

Home Testing and Home Self-Collection Guidance Roll-Out

June 8, 2020 11:00 am

Jenny McFarlane, Pam Mathie, Isabel Clark,

Jenna Burt, Karen Surita

Welcome



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Your Presenters Today

Jenny McFarlane – jenny.mcfarlane@dshs.texas.gov

Pam Mathie – pamela.mathie@dshs.texas.gov

Isabel Clark – isabel.clark@dshs.texas.gov

Jenna Burt – jenna.burt@dshs.texas.gov

Karen Surita – karen.surita@dshs.texas.gov

Purpose of the Guidance

This document is to provide interim guidance on the creation of policies for the use of Food and Drug Administration (FDA) approved home testing kits for Human Immunodeficiency Virus (HIV), and Laboratory Developed Tests (LDTs) for self-collection kits for HIV, sexually transmitted diseases (STDs), hepatitis C (HCV) and tests required for pre-exposure prophylaxis (PrEP) prescriptions. This interim guidance is intended for use by programs funded or otherwise supported by the Department of State Health Services (DSHS) TB/HIV/STD Section.

Brief Overview of Guidance-Definitions

- **Home testing kits** – FDA approved tests which allow an individual to complete the entire testing process in their home (or other private location) including the interpretation of the preliminary test result.
- **Home self-collection kits** – LDTs (under a medical order by a licensed provider) which allow an individual to collect specimens in their home (or other private location) to be submitted to a laboratory that processes the test and reports the test result to the provider who ordered the test.
- **Laboratory developed tests (LDTs)** – For the purposes of this document, manufacturer's tests which have been validated by a laboratory for off-label alternative collection methodologies. This applies to tests that were not FDA cleared for this use (e.g. self-collection in the home setting). LDTs are subject to review of validation methods and outcomes by their prevailing CLIA authority.

Brief Overview of Guidance-Background

- Through the dissemination of this interim guidance, DSHS aims to increase access to HIV, STD, and HCV testing and linkages to medical treatment and other prevention services, including the tests required for PrEP prescriptions.
- Please note that this interim guidance does not endorse a specific test technology, manufacturer, or laboratory.
- Agencies should not open the kits prior to distribution. The FDA approved home testing kits include required instructions on how to perform and interpret the results of the test. The self-collection kits include specimen collection and submission instructions, which have been developed by laboratories and vendors who distribute LDT kits. Agencies may not replace, alter, or remove the instructions and inserts. Agencies may add locally relevant materials including local phone numbers and contact information for support and referrals.

Brief Overview of Guidance-Required Items

Programs funded or supported by DSHS may use home testing kits or self-collection kits for distribution to eligible individuals. Programs implementing this activity must develop and maintain a DSHS-approved policy and address the following required items:

- Identify the populations who are eligible to receive test kits;
- Identify which home testing and/or self-collection kit(s) are appropriate for the populations being served and why;
- Identify the funding source that will be used for the purchase of tests, staff time, postage, and other associated costs;
- Describe the processes in place to protect the security of program reporting data and the confidentiality of client information;
- State how the agency will obtain and document informed consent;
- Describe how kits will be shipped, stored, and maintained, including inventory and quality control measures;

Brief Overview of Guidance-Required Items

- Describe how the distribution of test kits will be documented and tracked;
- Describe how demographic, priority population group, test result(s), and linkage data will be documented and tracked;
- Describe how the notification of test results, referrals for confirmatory testing as required, referral to and confirmation of medical care/treatment, partner services, and referrals for other essential prevention services will be made and tracked;
- Identify required staff training(s) specifically for home testing and self-collection kits and how staff will relay relevant information to persons requesting tests;
- Describe how test results will be accessed and reported to the local health authority; and
- If applicable, list incentives and describe how they will be used during the interaction with persons being tested.

