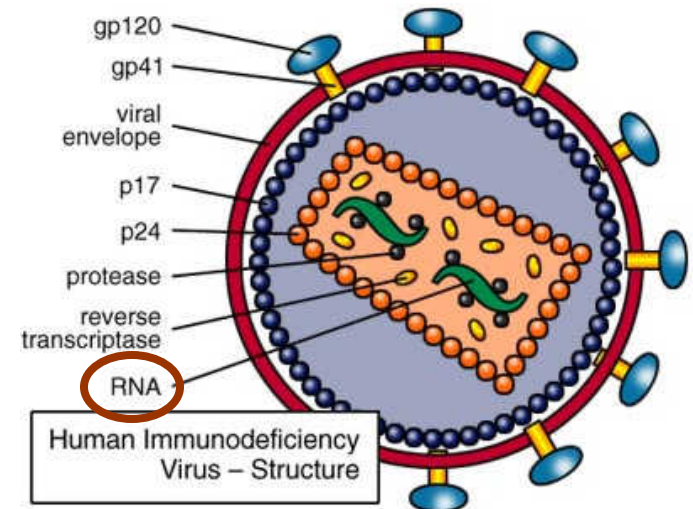
## Step 2



**What if you get a non-reactive result from the Multispot antibody test?**

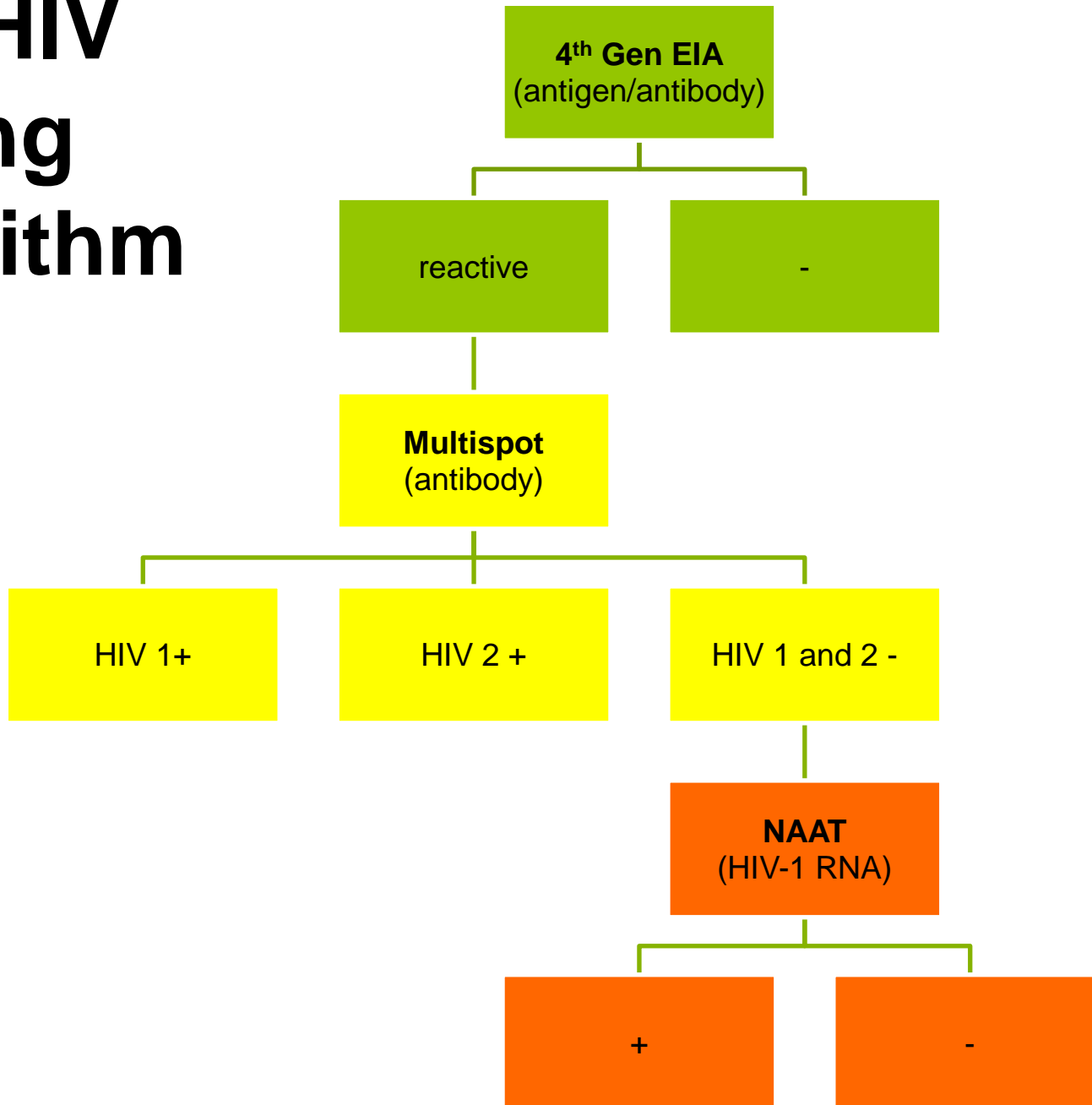
# Nucleic Acid Amplification Test for HIV-1 RNA

