HIV/STD/TB Section



Tina Kotek, Governor

HIV Testing Policies and Procedures

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HIV Testing Policies and Procedures

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Introduction and Summary of OHA-Sponsored HIV Testing

This document is intended for any staff person providing HIV testing services funded by the Oregon Health Authority.

The document addresses:

- Important policies and procedures relating to the HIV testing process.
- HIV testing provided in-person, either with conventional lab-based testing or a rapid HIV test kit.

LPHAs should use information from the <u>End HIV/STI Oregon 5 Year Strategy (2022-2026)</u> on groups disproportionately impacted by HIV, as well as local epi data, to guide decisions on which populations to focus their HIV testing efforts.

All staff performing publicly funded HIV testing are expected to complete the online <u>HIV</u> <u>Essentials training</u> as well as appropriate training in rapid testing methods from the rapid test kit manufacturer if offering rapid testing.

OHA funding supports confidential HIV testing only; anonymous testing is not permissible using OHA funds. HIV testing data collection and submission is a requirement for all publicly funded tests. Required data variables for all publicly-funded HIV tests must be entered into CDC's HIV testing database using the REDCap HIV Prevention Testing Form (PDF form available here).

Usage of rapid HIV self-test kits are not addressed in this document. Please contact the OHA HIV/STI Prevention Program at prevention.info@odhsoha.oregon.gov with questions pertaining to the use of rapid HIV self-testing kits as part of your overall HIV testing strategy and data collection.

No-Cost HIV Testing Through the State Public Health Laboratory

No-cost laboratory-based HIV testing is available through the Oregon State Public Health Laboratory (OSPHL) for eligible clients at all LPHAs and Program Element 81 funded LPHA subcontractors. This program is intended as the payer of last resort and should not be used if other payer sources such as private insurance, Oregon Health Plan/CCOs, or Oregon Contraceptive Care Program (CCare) are available.

To qualify for no-cost HIV testing, the client must be uninsured or underinsured and meet at least one of the eligibility criteria listed below:

- Gay, bisexual, other men who have sex with men (MSM) or transgender/nonbinary persons
- Persons who inject drugs
- Persons with a sex or needle-sharing partner who is HIV+
- Persons diagnosed with a bacterial STI
- Contacts of persons diagnosed with a bacterial STI
- Persons with active TB infection
- Persons who specifically request an HIV test without it being offered first (self-screeners)

In addition, no-cost STI Wraparound Screening for chlamydia, gonorrhea, and syphilis is also available for qualifying clients presenting for HIV testing at LPHAs and Program Element 81 funded LPHA subcontractors. To qualify for no-cost STI Wraparound Screening, the client must be uninsured or underinsured, presenting for HIV testing, and meet at least one of the eligibility criteria below:

- Gay, bisexual, other men who have sex with men (MSM) or transgender/nonbinary persons
- Persons who inject drugs
- Persons with a sex or needle-sharing partner who is HIV+
- Persons diagnosed with a bacterial STI
- Contacts of persons diagnosed with a bacterial STI

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Ordering:

¹ Underinsured refers to: 1) an individual with prohibitively high deductibles or cost-sharing for lab services or 2) an individual on a parent/guardian's insurance plan who declines screening because of privacy concerns. A 2015 Oregon law guarantees the right of individuals to request to have protected health information such as the explanation of benefits sent directly to them instead of to the primary account holder—visit this <u>site</u> for more information).

- HIV tests should be ordered using the <u>OSPHL Virology/Immunology Test</u> Request Form (Green text; Form #42).
 - Indicate that this is a funded HIV test by entering "HIV CTS" in the Study box on the test request form.
- All variables on the <u>REDCap HIV Prevention Testing Form</u> must be completed in full.
 - All variables must be entered in EvaluationWeb or REDCap by the LPHA or their sub-contractor.
 - No variables should be left unanswered; blank response fields are not accepted.
 - If your facility submits lab orders electronically, please contact the OHA HIV/STI Prevention Program to discuss alternate methods for uploading data into EvaluationWeb.
- All other requirements must be met as described in Program Element 81, available at <u>OHA's Program Elements page</u>.

Lab and Testing Information

The OSPHL tests all HIV specimens using a chemiluminescent microparticle immunoassay (CMIA). The chemiluminescent microparticle immunoassay detects p24 antigen and antibodies to HIV-1 and/or HIV-2, resulting in a shorter window period² than rapid HIV antibody tests. The CMIA uses anti-HIV-1 p24 antibodies as reagents to detect HIV-1 p24 antigen, thereby decreasing the window period and improving early detection of HIV infection.

The test used will detect HIV-1 p24 antigen, HIV-1 & HIV-2 antibodies. Specimens reactive by chemiluminescent microparticle immunoassay (CMIA) will automatically be reflexed to an HIV differentiation test. When results from these two assays are discordant, specimens are forwarded to a reference lab for HIV-1 NAT viral load testing.

² The window period is the time between first infection and when a test can reliably detect that infection.