HIV Testing Technology and Diagnosing HIV

In-Home HIV Testing

Isabel Clark, MA RD

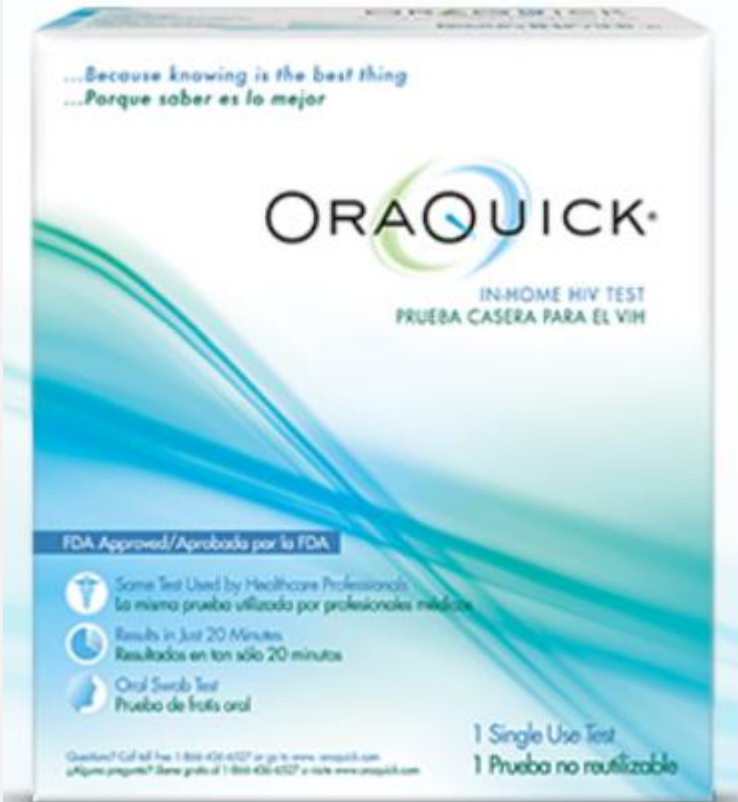
Routine Screening and HIV Prevention Sr. Consultant



TEXAS
Health and Human
Services

Texas Department of State
Health Services

OraQuick Advance Rapid HIV-1/2 Antibody Test In-Home HIV Test Kit: Pros & Cons



PROS

- In-home HIV test is non-invasive (oral swab).
- More persons may get tested, increasing the number of persons who know their status.
- Fast –results in 20 minutes.
- A 3rd generation test and detects IgM and IgG antibodies.
- FDA approved.

CONS

- An HIV screening test – it requires follow-up lab-based testing to confirm HIV infection.
- Potential false negatives during acute or early HIV infection.
- Potential problems:
 - inaccurate specimen collection (rare).
 - inaccurate reading of results due to weak reactive lines.

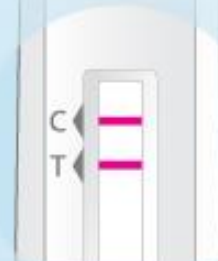
1 HIV antibodies from oral fluid are collected through the swab.



2 Once the device is inserted into the test tube, the oral fluid mixes with the liquid and travels up the test stick.



3 If C-Line turns dark it confirms the test is working properly. If no C-Line appears, the test is not working.
If only C-Line appears, the test is negative.



4 HIV antibodies collecting at the T-Line indicate the test is positive.

Stages of HIV Life Cycle

Window Periods: Detecting HIV Infection

Window Period – the time after infection before seroconversion when markers of HIV infection are absent or too scarce to be detected. Windows are specific to each type of test technology.

Eclipse – the stage after infection when no test can detect HIV infection.