- Supplemental test
  - Used after a reactive EIA and a non-reactive Multispot
- Highly sensitive test which can detect the presence of viral RNA
- HIV-1 RNA/NAAT testing can detect acute HIV-1 infection

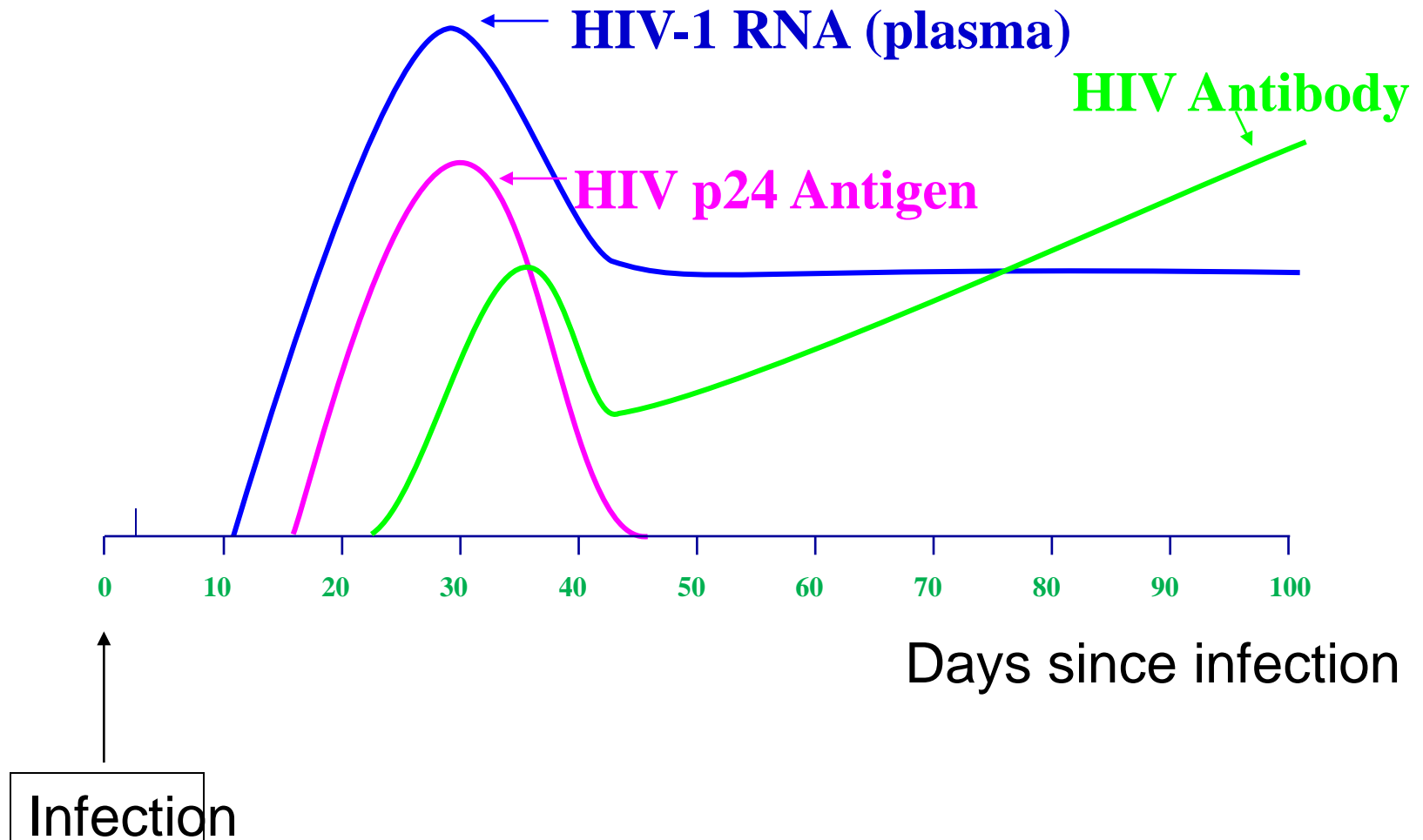


# New HIV Testing Algorithm

## Step 3



# HIV Progression and Detectable Response



# New HIV Testing Algorithm Results

Lab Report	<i>Interpretation</i>
<b>Negative.</b> HIV-1 p24 antigen, HIV-1 and HIV-2 antibodies not detected.	<i>If client did not have risk in the two weeks before the test or since, the client does not have HIV.</i>
<b>Positive.</b> HIV-1 antibodies detected.	<i>The client has HIV-1.</i>
<b>Positive.</b> HIV-2 antibodies detected.	<i>The client has HIV-2.</i>
<b>Positive.</b> A reactive HIV antigen/antibody test and a positive HIV-1 RNA test indicate acute HIV-1 infection.	<i>The client has HIV-1 and the test result indicates that s/he was recently infected (likely 2-8 weeks before taking the test).</i>
<b>Negative.</b> HIV antibodies not detected. No detectable HIV-1 RNA. HIV-2 infection cannot be excluded.**	<i>The client does not have HIV-1. The client should be retested in two weeks to rule out possibility of acute HIV-2.</i>

# Point of Care Tests in Iowa



**OraQuick  
ADVANCE**

If Positive  
and blood  
not drawn

SHL performs  
Oral Fluid  
Western Blot



