



HIV PREVENTION COUNSELING: THE FACTS

HIV TESTING OPTIONS

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Choosing A Test

Things to consider:

- Accessibility
- Ease of Use
- Accuracy
- Cost of Test



Anonymous vs. Confidential Testing

Anonymous

- No identifying information
- Not reported
- Not available in all states
- Includes home-based testing

If positive:

- Cannot be linked to care/services until confidential testing is done

Confidential

- Name or unique identifier
- Reported
- Available nationwide

If positive:

- Can be referred to services immediately



Understanding Test Accuracy

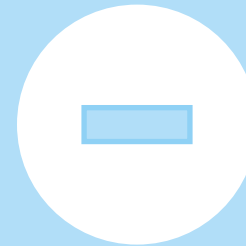
Sensitivity

True positive rate – how well can the test detect a real positive?



Specificity

True negative rate – how well can the test detect a real negative?



Understanding Test Accuracy

False Positives

LAB

Detects HIV
antibodies/antigens

BODY

No antibodies/antigens
present

False Negatives

LAB

Does not detect
antibodies/antigens

BODY

Antibodies/antigens are
present

Understanding Test Types

Rapid

- Specimen is collected and the test is performed right away
- Produces results in 20 minutes or less

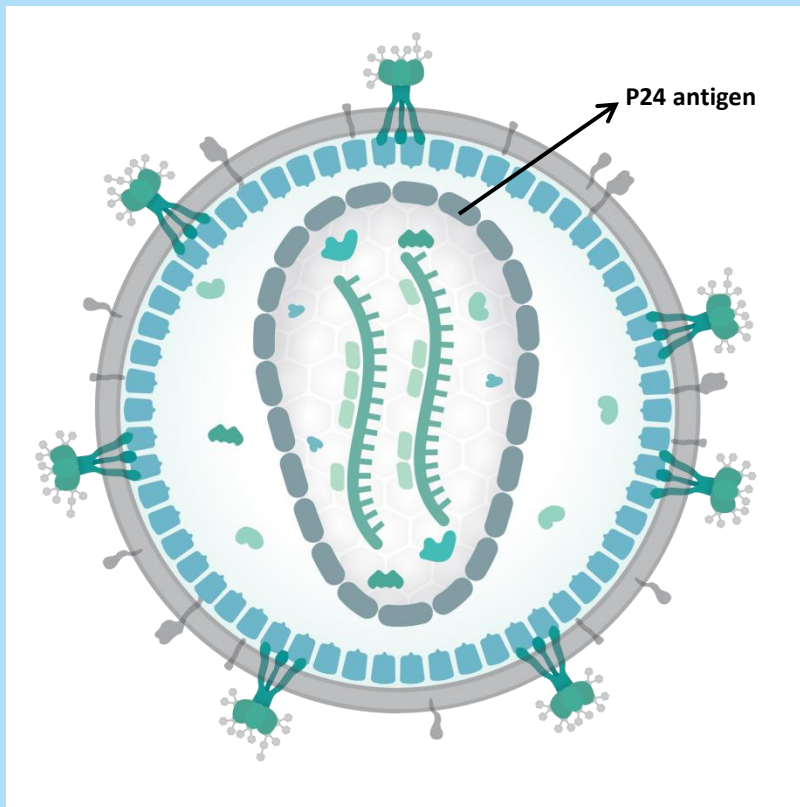
Conventional

- Specimen is collected and sent to a laboratory for testing
- Results can take several days to 1-2 weeks