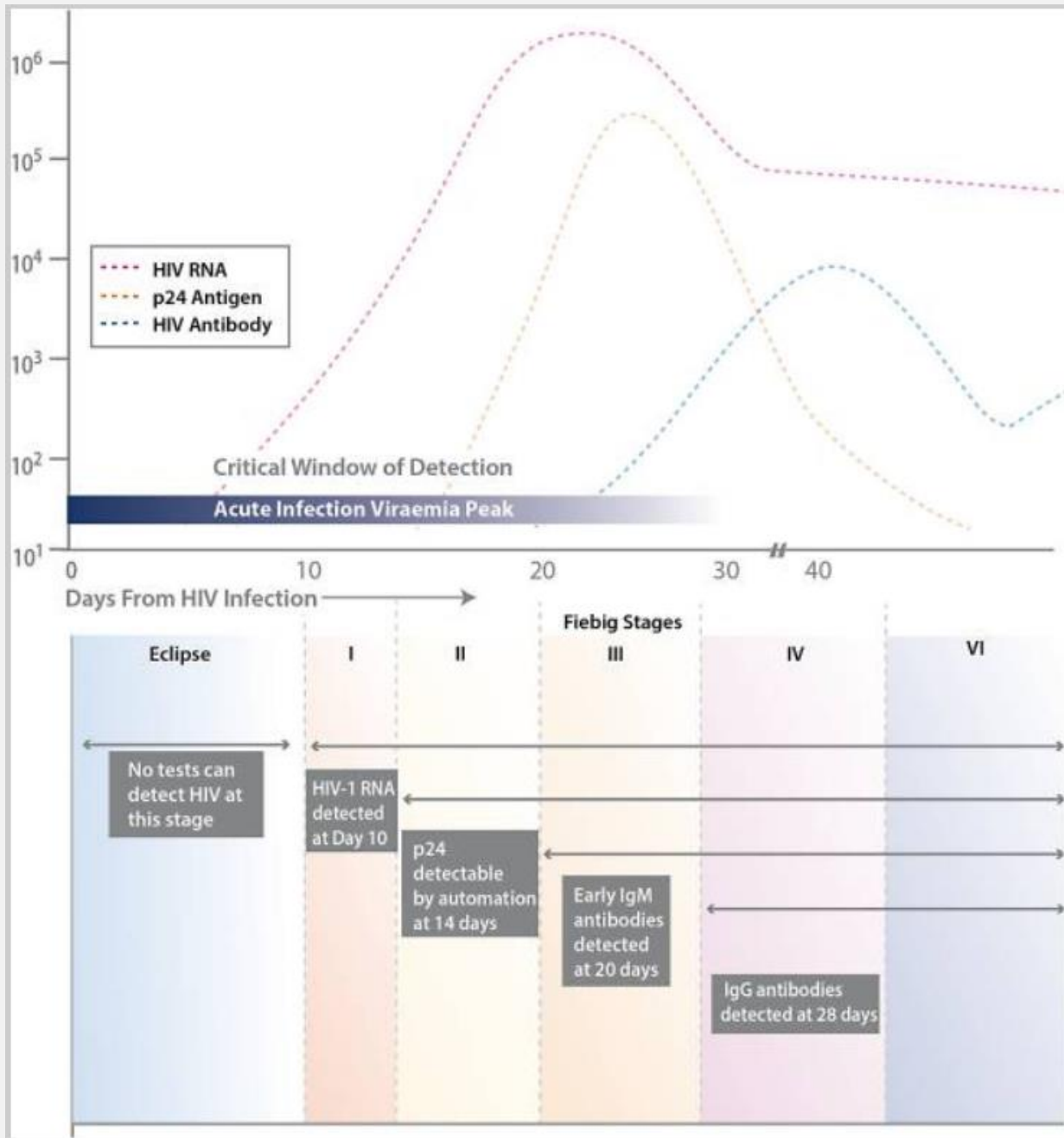
HIV-1 RNA – 10-11 days post exposure when the HIV virus can be detected.

p24 antigen – can be detected around day 14-16 via 4th generation automated lab based testing.

IgM* – the earliest HIV antibody detected around 21 -24 days.

