WASHINGTON STATE NONCLINICAL SETTING HIV TESTING GUIDELINES

REVISED July 1, 2021

This document is consistent with the Revised Code of Washington (RCW), Washington State Administrative Codes (WACs) and Guidelines recommended by the Center for Disease Control and Prevention

Use of trade names and commercial sources is for identification only and does not imply endorsement by the Washington State Department of Health

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Purpose of Manual

The purpose of this *Washington State Nonclinical Setting HIV Testing Guidelines* manual is to familiarize testing providers working in nonclinical settings with key testing policies and procedures that impact HIV testing services and deliverables. This includes, but is not limited to, licensing requirements to collect blood specimen and providing collection oversight, HIV training and education requirements, protocols for conducting HIV counseling, testing and referrals, HIV testing technologies and algorithms, and targeting and recruitment strategies to improve outreach performance. HIV testing providers who are aware of these issues are more likely to provide high-quality HIV testing services to their clients.[2] CDC's *"Implementing HIV Testing in Nonclinical Settings – A Guide for HIV Testing Providers"* was a source document used extensively throughout this manual. The CDC manual covers other topics not discussed in this document. Washington State Department of Health recommends agencies utilize CDC's HIV testing manual as a supplemental tool for supporting their testing programs. Please see https://www.cdc.gov/hiv/testing/nonclinical/ for more info.

Defining Nonclinical Settings

As a general rule, nonclinical settings are sites where medical, diagnostic, and treatment services are not routinely provided, but where select diagnostic, screening, and minor invasive services are routinely offered. Examples of nonclinical settings where HIV testing may be offered include, but are not limited to, agency on-site testing, mobile testing units, churches, bathhouses, parks, shelters, syringe services programs, health-related storefronts, homes, and other social services organizations.[1] Specific types of non-clinical settings for testing will be discussed below in the section entitled "Outreach/Event Testing".

Whole Blood Specimen Collection

In Washington State, the following three categories of professionals have the authority to collect blood specimens through capillary puncture (fingerstick) and venipuncture (vein):

- Some licensed health care professions (whose scopes of practice allow it, e.g., RNs)
- Certified health care assistants
- Disease Intervention Specialists (DIS) who investigate cases of HIV/STI/HCV infections.

Licensed Health Care Professionals

The scope of practice of some licensed health care professionals (including physicians and nurses) allows those licensed individuals to collect blood specimens by capillary draw (fingerstick) and venipuncture. Therefore, no additional licensing is required to conduct blood specimen collection for rapid testing.

Certified Health Care Assistants

The Washington State Medical Assistants Law, Chapter 18.360 RCW, requires certification of unlicensed individuals who may be administering skin tests, subcutaneous, intradermal, intramuscular, and intravenous injections, or performing minor invasive procedures to withdraw blood and/or hemodialysis. Fingerstick, venous and capillary collection of blood specimens are procedures that require certification as a health care assistant for all unlicensed individuals (exception to this: sexually transmitted disease case investigators/DIS). For further discussion of Medical Assistant certification and medical oversight rules please see below at pp. 5-6.

To obtain information regarding the licensing of health care professionals, contact:

Health Professions Quality Assurance
Customer Service Center
P.O. Box 47865
Olympia, WA 98504

Phone: (360) 236-4700
Website: HSQA DIVISION

Health Systems Quality Assurance

Health Systems Quality Assurance (HSQA) regulates and supports more than 404,000 health professionals in 83 health professions, and 7,000 health groups and programs. The HSQA is the primary contact for the public, health providers, facilities, emergency management services and many other customers.
http://www.doh.wa.gov/AboutUs/ProgramsandServices/HealthSystemsQualityAssurance
A list of Healthcare Professions requiring credentialing can be found here:
http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/HealthcareProfessionalCredentialingRequirements

Specimen Collection Oversight/Supervision

In Washington State, the supervision and oversight requirement for those with authority to collect blood specimens vary as follows:

Licensed Health Care Professionals

For those physicians whose licenses allow for blood specimen collection by capillary puncture and venipuncture, no additional supervision or oversight is needed.

RNs and LPNs are allowed to perform blood collection activities while under the direction of a licensed physician **(RCW 18.79.270).**

Certified Medical Assistants (MA)

Certified medical assistants are individuals who have been certified as health care assistants by DOH to perform certain medical procedures through the delegation of a licensed health care professional. Certified medical assistants who perform blood specimen collection require blood specimen training and supervision by a licensed health care practitioner.