HIV screening tests can only be performed using refrigerated specimens up to 7 days after specimen collection and frozen serum specimens up to 30 days.

Serum must be removed from the clot within 72 hours to ensure specimen can be tested for HIV differentiation if needed. If serum is not removed from the clot within 72 hours of collection, a second specimen will be required if HIV differentiation testing is indicated.

Further information on OSPHL's HIV testing laboratory services can be found on the OSPHL website.

LPHAs and subcontractors can order test request forms, test kits and supplies from the state lab using the <u>OSPHL Stockroom Order Request Form #71-54</u>.

All HIV screening results released from OSPHL will include the following comments to guide your patient care:

If HIV screening is **Positive**: "If this test was ordered to confirm a positive or preliminary positive rapid HIV test, the OHA HIV/STD/TB Medical Director recommends that the patient be referred for immediate medical care."

If HIV screening is **Negative**: "If this test was ordered to confirm a positive or preliminary positive rapid HIV test, but the client's risk raises concern for acute or early HIV infection, the OHA HIV/STD/TB Medical Director recommends viral load testing or immediate referral to medical care for a timely diagnosis."

Rapid HIV Testing

In addition to laboratory-based testing, there are also FDA-approved rapid HIV tests that can be used in non-clinical settings. Rapid testing technology provides an HIV screening test result within 30 minutes or less. See this <u>table of rapid HIV tests</u> <u>suitable for use in non-clinical settings</u> to compare the cost, sensitivity and specificity, shelf life and other features of currently available FDA-approved, CLIA-waived rapid HIV tests.

Most rapid HIV tests only detect HIV antibodies, and some may not produce a reactive test result for up to several months following infection. The manufacturer's pamphlet included with the test kit should contain more detailed information about the window period. All rapid test kits can be processed using fingerstick whole blood samples.

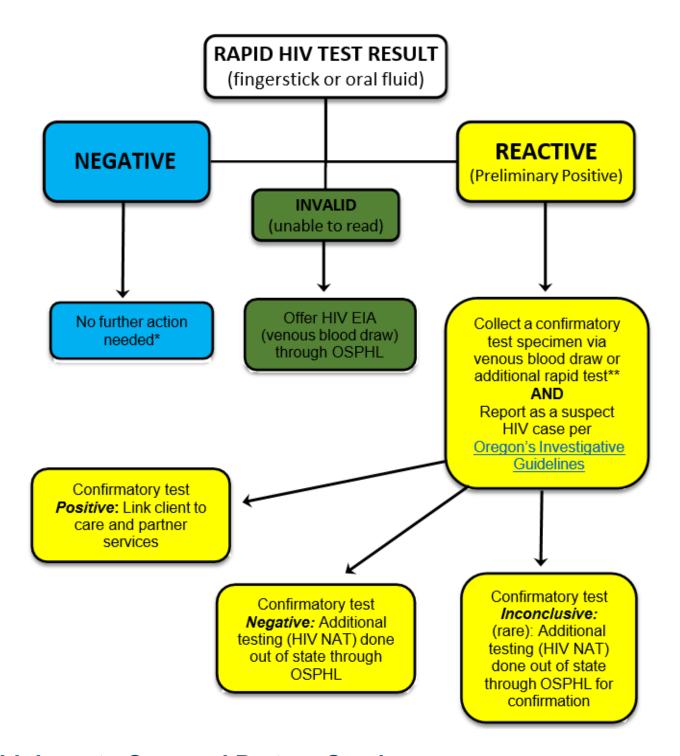
Some rapid test kits also may be processed with oral fluid. OHA encourages the use of rapid testing using whole blood samples due to increased detection of HIV antibodies in blood when compared to oral fluid.

Staff offering rapid HIV testing should complete appropriate training in rapid HIV test methods from the rapid test kit manufacturer(s) and follow manufacturer instructions for test use and interpretation exactly. OHA HIV/STI Prevention staff can help connecting with HIV test kit manufacturers to obtain the required training.

Agencies conducting rapid HIV testing should be in compliance with CLIA and other regulatory requirements. Resources pertaining to CLIA applications and Oregon laboratory requirements are available on <u>OSPHL's Certificate of Waiver page</u>.

The algorithm on the following page describes the possible outcomes of rapid HIV testing and the resulting actions needed. If a client shows symptoms of acute HIV infection during the rapid HIV test, is assessed to be at risk for HIV infection, and may have been exposed during the window period, consider additional testing after consultation with your site's Medical Director or the OHA HIV/STD/TB Medical Director.

A reactive rapid test result is considered a preliminary positive and requires confirmatory testing. Confirmatory testing may be done in either of two ways: either a confirmatory test specimen may be collected via venous blood draw for laboratory testing, or an additional rapid test may be administered. If rapid tests are used for both preliminary and confirmatory testing, the rapid test kits must be produced by different manufacturers and the rapid test used for confirmatory testing should be one with an equivalent or greater sensitivity.