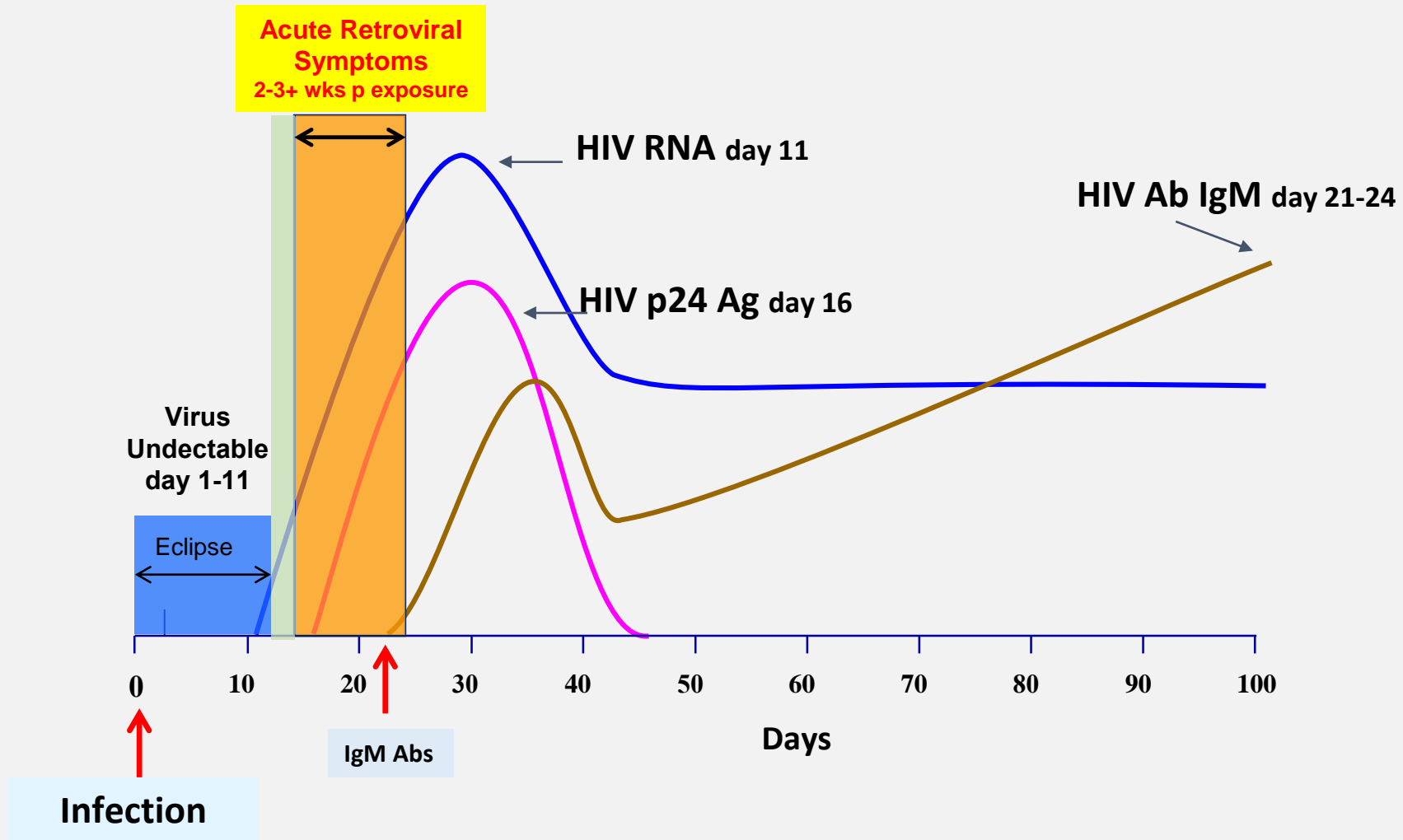
IgG* – antibodies may be detected as early as 24 days.

*The detection of antibodies is dependent on the immune status of the individual and detection of antibodies may be delayed several weeks and up to months before antibodies are detected.