DOH supports training for the Medical Assistant – Phlebotomist (MA-P) certification, which allows testing staff to conduct fingerstick and venipuncture for HIV, Syphilis and Heptatis testing of clients. For requirements of the MA-P certification, please see https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/MedicalAssistant/LicenseRequirements/Phlebotomist.

Medical Assistant Phlebotomy courses are periodically offered through the University of Washington STD Prevention Training Center. Posting of classes can be found here: http://uwptc.org/ DOH can sponsor testing partner staff to attend this training. DOH will cover training costs for those who are sponsored. Please contact the DOH Infectious Disease Testing Consultant for more information.

Medical Oversight:

Washington State laws and rules do require non-clinical testing programs and staff have medical oversight for their blood testing work. Therefore, each non-clinical testing program must have in place a licensed medical professional (usually an M.D.) who is legally able to delegate and oversee blood testing work (capillary and venipuncture) by non-licensed/non-clinical, MA-certified testing staff. For Medical Assistant – Phlebotomist, the delegating health care practitioner does not need to be present when a MA-P is performing capillary or venous procedures to withdraw blood, but must be immediately available for consultation by phone or in person within a reasonable period of time (WAC 246-827-0420, and see also WAC 246-826-030). For more detail on Oversight testing rules in Washington, please refer to WAC 246-827-

0420. Staffing and supervision policies and procedures for each test conducted should reflect this in writing with a copy submitted to DOH – Office of Infectious Disease (QA Plan).

SEXUALLY TRANSMITTED DISEASE CASE INVESTIGATORS (DIS)
In accordance with **RCW 70.24.120**, sexually transmitted disease case investigators, upon specific authorization from a physician, are authorized to perform venipuncture or skin puncture on a person for the sole purpose of withdrawing blood for use in sexually transmitted disease tests, which include HIV, Syphilis, and Hepatitis infections. DIS are still subject to rules governing supervision of blood testing activities by a licensed medical professional.

Agency License Requirements

In accordance with **RCW Chapter 70.42**, the Washington State Medical Test Site Law requires all sites performing clinical laboratory testing obtain a state Medical Test Site (MTS) license.

All entities conducting CLIA-waived rapid HIV, Syphilis and/or HCV testing must obtain an MTS license (Category: Certificate of Waiver). The Washington State MTS license and the federal CLIA Certificate of Waiver are essentially the same documents. Agencies apply for their MTS license through the Washington State DOH Laboratory Quality Assurance (LQA). Refer to the LQA website for additional information. MTS/FAQ

If the site already has an MTS license covering other laboratory testing, CLIA-waived rapid HIV, syphilis and HCV testing can be performed under that license. However, the site must still inform LQA (via email, fax or regular mail at the address below) that this testing will be added to their existing license by filing a Test Change Form.

For more information on informing the department that rapid or any additional CLIA-waived testing will be added to an existing license, or to obtain a license application, contact:

Department of Health
Office of Laboratory Quality Assurance
1610 NE 150th St.
Shoreline, WA 98155

Phone: (206) 361-2802
Website: Laboratory Quality Assurance

The fee for a two-year MTS Certificate of Waiver to perform CLIA-waived testing is $150. A fee statement will be sent once the license application has been received. If the site already has an MTS license that covers other laboratory tests, there will be no additional fee for adding a rapid HIV, Syphilis or HCV test.

If your office has any questions about the MTS/CLIA process, please contact the DOH/OID Infectious Disease Testing Coordinator.

Confidentiality

All testing and related records pertaining to clients are confidential and precautionary measures must be taken to secure all such information.

All client information and records must be maintained using an approach consistent with Washington State Law **(RCW 70.02 and RCW 70.24**) and, if applicable, the Privacy and Security Requirements promulgated by the federal government in the Health Insurance Portability and Accountability Act (HIPPA). Client information must be kept strictly confidential and records should be managed and stored in a secure manner.

Agencies providing DOH-supported HIV, STI and HCV testing must develop confidentiality policies and procedures that will prevent unauthorized persons from access to information shared in confidence. Confidential information includes any material, whether oral or recorded in any form or medium that identifies (or can readily be associated with the identity of) a person and is directly related to their health and care. All information relating to an individual's HIV status is protected under medical confidentiality guidelines and legal regulations (RCW 70.24), (WAC 246-100).
Minimum professional standards for any agency handling confidential information should provide employees with appropriate information regarding confidentiality guidelines and legal regulations **(RCW 70.24, RCW 70.02**, and where applicable, the federal HIPPA privacy regulations).