Linkage to Care and Partner Services

For persons testing HIV positive, timely linkage to care and treatment and case management is critical. Treatment is instrumental in improving health outcomes for people with HIV. With treatment, most people with HIV live long and healthy lives,

similar to people who don't have HIV. Moreover, people with HIV who maintain viral suppression cannot transmit HIV to sex partners – this is known as U=U, which stands for "undetectable = untransmittable".

HIV case management supports people living with HIV by assisting with linkage to medical care, insurance navigation, and removing barriers to support sustained treatment and wellbeing. <u>HIV case management contact information by county is available online.</u>

Partner Services is critical for reducing future transmissions and are free services to help ensure that people diagnosed with HIV or other STDs:

- 1. receive their test result,
- 2. access treatment, and
- have an opportunity to identify their sex and needle-sharing partners and receive assistance notifying them of their potential exposure and with access to testing and/or treatment.

Partner Services are a highly effective means of identifying persons with undiagnosed infection. Often, Partner Services are initiated following case reports. However, if linkage to Partner Services can occur sooner (e.g., in conjunction with the delivery of test results), this practice can save time, reduce barriers to contacting the client (index patient) and result in timelier partner notification. Technical assistance and resources around the provision of Partner Services are available from OHA's website, as well as the CDC's Passport to Partner Services online training.

Case Reporting

Oregon Administrative Rules require laboratories and physicians to report HIV cases to Local Public Health Authorities (LPHAs) and LPHAs to report HIV cases to the OHA Public Health Division. HIV case reporting allows public health programs to monitor the epidemic, to evaluate prevention and care programs, identify persons who may need services (e.g., treatment, Partner Services) and link them to services.

For more information about HIV case reporting requirements, please review <u>Oregon's Investigative Guidelines for HIV</u>. Questions related to HIV case reporting in Oregon

may be directed to Lea Bush, HIV Surveillance Manager, at lea.bush@oha.oregon.gov.

Consent to HIV Testing

Clients receiving an HIV test from a licensed health care provider or designee must be notified that HIV testing may occur and be given an opportunity to decline testing (ORS 433.045, as amended Oregon Laws 2012, Chapter 26). Clients can be notified verbally or in writing via a general medical consent form, brochure, fact sheet, sign-in sheet, or signage in a waiting area. As each HIV test site funded by OHA is under the oversight of a physician, test sites may implement opt-out HIV testing as described above or use an HIV test consent form. This is a local decision.

Confidentiality

OHA-funded HIV testing must be confidential. Confidential HIV testing includes collecting names and other identifying information. This is a standard practice that helps health systems keep both their clients and the larger community healthy.

Public health agencies are better able to ensure clients receive their HIV test results and access care and Partner Services if they have access to client names and contact information. Confidential HIV testing also helps reduce stigma, normalize testing and foster trust in public health agencies. Research suggests that HIV testing rates do not decline when names are collected or reported to health departments.

HIV test counselors are encouraged to use or adapt the following talking points to help clients who are concerned about confidentiality.

Confidentiality

- Your test result is confidential. That means that we collect your name and other information, and we protect and limit access to that information according to state law.
- Generally, your HIV test result may only be shared with you, our agency, and a
 health department or a health care provider. It's up to you whether you choose
 to tell anyone else.

 We cannot tell your employer that you tested or your test result. Employment discrimination based on HIV status is illegal.

Data use

- Health departments collect information about people who test positive to watch public health trends and to help connect people with services. If you test positive, health department staff will contact you to:
 - 1. Be sure you received your test result
 - 2. Help you access health care and/or case management
 - Ask for help identifying partners who should be notified of their potential exposure and encouraged to get tested. You could notify partners yourself or ask public health staff to notify them without sharing your name.
- Under the Affordable Care Act, health insurers cannot deny coverage or charge more based on HIV status or other pre-existing conditions.

Referrals

If you would prefer to test anonymously, you can purchase rapid HIV self-tests from OraQuick.com and from many pharmacies, both online and in-store. You can also request free rapid HIV self-tests through the mail from TakeMeHome.

Disclosure of Test Results

The results of an HIV test may be disclosed to 1) the tested individual, 2) the health care provider or licensed health care facility or person ordering the test, and 3) any individual to whom the tested individual has authorized disclosure (ORS 433.045; OAR 333-022-0210). Test sites offering partner HIV testing (in which two individuals receive their results together) should document clients' consent to share HIV test results with their partners.

Resources

HIV Prevention Testing Form - REDCap

HIV Prevention Testing Form - PDF

Oregon HIV test process

Oregon HIV laws guide

HIV test specimen collection, handling and transportation

OSPHL Request Forms

Supporting clients that test HIV-positive: factsheet in English and Spanish

You can get this document in other languages, large print, braille or a format you prefer free of charge. Contact the HIV/STD/TB section at prevention.info@odhsoha.oregon.gov or 971-673-0153. We accept all relay calls.

Public Health Division HIV/STD/TB Section 800 NE Oregon St, Suite 1105 Portland, Oregon 97232 971-673-0153



https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/HIVSTDVIRALHEPATITIS/Pages/index.aspx