Antigen vs. Antibody Testing

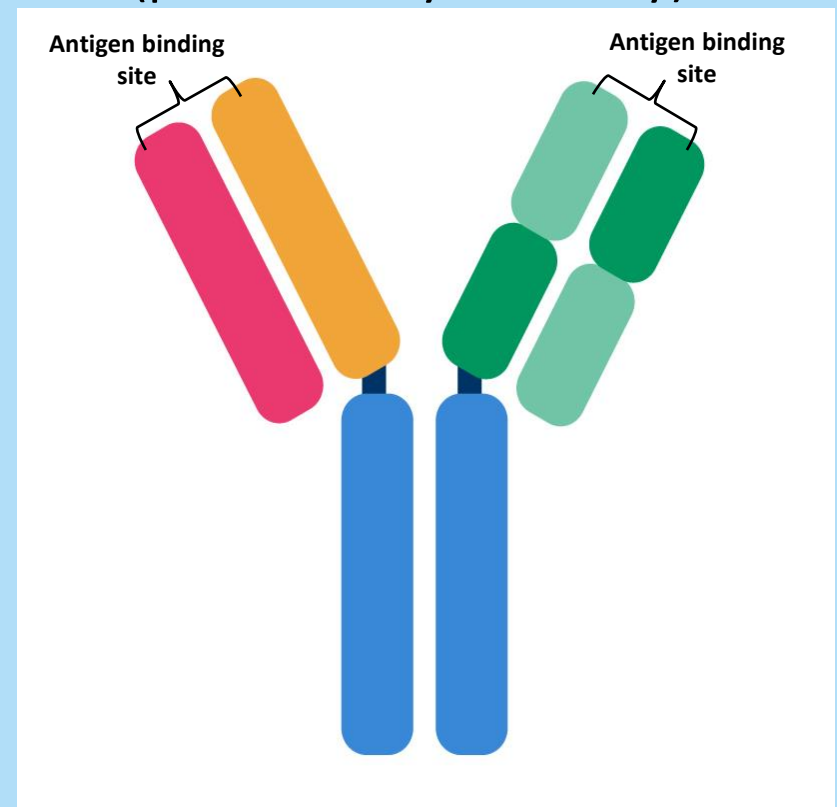
Antigen

(portion of the virus)



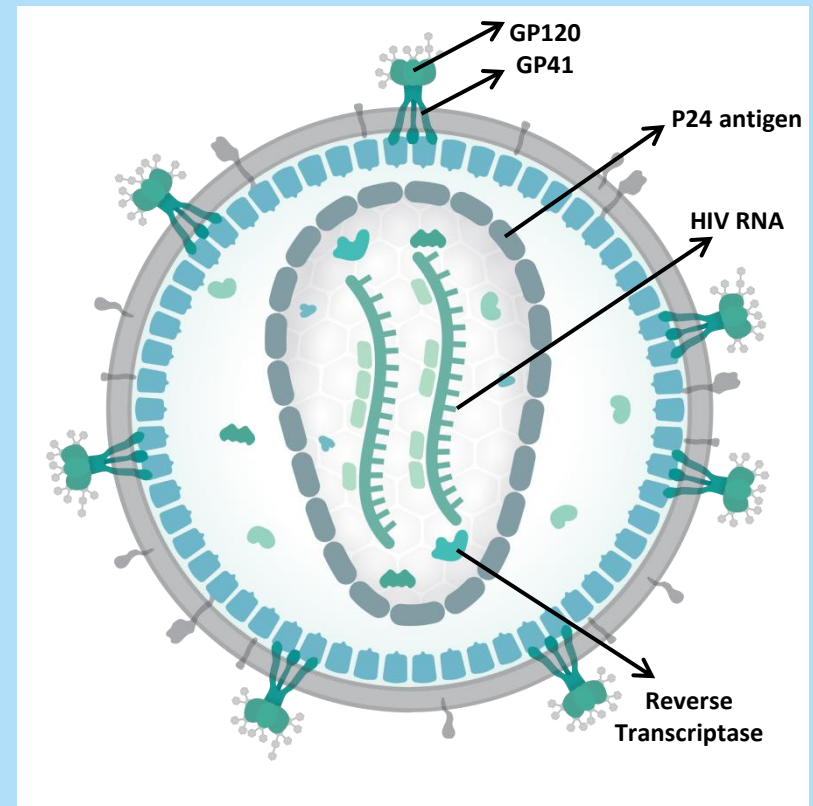
Antibody

(produced by the body)