All staff involved in HIV/STI/HCV testing and health education activities with access to testing results and education/risk information should sign a confidentiality statement with their agencies acknowledging their awareness and understanding of 1) the legal requirements under state and federal law not to disclose medical, health education, and results information, and 2) the legal and agency consequences of such a disclosure.

HIV/AIDS Required Training and Education

This requirement was eliminated by the legislature via ESHB 1551 in the 2020 legislative session.

As of June 11, 2020, Washington State 2, 4, and 7-hour HIV/AIDS trainings are no longer required. As of June 11, 2020, Washington State 2, 4, and 7-hour HIV/AIDS trainings are no longer required.

Engrossed Substitute House Bill (ESHB) 1551 (Chapter 76, Laws of 2020) repealed statutes concerning AIDS education and training for emergency medical personnel, health professionals, and health care facility employees. In support of ESHB 1551, the Department of Health repealed AIDS education and training requirements for professions and facilities under the Secretary's authority.

ESHB 1551 added a definition of Bloodborne Pathogen in RCW 70.24.017 to include HIV, Hepatitis B, and Hepatitis C and eliminated outdated and duplicative statutory requirements for HIV/AIDS occupational exposure education and training for health care professionals and certain categories of employees.

Bloodborne Pathogen (BBP) Training remains required under Chapter 296-823 WAC adopted by the Department of Labor and Industries. Training conducted in compliance with this rule meets the curriculum requirements for HIV/AIDS training. Contact your employer or the Washington State Department of Labor and Industries for more information and training options.

Background

In 2014, Governor Inslee issued a proclamation to end the HIV epidemic in Washington by achieving the goal to reduce new HIV diagnoses by 50 percent by 2020. The End AIDS Washington report (PDF) recommends that we modernize Washington's HIV laws to reflect current science and reduce HIV-related stigma. Washington's laws related to HIV/AIDS primarily sit within Chapter 70.24 RCW, Control and Treatment of Sexually Transmitted Disease.

Many parts of the statute have not been updated, since they were enacted in 1988. The law was outdated and inconsistent with current state and national best practices. ESHB 1551 addresses HIV stigma and modernizes the law; including eliminating the requirement for additional HIV/AIDS training for health care professionals.

History

The purpose of requiring specific HIV/AIDS training was to ensure health care professionals were adequately educated and informed about the latest etiology and epidemiology; testing and counseling; infection control guidelines; clinical manifestations and treatment; legal and ethical issues including confidentiality; and psychosocial issues including special population considerations. Until June 11, 2020, health care professionals were required to complete HIV/AIDS Training **and** Blood Borne Pathogen (BBP) Training. ESHB 1551 eliminated outdated and duplicative statutory requirements for HIV/AIDS occupational exposure education and training for health care professionals and certain categories of employees.

Additional Information from Labor and Industries

Bloodborne Pathogens WAC 296-823 - Laws and Rule

Labor and Industries Safety and Health Rules - Bloodborne Pathogens Chapter 296-823

DOH – Office of Infectious Disease will be working with our non-clinical testing partners in Fiscal Year 2022 to ensure compliance with Labor & Industries rules concerned Bloodborne Pathogen training and the implementation of a Bloodborne Pathogen Exposure Control Plan at the agency level.

Age of Consent

The same laws regarding age of consent for diagnostic HIV, STI and HCV testing apply to rapid testing screening technology for same. A person must be 14 years of age to provide independent consent for an HIV, STI and HCV test **(RCW 70.24.110).**

Informed Consent

Previously, Washington State required **separate** and written consent for all non-mandated HIV testing. That rule, RCW 70.24.335, was repealed July 2018 in favor of an opt-out testing scheme for HIV testing in Washington. **As a result of the rule change, HIV testing will be subject to the same notification and consent requirements that apply to any other medical test, meaning that separate consent for HIV testing alone is no longer required**. For a greater discussion on these rule changes involving consent, please refer to WSR 18-14-090 Proposed Rules State Board of Health at http://lawfilesext.leg.wa.gov/law/wsr/2018/14/18-14-090.htm . Therefore, for purposes of this guideline, informed consent should be obtained from the client prior to conducting either/any test for HIV, STDs and Hepatitis C in a manner that consent would be obtained for any medical testing generally. Informed consent for all testing should be documented in writing and kept on file for any testing of HIV, STIs and Hepatis conducted by the non-clinical testing agency. A consent form may be integrated to include any and all of HIV, STI and Hepatitis testing. For further discussion on consent, please refer to the Washington

Law Health Manual – 4th Edition at http://www.wsha.org/wp-content/uploads/HLM_Chapter2A.pdf .

