HIV TESTING POLICY & PROCEDURES

Oregon Health Authority
PUBLIC HEALTH DIVISION

OREGON HIV
PREVENTION PROGRAM

END HIV

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CONTENTS

INTRODUCTION

This document is intended for any staff person providing HIV testing services funded by the Oregon Health Authority, HIV Prevention Program (OHA HPP).

The document addresses:

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

Usage of at-home HIV test kits are not addressed in this document. Please contact the OHA HPP with questions pertaining to the use of at-home HIV testing kits as part of your overall HIV testing strategy.

SUMMARY OF OHA HPP-SPONSORED HIV TESTING

OHA HPP funding supports confidential HIV testing by all local public health authorities (LPHAs) and by LPHA subcontractors. Anonymous testing is not permissible using OHA HPP funds.

LPHAs should use information from the End HIV/STI Oregon 5 Year Strategy (2022-2026) 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 individuals conducting HIV testing supported with OHA HPP funds must have received training in the essentials of HIV prevention (online HIV Essentials training is available at http://bit.ly/trainHIV).

Testing by LPHAs that receive HIV prevention or EISO funding (Program Elements 7, 73, 74)

To qualify for these programs, the client must be uninsured or underinsured[1] ***and*** *meet at least one of the eligibility criteria listed below:*

- Gay, bisexual, other men who have sex with men (MSM) or transgender/non-binary 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)

Ordering:

- HIV tests should be ordered using the Oregon State Public Health Laboratory's (OSPHL) green Virology/Immunology Test Request Form available at www.bitly.com/phl-forms

[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 site for more information).

- Indicate that this is a funded HIV test by placing "HIV- CTS" in the Study ID box on the test request form.

• All variables on the HIV Prevention Test Form (form OHA 9810) must be completed in full.
  - All variables must be entered in the EvaluationWeb database by the LPHA or their sub-contractor.
  - No variables should be left unanswered; blank response fields are not accepted in EvaluationWeb.
  - If your facility submits lab orders electronically, please contact the HIV Prevention Program to discuss alternate methods for uploading data into EvaluationWeb.
  - Sites which receive EISO funding, but no PE 7 funding should contact OHA HPP staff to discuss processes for uploading required data outside of EvaluationWeb.
• All other requirements must be met as described in Program Elements 07, 73 and 74. See http://bit.ly/LHD-PE .

Testing by LPHAs that *do not receive* HIV prevention or EISO funding (no Program Element 7, 73, 74)

For LPHAs that do not receive OHA HPP funding, HPP will continue to cover the cost of conventional (laboratory) testing. *To qualify for these programs, the client must be uninsured or underinsured*[2] ***and*** *meet at least one of the eligibility criteria listed below:*

- Gay, bisexual, other men who have sex with men (MSM) or transgender/non-binary 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)

Ordering:

- HIV tests should be ordered using the Oregon State Public Health Laboratory's (OSPHL) green Virology/Immunology Test Request Form available at www.bitly.com/phl-forms
  - Indicate that this is a funded HIV test by placing "HIV- CTS" in the Study ID box on the test request form.

• All variables on the HIV Prevention Test Form (form OHA 9810) must be completed in full.
  - All variables must be collected and entered in the spreadsheet or RedCap Survey provided by OHA.
  - No variables should be left unanswered, as blank response fields will not be accepted.
  - HIV testing data should be submitted to Cedric Cicognani by January 30th, and July 31st each year (CEDRIC.M.CICOGNANI@oha.oregon.gov).
  - If your facility submits lab orders electronically, please contact the HIV Prevention Program to discuss alternate methods for uploading data into EvaluationWeb.

[2] 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 site for more information).

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 period[3] 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.

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 at: https://public.health. oregon.gov/LaboratoryServices/.

LPHAs and subcontractors can order test request forms, test kits and supplies from the state lab using the Stockroom Order Request Form at http://bit.ly/OrderReq