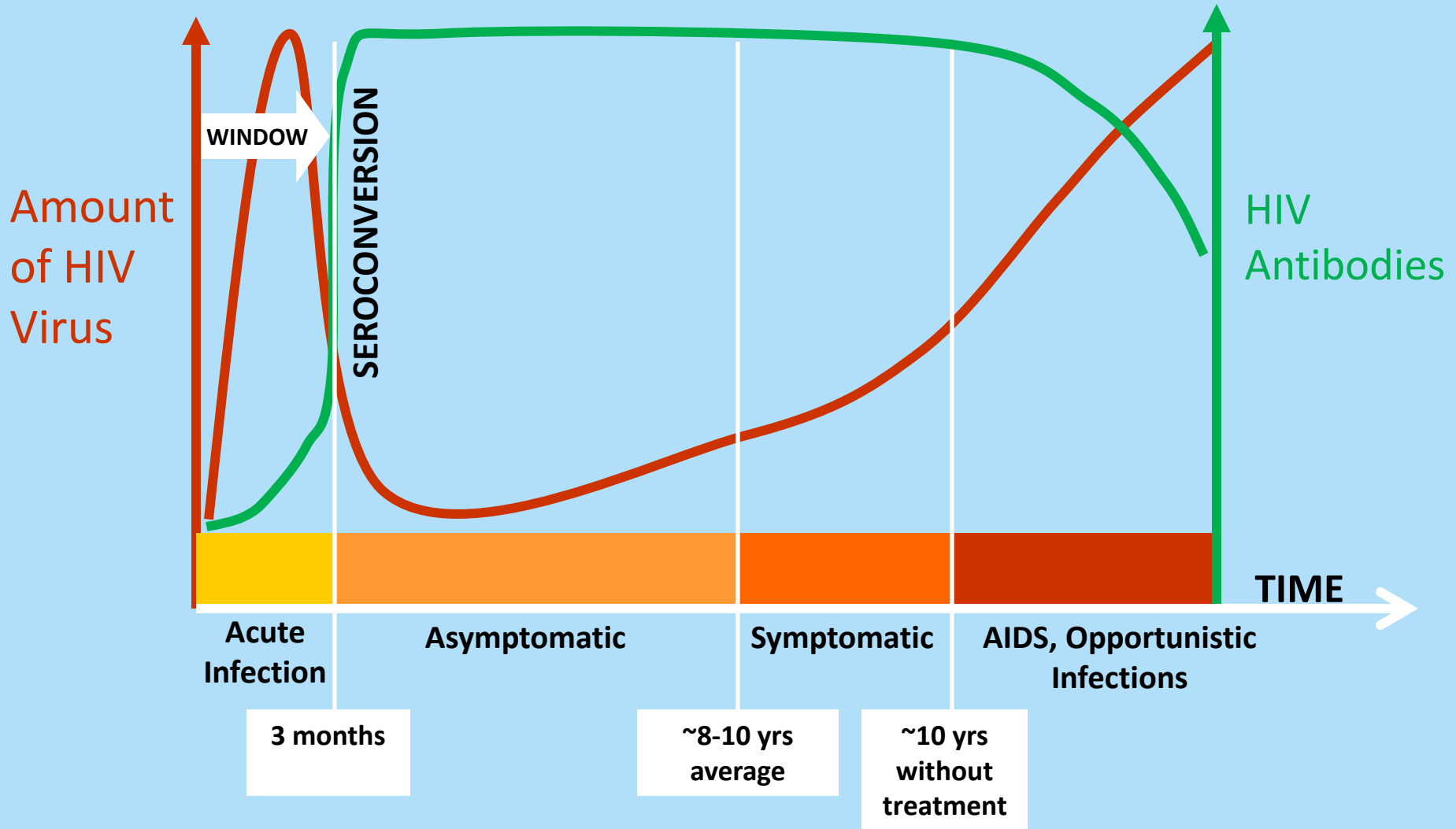


HIV-1 P24 Antigen (p24 Ag)

- Viral protein that makes up most of HIV-1 viral core
- Serum concentrations of p24 antigen high in **first few weeks after infection & appear again in end stage HIV infection**
- Tests sensitive to p24 antigen useful for diagnosing very early infection (i.e., acute) when antibody levels are below antibody-based assay detection limits



The Progression of HIV



RAPID HIV TEST TECHNOLOGIES



CLIA Waiver

- CLIA: Clinical Laboratory Improvement Amendments
- Under CLIA regulations, the FDA defines rapid HIV tests as **waived** because:
 - Simple laboratory examinations and procedures that are cleared by the FDA for home use
 - Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible
 - Or pose no reasonable risk of harm to the patient if the test is performed incorrectly



**U.S. FOOD & DRUG
ADMINISTRATION**



4th Generation Rapid HIV Testing

- Combined antibody/antigen test
 - Human HIV antibody
 - Viral capsid p24 antigen
- p24 antigen without antibody indicates early (acute) infection



Alere Determine (Rapid)