HIV Testing Technology[3]

These guidelines will focus predominately on rapid testing technologies used for HIV screenings; not diagnostic confirmation testing. These tests will be divided into two categories which are antibody detecting only and antigen/antibody combo tests. The Washington State Department of Health strongly recommends using blood-based specimen test technology. DOH recognizes that obtaining a blood specimen may not always be feasible and resorting to collecting an oral specimen may be more appropriate for that particular situation. Test agency leadership should use discretion when determining which testing technology to use; taking into consideration the health and safety of all parties involved. Your agency should have already determined which test technologies to use and staff appropriately trained to competently perform tests according to instructed procedures. Agencies should also be aware that the DOH Office of Infectious Disease is currently only offering support for whole blood-based rapid test kits described below.

Blood-based rapid HIV antibody tests are widely available in most nonclinical HIV testing sites, and blood (whole blood, serum, or plasma) is the preferred specimen for HIV testing because tests conducted with blood are more likely to detect early infection than those conducted with oral fluid. If your organization must use oral fluid for testing, then you should inform HIV testing clients and patients of the limitations of this type of specimen for testing, including a longer period to detection (window period).

The tests discussed below use only whole blood specimen collection.

Antibody Tests – (i.e. INSTI by bioLytical):

Whole blood HIV antibody tests detect the presence of antibodies against HIV, which typically develop within 2 to 8 weeks after exposure to the virus. An antibody test can be conducted on a sample of blood or oral fluid. Many antibody tests can be collected via point-of-care rapid test kits, meaning results can be returned on the same day, or within the same hour, or even within minutes. Rapid HIV antibody tests can be attractive for use in outreach and/or high-volume settings because these settings may not be equipped to conduct venipuncture, and clients can get the results from their screening test quickly, which can allow quicker linkage to care or to preventive services.

Combination Antigen/Antibody Tests – (i.e. Alere Determine by Abbott):

Combination antigen/antibody tests detect both the antibody to HIV and the antigen "p24" a protein that is part of the virus itself. Because the p24 antigen can be detected before antibodies appear, combination tests can identify very early infections. These tests, used with blood specimens collected from the vein, are recommended by CDC as the first test in the laboratory testing algorithm.

Combination antigen/antibody rapid tests can be used for point-of-care testing, but detect infection several days later than the laboratory-based combination tests. The evidence is inconclusive about the ability of combination antigen/antibody rapid tests to accurately detect the p24 antigen on whole blood specimens, and CDC has not provided recommendations about the use of these tests. It is important that non-clinical testing agencies are aware of this possible limitation with the rapid combo Ab/Ag test v. a lab-based combo Ag/Ab test even where the manufacturer is the same.

Testing Approaches[4]

Point-of-Care Testing:

Most rapid HIV testing performed in nonclinical settings is considered "point-of-care" or "point-of-contact" because the test is processed onsite where the client is receiving services. Results of rapid tests are often provided in less than 1 hour or even within minutes. The testing may be called "rapid HIV testing" or CLIA-waived rapid HIV testing." A list of CLIA-waived rapid HIV tests is available at https://www.cdc.gov/hiv/pdf/testing/rapid-hiv-tests-non-clinical.pdf.

Home Tests:

Home HIV testing was implemented in WA State expressly due to the COVID-19 pandemic that began in and ran through most of 2020. DOH, in consultation with federal, state and local non-clinical testing partners elected to use Molecular Testing Lab (MTL) for this project. MTL is based in Vancouver, WA and offers 4th generation laboratory-based HIV testing technology via Dried Blood Spot (DBS) collection. DBS testing allows for a test kit to be sent either directly to the client or to the testing agency for use with a client in any safe and secure location where the client can place a test. The test kit requires the client to conduct a finger-stick and place the blood sample on a testing card. The testing card is then prepared for shipment and the client drops the return package in the mail for laboratory processing. Results are usually ready within a week. Results are sent directly to the testing agency for documentation and disclose to the client. For more information on MTL DBS home testing please refer to the document "Home-Collected Dried Blood Spot (DBS) HIV Testing Program Guidance". Additional information on home testing is available at https://www.cdc.gov/hiv/testing/hometests.html.