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."*

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

RAPID HIV TESTING

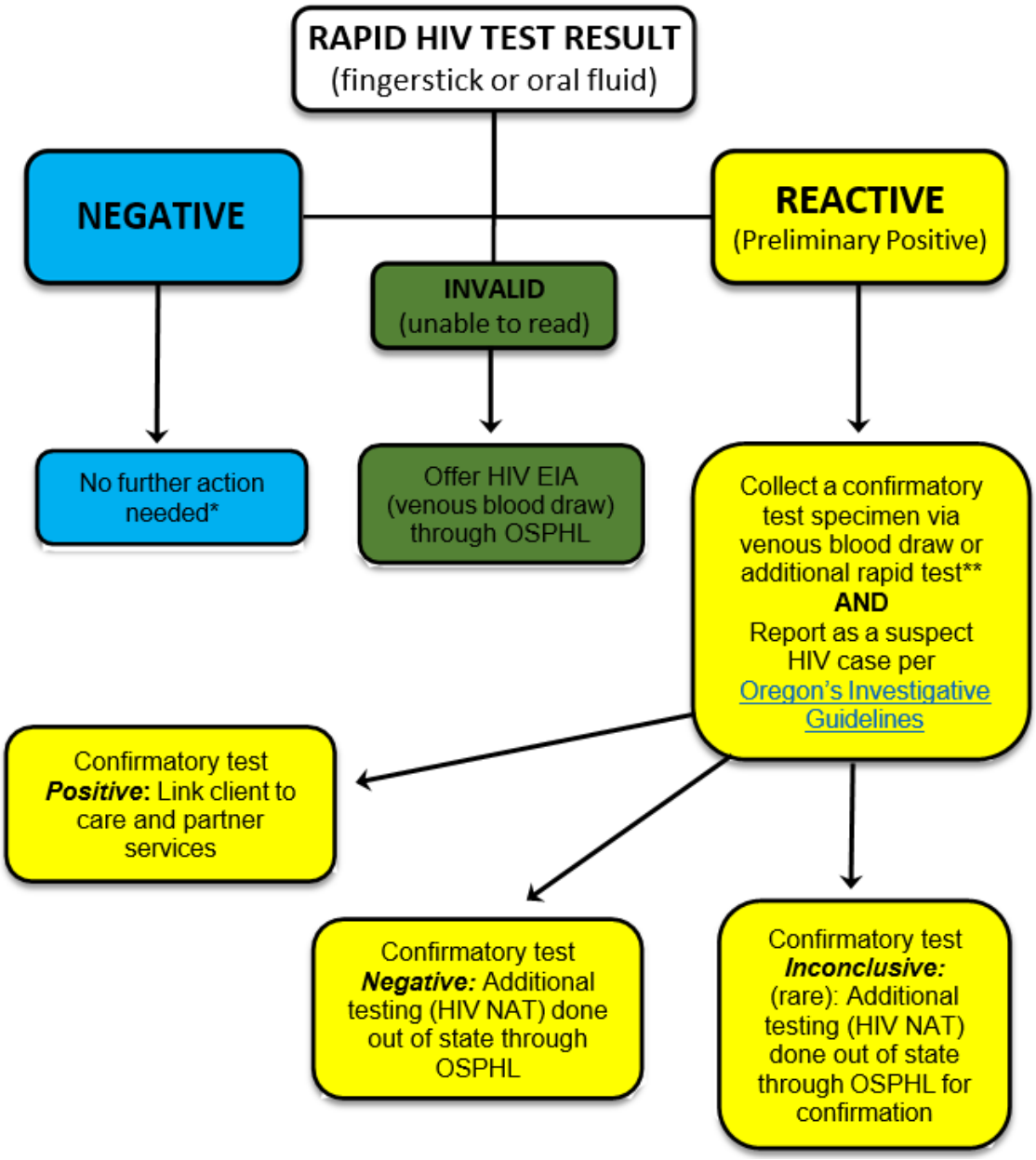
In addition to testing conducted at the OSPHL, some LPHAs and subcontractors offer rapid HIV testing. Rapid testing technology provides an HIV screening test result within 30 minutes or less. A variety of rapid HIV tests are approved by the U.S. Food and Drug Administration (FDA) and available for use in Oregon. A table comparing the cost, shelf life and other features of rapid tests suitable for use in non-clinical settings can be found at http://bit.ly/HIVrapidtests.

Most rapid 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. The OHA HPP 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). OHA HPP staff can help connecting with HIV test kit manufacturers to obtain the required training.

- The algorithms on the following page describe 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 Medical Epidemiologist.
- If rapid tests are used for both preliminary and confirmatory testing:
    - the test kits must be produced by a different manufacturer, and
    - the rapid test used for confirmatory testing should be one with an equivalent sensitivity.

RAPID HIV TEST ALGORITHMS



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 can live to their senior years. Moreover, people with HIV who maintain viral suppression cannot transmit HIV to sex partners.

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. For information about HIV case management by county, visit http://bit.ly/FindCaseMgr.

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
3. 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.

Early Intervention Services and Outreach (EISO) are available in several Oregon counties and provides additional support for linkage to care and enhanced partner services outreach and testing.

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 Oregon's Investigative Guidelines for HIV at http://bit.ly/OR-IG. Questions related to HIV testing in Oregon may be directed to Alison Goldstein, HIV/STD Prevention Program Manager, at alison.goldstein@oha.oregon.gov.

HIV TEST CONSENT

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.

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 test specimen collection, handling and transportation

HIV prevention test form (OHA 9810)

Supporting clients that test HIV-positive

HIV Testing Key Messages

Oregon HIV test process

Oregon HIV laws guide