- 4th Generation
- CLIA waived for fingerstick/whole blood
- 20 minutes
- Detects the **p24 antigen and HIV antibodies**
- Can detect HIV infection within about 4 weeks of infection
- Requires 50 μ l whole blood/finger stick blood



INSTI (Rapid)

- Detects HIV 1 and HIV 2 antibodies
- FDA Approved: December 1, 2010
- Flow-through technology, produces results in as little as 60 seconds
- Requires 50 μ l whole blood, finger stick blood, or plasma



OraQuick Advance (Rapid)

- Detects HIV 1 and HIV 2 antibodies
- 20 minute test
- CLIA waived for for whole blood/oral fluid/plasma
- Test kit must remain stationary
- Finger stick is more accurate than oral. With oral, must follow instructions so as not to over-swab



Clearview Complete (Rapid)

- Detects HIV 1 and HIV 2 antibodies
- 15 minute test
- CLIA waived for whole blood/serum/ plasma
- Test station does not need to be stationary!



Home Based Testing

OraQuick

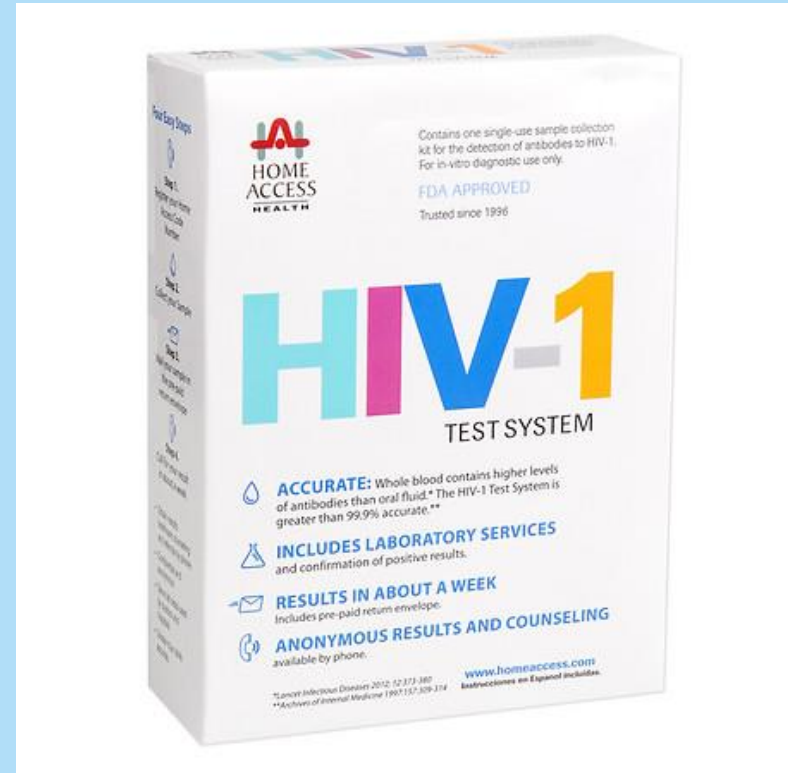
- Detects HIV 1 and HIV 2 antibodies
- 20 minute test
- Costs around \$40 at drug stores
- Oral swab only
- Anonymous
- 24/7 phone counseling available
- If result is positive, it's up to the client to seek care (after a confirmatory test)