Laboratory-Based Testing:

If a blood specimen is drawn for the laboratory, multiple tests can be conducted using the initially drawn specimen. For blood specimens sent to a laboratory, CDC and Association of Public Health Laboratories recommend the use of an antigen/antibody combination assay for the first test, and if reactive, additional testing with a HIV1/2 differentiation assay and NAT when needed.

Some nonclinical HIV testing sites work closely with laboratories to process the site's HIV tests and send back the test results. In this type of arrangement, your agency will collect and prepare blood samples from your clients and ship them to the laboratory where the HIV analysis will be performed. If your testing site is conducting laboratory-based HIV testing on blood samples, you will need to follow the appropriate sample collection and preparation procedures as defined by the laboratory doing the testing. The procedure for sample collection and preparation will vary depending on the test kits and testing algorithm used by the laboratory and according to the test manufacturer's established requirements. It is very important that you follow these procedures precisely to ensure an accurate test result. Each laboratory has procedures that dictate the type and minimum size of sample collection tubes to be used, shipping requirements, temperature requirements, preparation of the samples, timeframes associated with processing the test, and reporting results.

Some laboratories and health departments may provide training on sample collection and preparation, safe packaging, and transportation. Consult with your agency and the laboratory that will be performing HIV testing to see whether this training is available. More information on laboratory-based HIV tests is available at https://stacks.cdc.gov/view/cdc/23447/.

Testing Algorithms[5]

Most HIV testing conducted in nonclinical settings will include an initial HIV test (usually a rapid test) and, if the initial HIV test is reactive preliminarily positive, a follow-up HIV test (a blood draw/venipuncture) will be needed to confirm the preliminary result. If the testing agency is unable to provide the confirmatory test on-site for the client, then a linkage system should be in place to ensure that the client is linked to care for these and other services related to the preliminary positive HIV test result. If follow-up testing is required, both the initial and follow-up tests are considered part of the same testing event for reporting purposes for CDC-funded programs, including for input into EvaluationWeb®. Only the final test result should be reported in EvaluationWeb®. This means that an initial entry of "preliminary positive" in Evaluation Web will need to be changed to "positive" if the result of the client's confirmatory test is learned or otherwise known to the non-clinical testing agency.

Rapid/Rapid testing algorithm: using one rapid test to confirm preliminary test results with that of another rapid tests may be an appropriate course of action in certain circumstances. When used, the two rapid testing products should be from different manufacturers. Again, a follow-up diagnostic test (confirmation) should be performed if either test yields a positive result. (Please note that the rapid/rapid testing scheme as confirmation of a preliminary positive results is not currently supported by Washington State DOH.)

Laboratory testing algorithm:

In 2014, CDC published new recommendations for the HIV testing algorithm in laboratory settings, see https://stacks.cdc.gov/view/cdc/23447 and https://stacks.cdc.gov/view/cdc/50872 (updated 2018 and applicable to point-of-care rapid testing technologies). The updated recommendations outline a new testing algorithm that begins with a combination antigen/antibody test that detects both HIV-1 and HIV-2 antibodies. This algorithm has many advantages over previous ones:

- Follow up testing does not rely on the Western blot, which does not detect early infections
- Accurate diagnosis of HIV-2
- Potential for earlier diagnosis of HIV-1
- Pathway to discover the existence of Acute HIV Infection

Note: The recommended HIV testing algorithm cannot be used with oral fluid specimens.

Some laboratories still allow submission of oral fluid specimens, but these specimens are not part of CDC's recommended algorithm and constitutes another reason why DOH is unable to support oral fluid testing in non-clinical settings. Testing oral fluid in the lab requires a different testing algorithm that includes the Western blot, which does not detect infection as early as the more sensitive blood tests recommended in the algorithm. If Oral testing is used and a preliminary positive result is obtained, the client should be referred to a location where whole blood testing is available, including confirmatory testing.

HIV Health Education and Risk Assessment[6]

Washington State requires that individuals who are tested for HIV receive health education and an individualized risk assessment. Please refer to WAC 246-100-209 for more information. (Please note that at the time of this publication, this WAC was under revision to reflect changes in this work under the umbrella of Blood Borne Pathogens as opposed to separate and stigmatizing stand-alone HIV work.