**Clearview Complete HIV 1/2**

If Positive

SHL performs  
Antigen/Antibody  
follows algorithm

If Positive  
and blood drawn

# What if the Multispot is Negative?

- SHL will send the serum to Florida's State Public Health Lab for NAAT testing.
  - If NAAT is positive, the patient is HIV positive
  - If NAAT is negative, the patient is HIV negative



hivrequestformNEW (2).pdf - Adobe Reader

File Edit View Window Help

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**Specimen Type:** Check appropriate specimen and fill in requested information (Only one sample per form).

Oral mucosal transudate  
 Serum  
 Plasma

**PATIENT:**  
 BIRTH DATE:  /  /  SSN #:  -  -   
 ADDRESS: \_\_\_\_\_  
 CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP: \_\_\_\_\_  
 PHONE: ( ) - \_\_\_\_\_ GENDER:  Female  Male  
 RACE:  White  Black  Asian  American Indian / Alaskan Native  
 Native Hawaiian / Pacific Islander  Unknown  
 ETHNICITY:  Hispanic  Non Hispanic  Unknown

PATIENT ID #: \_\_\_\_\_ CLINICIAN ID #: \_\_\_\_\_  
 CLINICIAN: \_\_\_\_\_  
 please print last first  
 PHONE: ( ) - \_\_\_\_\_ CLINICIAN'S Signature: \_\_\_\_\_

As the clinician providing care to this patient, I request that this test be performed without charge to this patient because of the imminent and significant public health threat posed by the differential diagnosis.