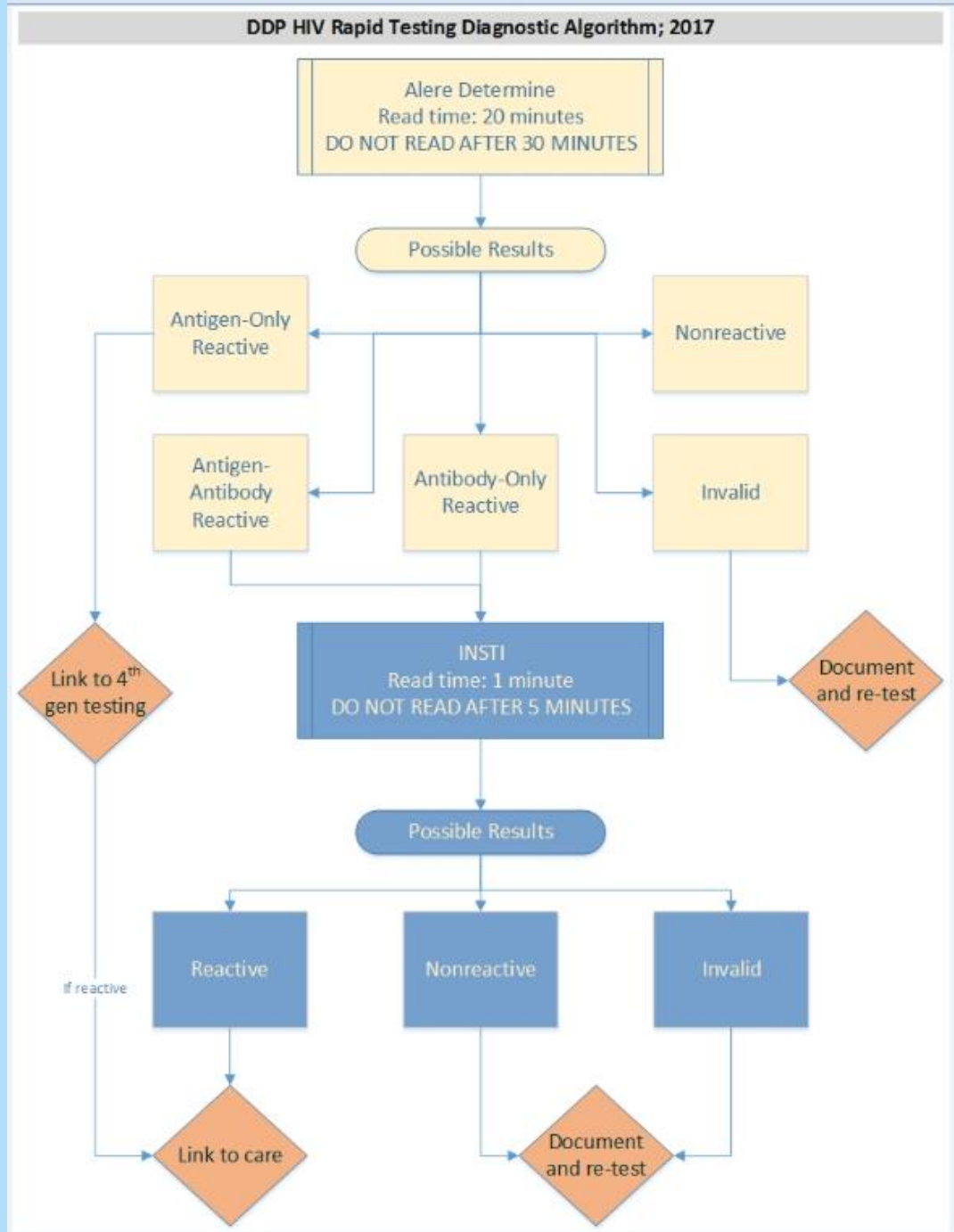
Home Based Testing

Home Access

- Detects HIV 1 antibodies
- Specimen: dried blood spot
- Accuracy: comparable to standard serology
- Results provided by phone
- Anonymous



4th Generation Rapid-Rapid Algorithm



HIV Conventional Testing Through the Generations

Screening Tests : EIA (Enzyme Immunoassay)

- **1st Generation EIA (1985)**
 - Detects HIV-1 IgG **Antibody**
- **2nd Generation EIA (1991)**
 - Detects HIV-1 IgG **Antibody**
- **3rd Generation EIA (1992)**
 - Detects HIV-1/HIV-2 IgM & IgG **Antibodies**

Old Algorithm:

Confirmation of HIV-1 by Western Blot Assay

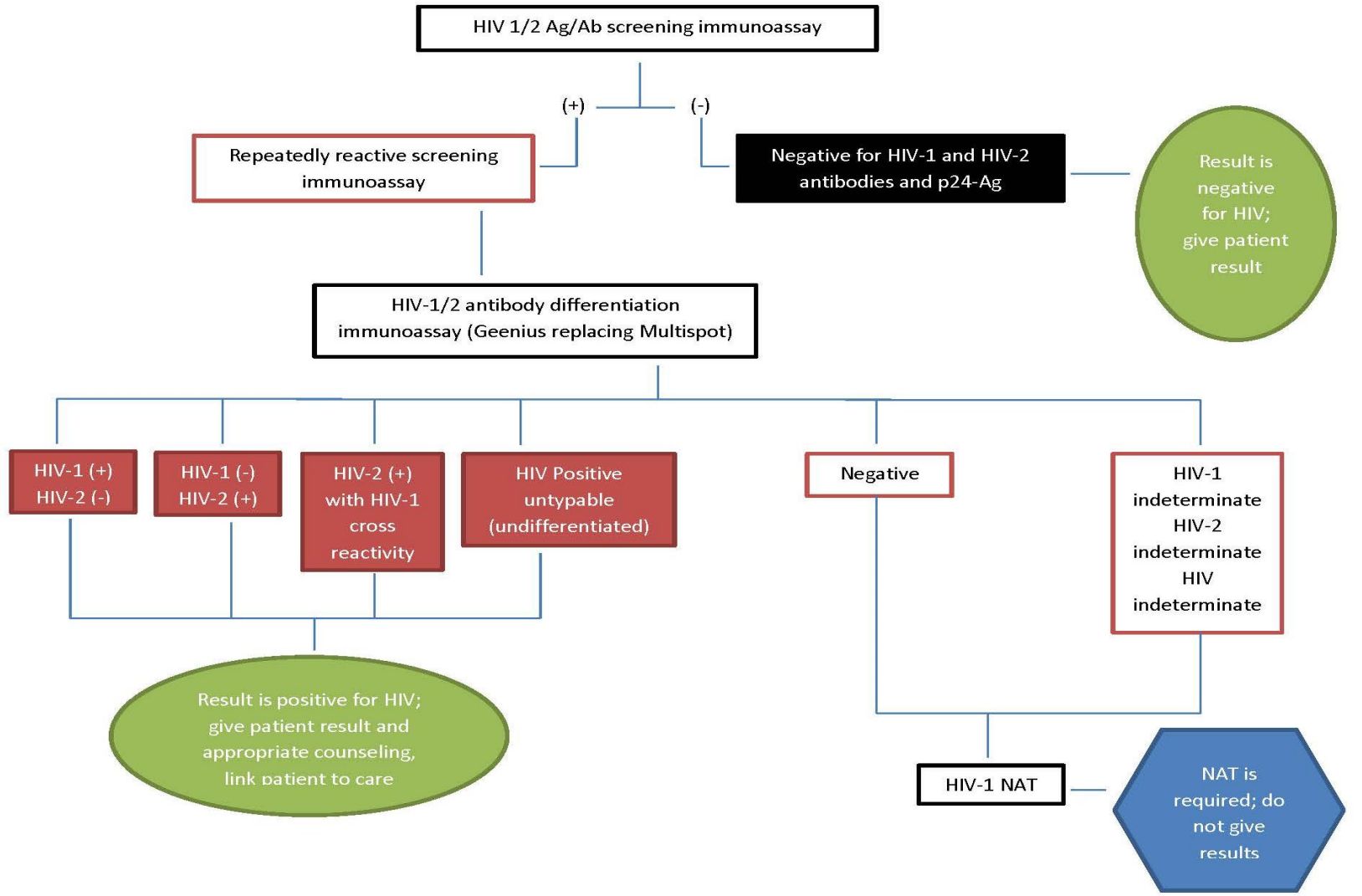
- **4th Generation EIA (2010)**
 - Detects HIV-1/HIV-2 IgM, **IgG Antibodies PLUS p24 Antigen**, however does NOT distinguish which test component of the assay is positive

New Algorithm:

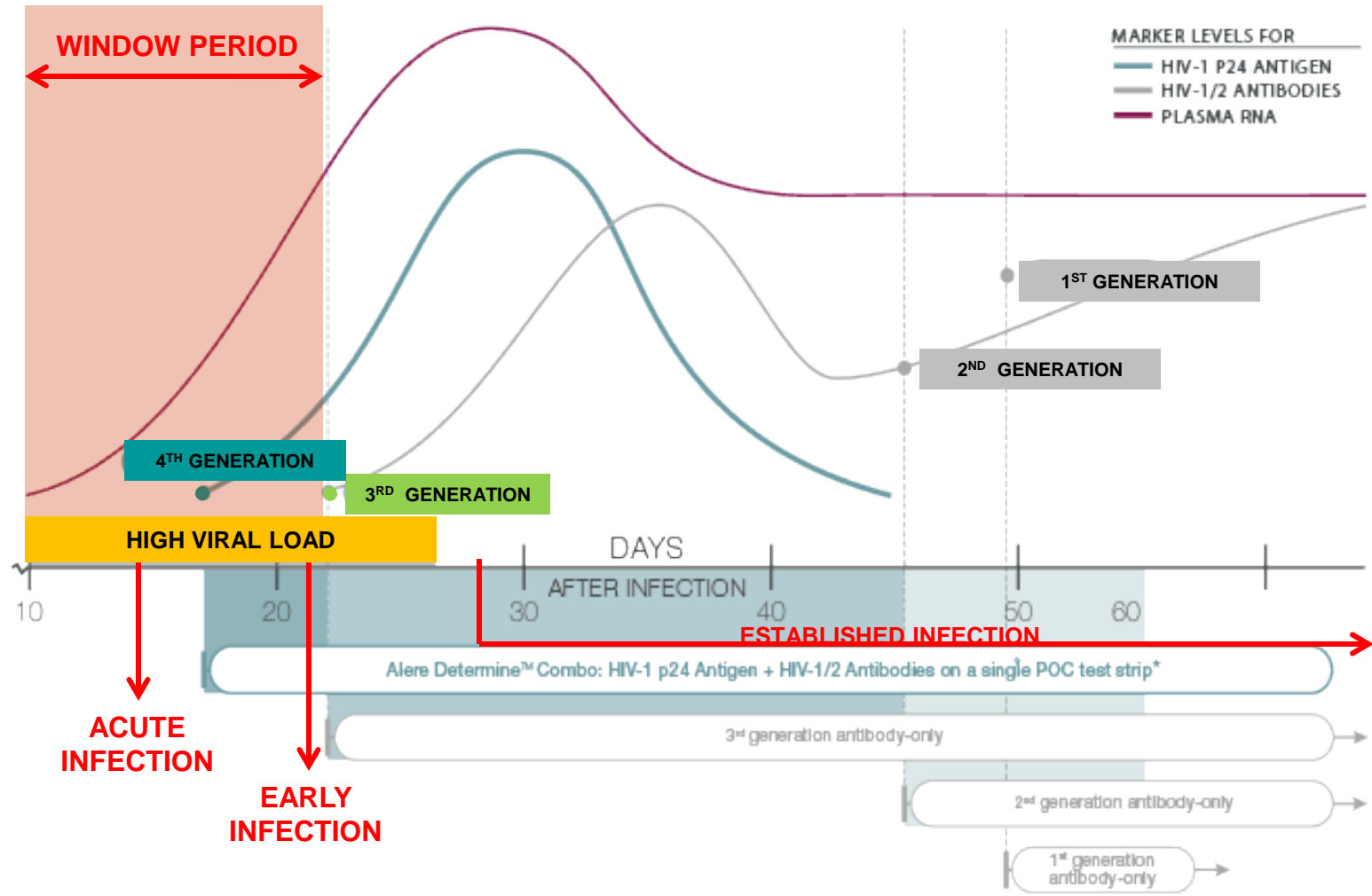
Identification of HIV-1 & HIV-2 by Differentiation Assay (Geenius)



4th Generation Conventional Algorithm



Window Period: Infection to Detection



*Not comparable to molecular testing

US Food and Drug Administration

Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays

- Licensed/Approved HIV, HTLV, and Hepatitis Tests.
- Found at www.fda.gov/cber/products/testkits.htm