HIV/STI/Hepatitis health education is a vital step in the testing process as it sets the stage for forming relationships, creating medical records, collecting surveillance data and other related service deliverables. Health Education and risk assessment should be client focused. Health Education and risk assessment may take several forms and approaches have changed over the years. For individual testing, CDC no longer supports extensive pretest and posttest counseling; but rather health education tailored to the client's needs. This strategy is recommended in rapid HIV testing environments.[6] HIV counseling usually has two defining steps; pretest results and posttest results. Test technology and testing environment will impact what happens between these two steps. Below is an illustration of how different settings and technology influences testing approaches.

Figure 2: Three scenarios for conducting an individual HIV test

Rapid HIV testing (10–20 minute read time)	**Instant HIV testing** (~1 minute read time)	**Nonrapid HIV testing** (Laboratory)
Preresults steps	**Preresults steps**	**Preresults steps, initial visit**
Step 1: Introduce and orient client to session	**Step 1**: Introduce and orient client to session	**Step 1**: Introduce and orient client to session
Step 2: Prepare for and conduct initial rapid HIV test (10–20 minute read time)	**Step 2**: Conduct brief risk screening	**Step 2**: Conduct brief risk screening
Step 3: Conduct brief risk screening	**Step 3**: Prepare for and conduct initial instant HIV test (~1 minute read time)	**Step 3**: Prepare for test and collect sample to send to laboratory
Postresults steps	**Postresults steps**	**Postresults steps, return visit** (ideally, no more than 1 week after initial visit)
Step 4: Provide results of initial rapid HIV test and follow your agency's protocol for conducting follow-up confirmatory testing	**Step 4**: Provide results of initial instant HIV test and follow your agency's protocol for conducting follow-up confirmatory testing	**Step 4**: Check in with client
Step 5: Develop care, treatment, and prevention plan based on results	**Step 5**: Develop care, treatment, and prevention plan based on results	**Step 5**: Provide confirmed results
Step 6: Refer and link with medical care, social and behavioral services	**Step 6**: Refer and link with medical care, social and behavioral services	**Step 6**: Develop care, treatment, and prevention plan based on results
		Step 7: Refer and link with medical care, social and behavioral services

As you can see, the steps are more or less the same for all three scenarios, with minimal modifications. In the rapid testing scenario, the HIV test is conducted as step 2 and then while the test is developing you will conduct brief risk screening. However, in the instant and nonrapid testing scenarios, you will conduct brief risk screening and then conduct the instant test or collect the sample.

Initiating PrEP Awareness and Intervention[7]

It is important to reinforce HIV prevention messages, to motivate the client to remain HIV-negative, and support them to access medical, social, and behavioral referral services, as indicated based on their risk and specific situation.

As the first point of contact for many high-risk HIV negative clients, HIV testing providers in nonclinical settings should not only educate clients about PrEP, but they should also know and assess for PrEP indications and refer persons at substantial risk for acquiring HIV to a PrEP navigator or subscriber where PrEP is available. PrEP navigators and providers will conduct additional risk behavior assessments or use a risk index to determine if clients are appropriate for PrEP. The tools for assessing risk behavior and the risk index can be found in the 2014 PrEP clinical Practice Guideline and Clinical Providers' Supplement. Consumer basic fact sheet about PrEP may be found here: https://www.cdc.gov/hiv/pdf/library/factsheets/prep101-consumer-info.pdf. The Washington State Testing Template also provides a guide for who might be a good candidate for PrEP and eligibility for PrEP program and support work.

The criteria that HIV testing providers use to determine whether HIV negative clients are at substantial risk of acquiring HIV and should be offered PrEP may be assessed over the course of the client's HIV testing session or at the end of the session after results have been delivered. This is considered an important part of revisiting the risk discussion and reinforcing decisions that will help the client remain HIV negative. PrEP is currently recommended for the following persons in Washington State who meet any of the below criteria:

- Currently having sex with a person living with HIV (PLWH) that is not on ART or is on ART but is not virally suppressed
- In the last 12 months, the client has used methamphetamines
- In the last 12 months, the client has used poppers
- In the last 12 months, the client has been diagnoses with gonorrhea
- In the last 12 months, the client has been diagnosed with chlamydia
- In the last 12 months, the client has been diagnosed with syphilis
- In the last 12 months, the client has exchanged sex for something of value

PrEP should be considered as a biomedical prevention tool for MSM at substantial risk of HIV acquisition, as well as heterosexual men and women and PWID at substantial risk of HIV acquisition. This may include persons who have unprotected sex or share needles with multiple partners of unknown HIV status, or persons who are in known HIV discordant relationships, where one partner is HIV negative and the other partner is HIV positive and not virally suppressed.[7]