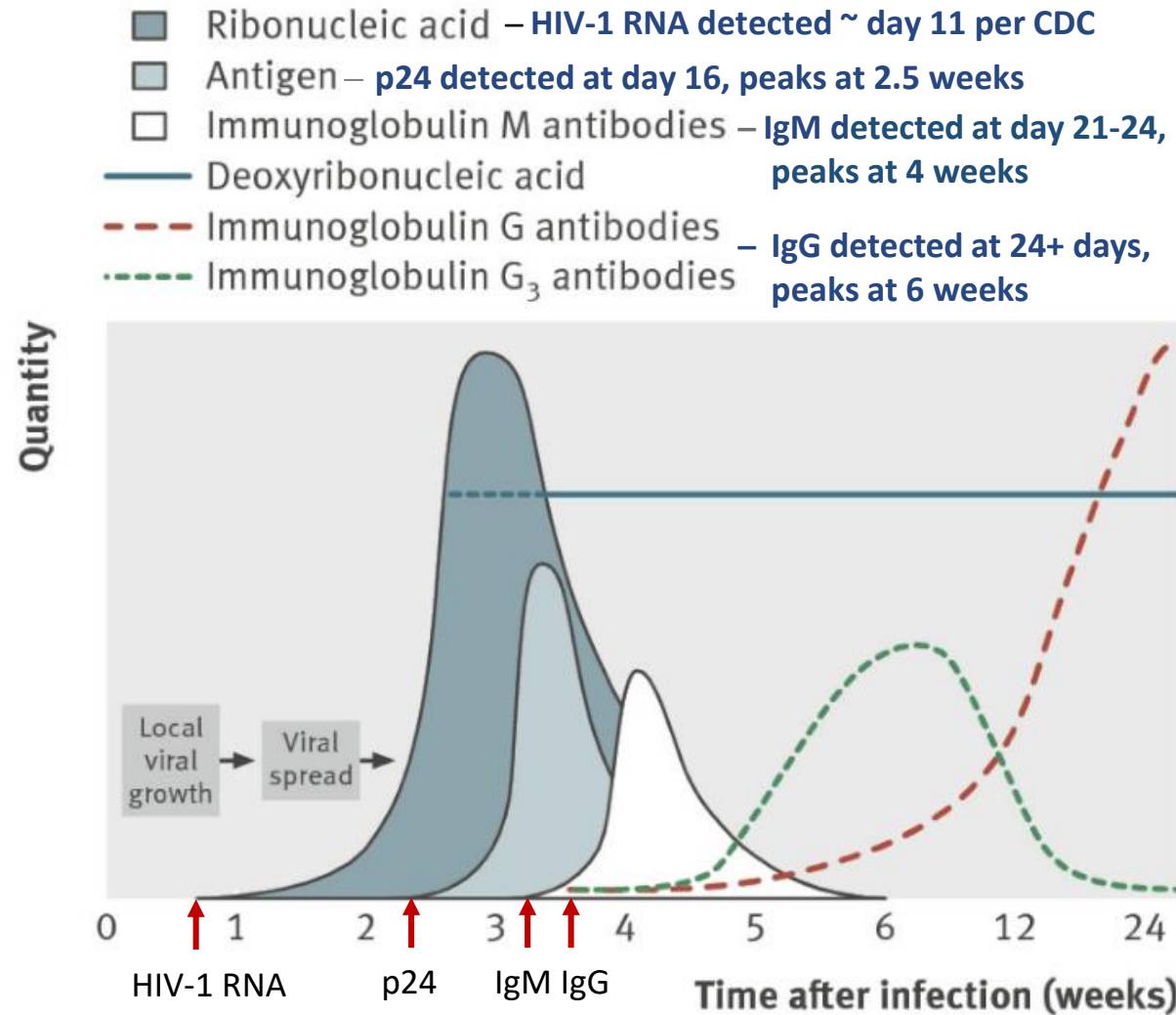


Adapted from Fiebig et al. (2003)