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| Anti-HIV-1 Assays (detect antibodies to Human Immunodeficiency Virus type 1) | | | | | | | |
|--|------------------|--------|---|--|---|-----------------------|----------------------|
| Tradename | Infectious Agent | Format | Specimen | Use | Manufacturer | Approval Date | STN |
| Fluorognost HIV-1 IFA | HIV-1 | IFA | Serum / Plasma Dried Blood Spot | Diagnostic and Donor Supplemental: Qualitative detection of antibodies to HIV-1 for use as an additional, more specific test in specimens found to be repeatedly reactive by screening procedures. Donor Screening: Only in special cases. | Sanochemia Pharmazeutika AG Vienna, Austria US License 1631 | 2/5/1992 5/14/1996 | BL103288 BL103651 |
| Cambridge Biotech HIV-1 Western Blot Kit | HIV-1 | WB | Serum / Plasma | Diagnostic and Donor Supplemental: Qualitative detection of antibodies to HIV-1 for use as an additional, more specific test in specimens found to be repeatedly reactive by screening procedures. | Maxim Biomedical, Inc. Rockville, MD US License 1741 | 5/28/1998 | BL103843 |
| GS HIV-1 Western Blot | HIV-1 | WB | Serum / Plasma Dried Blood Spot | Diagnostic and Donor Supplemental: Qualitative detection of antibodies to HIV-1 for use as an additional, more specific test in specimens found to be repeatedly reactive by screening procedures. | Bio-Rad Laboratories Redmond, WA US License 1109 | 11/13/1998 | BL103655 |
| Avioq HIV-1 Microelisa System | HIV-1 | EIA | Serum, Plasma, Dried Blood Spot, Oral Fluid | In Vitro Diagnostic: Qualitative detection of antibodies to HIV-1. | Avioq Inc., Rockville, MD | 9/21/2009 | BP090022 |
| Maxim | HIV-1 | EIA | Urine | In Vitro Diagnostic: Qualitative | Maxim | 1/12/2001 | BP000009 |



Confidential HIV Testing Locations in Northern Virginia

To find a HIV testing site near you, visit www.hivtest.org or Text your zip code to **KNOWIT (566948)** to learn about the nearest testing location.

| Agency | Street Address | City | Phone | Regular Testing Hours |
|---|---|----------------|--------------|--|
| AIDS Response Effort (ARE) <i>Rapid Testing Only</i> | 124 W. Piccadilly St. | Winchester | 540-536-2971 | By Appointment, Monday - Friday |
| Alexandria City <i>Rapid Testing Wed and Thurs afternoons</i> <i>Rainbow Tuesday Clinic (separate listing below)</i> | 4480 King St. 2 nd Floor | Alexandria | 703-746-4976 | Wed: 1:00pm – 3:00pm Thursday: 5:00pm – 6:30 pm |
| Arlington County <i>Rapid Testing Available</i> | 2100 Washington Blvd., 2nd Floor | Arlington | 703-228-1200 | HIV testing services by appointment or walk-in at the STI clinic on Thursday 2-6pm |
| FAHASS (Fredericksburg Area HIV/AIDS Support Services) <i>Rapid Testing Only</i> | 415 Elm Street 4701 Market Pl. 2 nd Floor | Fredericksburg | 540-371-7532 | Monday - Friday: 9:00am – 5:00pm Wednesday: 9:00am – 7:00pm |
| Fairfax County: Annandale | 7611 Little River TnPk # 400 (East Wing) | Annandale | 703-534-8343 | By appointment Monday – Friday HIV testing also available during the following times (walk-in service only): Monday: 8am – 12:30pm and 1:30pm – 3:00pm Tuesday: 10am – 2pm Wednesday: 8am – 12:30pm |
| Fairfax County: Herndon Reston | 1850 Cameron Glen Dr # 100 | Reston | 703-481-4242 | By appointment Monday – Friday HIV testing also available during the following times (walk-in service only): Monday: 8am – 12:30pm Tuesday: 10am – 2pm Wednesday: 8am – 12:30pm Thursday: 1 – 3pm |
| Fairfax County: Mt. Vernon | 8350 Richmond Hwy #233 | Alexandria | 703-704-5203 | By appointment Monday – Friday HIV testing also available during the following times (walk-in service only): Monday: 8am – 12:30pm and 1:30pm – 3:00pm Tuesday: 10am – 2pm Wednesday: 8am – 12:30pm Friday: 9 – 10:30am |
| Fairfax County: Springfield | 8136 Old Keene Mill Rd. The Cary Building # A-100 | Springfield | 703-569-1031 | By appointment Monday – Friday HIV testing also available during the following times (walk-in service only): Monday: 8am – 12:30pm Tuesday: 10am – 2pm and 3 – 5:30pm Wednesday: 8am – 12:30pm |
| Fairfax County: Joseph Willard | 3750 Old Lee Hwy | Fairfax | 703-246-7100 | By appointment Monday – Friday HIV testing also available during the following times (walk-in service only): Monday: 8am – 12:30pm Tuesday: 8am – 12:30pm and 1:30 – 3pm Wednesday: 10am – 2pm and 3 – 5:30pm |
| | | | | Anonymous HIV Testing is available at Joseph Willard |





MidAtlantic AIDS Education and Training Center - Contact Information

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