Specimen Collection and Preparation[8]

Regardless of the HIV testing method you are using, you should perform specimen collection and preparation correctly and consistently to ensure the accuracy of your clients' test results. All HIV testing providers should be trained in the specimen collection procedure that is used at their agency, whether venipuncture, fingerstick, or oral fluid. Practical hands-on training should be available through your local health department, test technology sales representatives, or other capacity building organization, including DOH Office of Infectious Disease. CDC's Rapid HIV Testing Online also provides some of this information, and can be accessed at https://effectiveinterventions.cdc.gov/en/2018-design/TrainingCalendar/EventList/2013/04/01/default-calendar/Rapid_HIV_Testing_Online. This resource also contains an in-depth online training module that covers several HIV Rapid Testing topics.

Every test kit also has a product insert, which should be readily available to all persons who conduct the HIV test. This insert should be consulted to ensure accurate procedures. However, although job aids such as the test kit insert are helpful, they should not be relied upon as the sole source of information for conducting tests. All agencies should have HIV testing policies and procedures that describe instructions for accurate specimen collection and preparation, as well as safety precautions and a biohazard disposal protocol to protect clients and testing personnel. For more information, see "Universal precautions for employee and consumer safety" in Chapter 2 of the *Implementing HIV Testing in Nonclinical Settings – A guide for HIV Testing Providers"* manual (see https://www.cdc.gov/hiv/pdf/testing/cdc_hiv_implementing_hiv_testing_in_nonclinical_settings.pdf at pages 17-18).

Window Periods and Interpreting Results[9]

In order to deliver an accurate message about the meaning of HIV test results, you should be familiar with the testing algorithm used by your agency. Remember to use simple and clear language to explain test results to clients.

Reactive (Positive) Results: If the initial rapid HIV test is reactive, this indicates that HIV antibodies or antigen have been detected. The result is interpreted as a preliminary positive test result and follow-up testing is required to confirm the diagnosis. In most cases, clients who are reactive on their initial rapid HIV test are true positives; that is, they are likely to be reactive on a follow-up test as well and should be prepared to receive a confirmed positive result. For this reason, it may be beneficial to immediately link clients who have preliminary positive test results to HIV medical care and to Partner Services if follow-up testing cannot be conducted

onsite. It is also important to counsel clients and to assist them with risk-reduction strategies while they wait for their follow-up test results.

If the results from the CDC-recommended laboratory algorithm or an algorithm using oral fluid in the laboratory indicate HIV infection, clients should be linked to HIV medical care and referred to partner services (PS) and/or other prevention services. If the laboratory algorithm results indicate an acute infection, linkage to care should be expedited, if possible, due to the increased risk of transmission to partners. In addition, it is beneficial for clients to be counseled to assist them in adopting risk-reduction strategies**. You might say to the clients: "The test result shows that you have with HIV."**

Nonreactive (Negative) Results: A nonreactive test result indicates no evidence of HIV infection and can be interpreted as HIV negative. Depending on the window period associated with the test that you are using, clients that report recent known or possible exposure to HIV can be advised that, because of their recent exposure, it is possible the test did not detect HIV antibodies or antigens at this time. You should recommend retesting at an appropriate interval based on the client's risk and the type of test used. **You might say to clients: "The test result shows that there is no evidence of HIV**. **If you've had a recent exposure, it may be too early to tell if you have the virus. You should be retested in_____ weeks."**

Also upon receipt of a negative test result, the tester should consider initiating or continuing a discussion about PrEP, PrEP eligibility assessment, and potential PrEP and benefits navigation services to assist linking the client to PrEP medical services, including information on DOH's PrEP_DAP program (PrEP Drug Assistance).

Indeterminate (Invalid) Results: On occasion testing with either a rapid test or laboratory level technology test will yield *indeterminate* results, and therefore cannot be interpreted. These results may be related to recent infection or infection with HIV-2, concurrent infection with other viruses or diseases, vaccination (e.g., HIV vaccine trial participants, or problems with the sample or testing procedure). Additional tests should be performed to rule out extenuating factors and a conclusive determination can be obtained. **You might say to the clients: "Your test result is indeterminate, which means that the test cannot tell whether or not you have HIV. Because you may have been recently exposed to HIV; we need to follow up with more testing. We can help you set up those appointments for additional tests." Referrals may be necessary for this additional testing. Please check with your agency's testing Quality Assurance plan, filed with DOH-OID, for more information.**

Cautions regarding the window period and acute infection: In an attempt to address the window period, many agencies recommend that HIV-negative clients return for retesting 3 months after a potential exposure to HIV in order to feel more confident with their results.