DATE COLLECTED:  /  /

**Test(s) Requested**

HIV Antigen/Antibody Screen  
 HIV Confirmation Testing  
 Previous Reactive Test Method \_\_\_\_\_ (required for confirmation)

**MEDICAID / MEDICARE INFORMATION**

Patient's Medicaid/Medicare #: \_\_\_\_\_  
 Physician Provider #: \_\_\_\_\_  
 ICD9 Diagnosis Code (REQUIRED): \_\_\_\_\_  
 Referring Physician # (Medipass only): \_\_\_\_\_  
**If insurance is primary to Medicaid / Medicare**  
 Insured's Name: \_\_\_\_\_  
 Insured's ID#: \_\_\_\_\_ please print  
 Insurance Company Name: \_\_\_\_\_  
 Insurance Company Address: \_\_\_\_\_  
 City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

**State Hygienic Laboratory**  
 University of Iowa Research Park  
 2490 Crosspark Road, Corvallis, IA 52241  
 Phone #: 319-335-4500  
 Fax #: 319-335-4555  
 http://www.sni.uiowa.edu

Place IDPH Label Here

Enter your facility address  
 Results are returned to this address

hiv 102012

# HIV Testing Instructions

## Submission Requirements:

- Serum, Plasma and Oral Fluids are accepted for HIV antibody testing.
- Acceptable specimens for HIV Ag/Ab Combo testing include serum and plasma ONLY.
- Label tube with patient's name or unique identifier, date of birth (DOB), and the date of collection.
- **UNLABELED SPECIMENS WILL NOT BE TESTED.**
- A completed HIV Test Request Form must accompany specimen.

## Specimen Collection and Handling:

- Blood samples must be collected in a red stopper, serum separator (SST), or a tube without anticoagulants.  
When possible samples should be centrifuged to separate serum from cells.
- Following collection serum samples may be stored at room temperature for 3 days or 2-8°C for 7 days.
- 1 ml of serum is the minimum recommended volume for submission.
- Oral fluid samples must be collected in an OraSure collection device. See device for collection instructions.
- OraSure specimens may be stored from 4-37°C for a maximum of 21 days from the time of collection, including the time for shipping and testing.
- Label specimen, wrap the collection tube in absorbent material, and place into a biohazard bag.

# HIV Testing Instructions (continued)

## Complete Test Request Form

- Complete a Test Request Form which includes the following information:
  - Two unique identifiers including the patients name if an Iowa test site, other states can use unique identification number.
  - Must indicate patient's date of birth.
  - Specimen type and date of collection.
  - Test requested marked clearly.
  - Previous reactive test method (if applicable).
  - Clinician and return address of the submitter.
  - ID on specimen collection container must match the ID on the Test Request Form.

## Shipping Instructions

- Include completed HIV Test Request Form in outside pocket of biohazard bag.
- Roll up the bag and place in mailer.
- Seal mailer with a S-coded self-adhesive wrapper provided with SHL kit or equivalent.
- Ship at ambient temperature as soon as possible via first class mail. **DO NOT USE WET ICE.**
- Ship multiple specimens in packaging compliant with USPS or IATA regulations.
- If delays in transport are anticipated, refrigerate specimens until shipment.

## Contact Information

- For test request forms and kits call 319-335-4379.
- Test request forms may be obtained online at <http://www.shl.uiowa.edu/testmenu/clinicaltestmenu.xml>
- Any questions should be directed to Serology @ 319-335-4275.

# Also Remember

- Test must be received in 3 days by SHL or refrigerate for up to 7 days

# Iowa Guidelines

- Use Clearview Rapid
- Architect Ag/Ab Test is performed at SHL and confirms positive Clearview Rapid

# For More Information

Proposed HIV Test Algorithms:

<http://www.hivtestingconferencearchive.org/hivtesting2010/>

Click on "[HIV Testing Algorithms: A Status Report](#)"

CDC HIV testing resources:

<http://www.cdc.gov/hiv/topics/testing/index.htm>

<http://www.cdc.gov/dls/waivedtests>

APHL resources:

<http://www.aphl.org/aphlprograms/infectious/hiv/Pages/default.aspx>

NASTAD resources:

<http://www.nastad.org/resources.aspx?searchkey=hiv%20prevention>

# Questions?