HIV Infection and Laboratory Markers



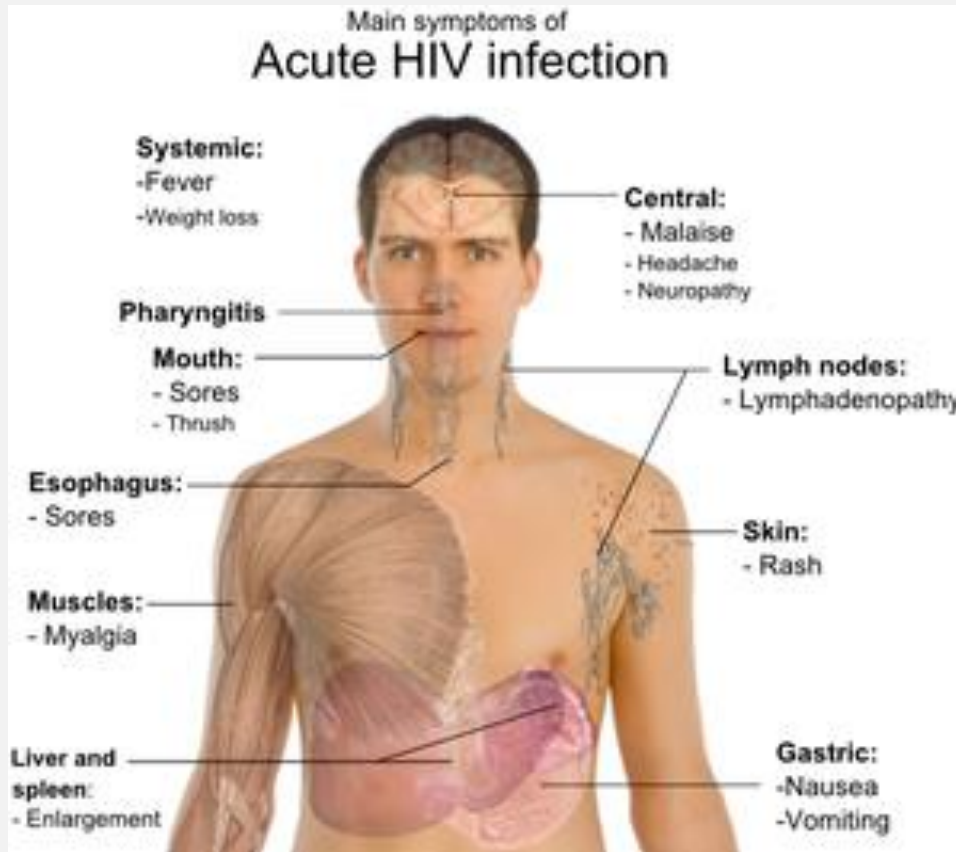
Detection of Acute/Early HIV Infection



Adapted from Murphy and Parry. Assays for the detection of recent infections with human immunodeficiency virus type w. Euro Surveill 2008

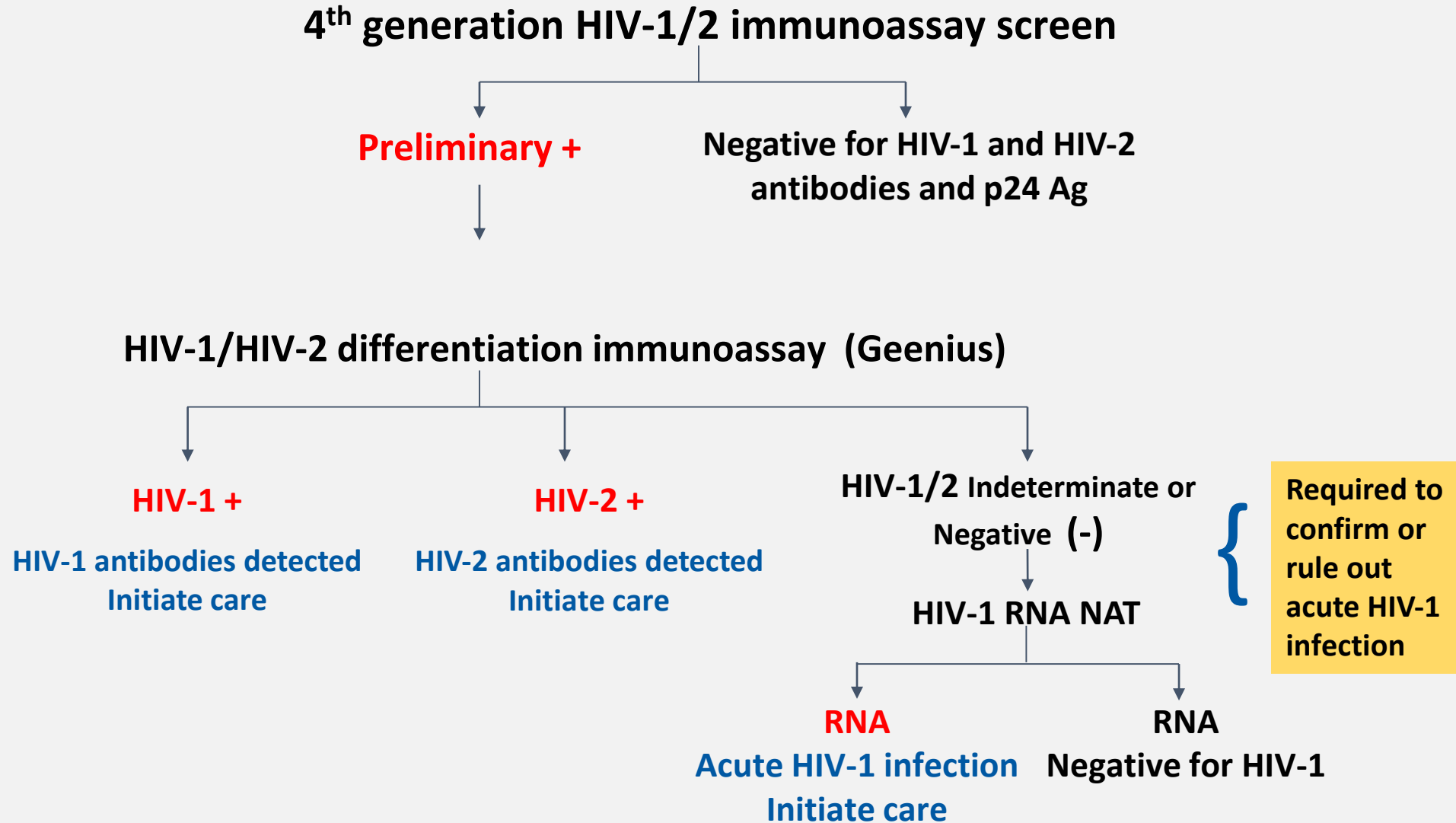
Acute HIV Infection Symptoms

may occur 2 to 4 weeks after infection/exposure



- Malaise/fatigue
- Fever/chills/night sweats
- Weight loss, loss of appetite
- Sore throat
- Nausea/vomiting/diarrhea
- Swollen lymph nodes
- Aching muscles or joints
- Rash
- Rarely headache, neurologic symptoms

CDC/APHL HIV Diagnostic Algorithm – Conventional specimen processing in a reference laboratory (serum or plasma)



Summary

- The HIV in-home test kit is only a screen.
- An HIV positive screening test needs to be confirmed with a conventional lab-based 4th generation test (blood draw).
 - Educate/counsel clients about the importance of confirming HIV infection (lab follow-up)
 - Assess the time when the client suspects they were exposed to HIV and ask about symptoms that may indicate acute infection.
- If client has a positive screen result counsel about the importance of engaging in HIV healthcare ASAP to achieve viral suppression and to prevent further HIV transmissions

We will be offering a couple of more in-depth trainings when we will have time to dig deeper into the test technology.

Home Self-Collection Kits – The Technology

- The Food and Drug Administration (FDA) reviews diagnostic devices for clearance and approval.
- Diagnostic assays that are most commonly in use to test for sexually transmitted infections (STIs) and PrEP labs are FDA cleared for use of specified collection methodology in a clinical setting.
- However, these tests are not FDA cleared for the alternative collection methodology of self-collection of samples in a non-clinical setting, e.g. at home.
- Laboratories can validate alternative collection methodologies, such as home collection, as LDTs subject to review of the validation methods and outcomes by their prevailing CLIA authority.

Home Self-Collection Kits – The Options

- **In-house/“home-grown”**-Program uses in-house clinicians and partners with a public health laboratory for processing. Program does in-house kit fulfillment/shipping.
- **Integration with a lab service**-Program uses in-house clinicians and partners/contracts with a lab for kit fulfillment/shipping, specimen handling, and processing. There can also be an intermediary vendor that provides kit fulfillment/shipping for a “back-lab” that processes the tests.
- **Integration with a digital health care provider**-Program integrates with digital healthcare provider to offer end-to-end care and testing solution. Lab/specimen logistics and processing, clinician ordering, and medical care are all outsourced.

Overview of The Readiness Table

READINESS FOR HOME TESTING/SELF-COLLECTION TABLE: Items for Consideration Prior to Distribution of Home Testing and Self-Collection Kits

Instructions: If you are interested in providing home self-collection kits, **read the attached** Technical Assistance Brief (5/20/2020) from the National Coalition of STD Directors (NCSD) entitled *At-home Self-Collection Lab Testing for Sexually Transmitted Infections*. Please communicate with your DSHS consultant regarding your plans to facilitate home testing and home self-collection. The DSHS staff are available to assist you with your planning. Complete the following table as thoroughly as possible. Use this document to inform the creation of an agency-specific policy. Once both are completed, submit this Readiness Table AND your proposed agency-specific policy to your designated DSHS consultant(s) for approval. DO NOT begin activities until your policy has been approved by DSHS.

Questions for Consideration	Agency Answer
What funds will your agency use to purchase test kits and staffing to support the serves?	
Which tests will you offer (e.g. HIV home testing, home self-collected HIV, GC/CT urogenital and extragenital, creatinine, HBV/HCV, or syphilis specimen)? Please specify the manufacturer of the home test kits and home collection kits. How will your agency select tests and tailor for individuals with specific risk factors or testing needs?	
If you will offer home self-collection kits, which laboratory or vendor will you partner with to process home self-collection kits? If you will partner with a vendor, which test processing laboratory will be used?	

Overview of The Readiness Table 2

<p>How will confirmatory testing be performed with individuals who receive a <i>preliminary positive</i> test result from a <u>home testing kit</u>?</p> <p>For individuals who receive a preliminary positive result from a home testing kit, how will linkage to care/treatment be performed?</p> <p>How will referrals for other services be performed for persons testing preliminary positive with a home testing kit?</p>	
<p>How will individuals with a positive treponemal test receive an RPR test prior to initiation of treatment?</p>	
<p>How will referrals for PrEP be handled for persons testing <i>negative</i> on a <u>home testing kit</u>?</p> <p>How will referrals for other services be performed for persons testing negative from a home testing kit?</p>	
<p>For individuals who receive a <i>positive</i> result from a <u>home self-collection kit</u>, how will medications be provided (e.g. in-clinic, by mail, outside pharmacy)?</p> <p>Will Expedited Partner Therapy be an option for someone with a reactive GC or CT test result?</p> <p>Do outsourced providers have the appropriate licensure and prescriptive authority in Texas?</p> <p>What follow-up will occur for persons treated for STDs (e.g. RPR testing, schedule in-person visit if symptoms do not resolve).</p>	

Overview of The Readiness Table 3

<p>What information will be included with the test kit when it is mailed?</p> <p>What local or national resources will be included?</p> <p>What information will be given about when to contact your agency with questions and when to contact a test kit company directly?</p>	
---	--

Considerations Moving Forward: It is recommended that your agency conduct on-going assessments regarding access, acceptance, and uptake of home testing and/or home self-collection kits. Please discuss this consideration with your designated DSHS consultant(s).

Note for Remote Staff: If home testing and/or home self-collection is to be implemented by staff working in remote locations, include information about how staff will ensure confidentiality is maintained while working from home. Be sure to address confidentiality of data (both physical and electronic) of the individual being tested when staff engage with them from their homes, including how information will be protected from members of the staff's household.

Additional Resources

Additional Resources:

CDC Resources

HIV Testing Information

<https://www.cdc.gov/hiv/testing/laboratorytests.html>

<https://www.cdc.gov/hiv/testing/self-testing.html>

Information about Testing for STDs Outside of Healthcare Settings/Clinics

<https://www.cdc.gov/std/prevention/disruptionGuidance.htm>

FDA Resource

Definition and Information About LDTs

<https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests>

NCSD Resource

Attachment: At-home Self-Collection Lab Testing for Sexually Transmitted Infections Technical Assistance Brief Updated May 20, 2020

Questions

What questions do you have?

If you are not on the web and would like to text questions – 512-983-3554

Thank you!

Home Testing and Home Self-Collection Guidance

Please contact your DSHS Consultant with additional questions or email jenna.burt@dshs.Texas.gov