However, if this message is given to all clients regardless of their specific risk, this message can be diluted and clients may not fully understand the importance of identifying acute HIV infection. Furthermore, many clients may interpret this message as "3 months from their last HIV negative test," prolonging the time until they are retested and potentially missing opportunities for identifying acute or early infection.

If someone has acute HIV infection, they can be highly infectious and may be likely to transmit the virus to others. Clients should understand the importance of identifying HIV infection as early as possible. If a client is concerned about a recent exposure or they report symptoms of acute HIV infection such as persistent fever, swollen throat or lymph nodes, or other severe flu-like symptoms, they should be referred immediately to their doctor or other local clinic for acute infection (viral load) testing. You should emphasize the need for using protection until acute infection can be ruled out. If testing immediately for acute infection is not an option, then the client should be tested at your site and then retested 3 months or less after their potential and most recent exposure.

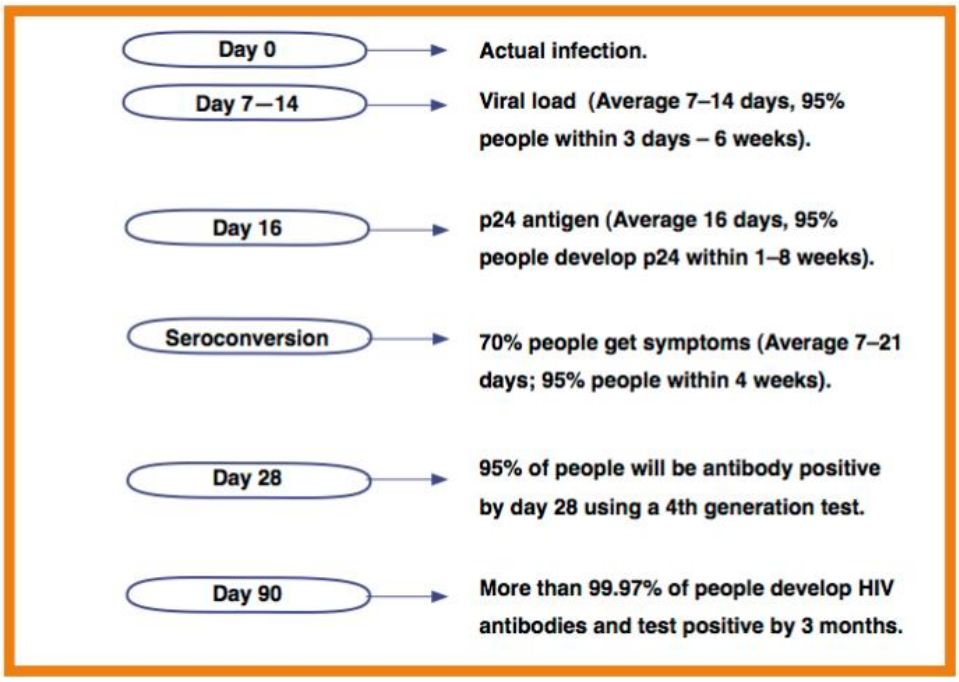
Window periods will be determined based on the testing technology that is used. The following are examples of window periods:

3rd Generation Rapid Antibody Tests (INSTI) - Minimum 22 days, Median: 35 days, Max: 60 days

4th Generation Rapid Antigen/Antibody (Alere Determine) – Minimum 15 days, Median: 33 days, Max: 60 days

4th Generation Laboratory-based Antigen/Antibody (MTL_DBS) – Minimum 8 days, Average: 28 days (95% will convert by day 28; Max: 44 days

A good rule of thumb is that most infections will be picked up within about 6 weeks after exposure, with a likely maximum of 60 days or 2 months. For those who are super concerned about the window period, the absolute max is considered to be 90 days where 99.97% of people who are newly living with HIV should have detectable antibody and a positive test. You may also refer to this graph generally that applies to laboratory-based HIV testing as well as consult http://i-base.info/guides/testing/what-is-the-window-period



False-negative test results: False-negative test results occur when someone who has HIV receives an HIV-negative test result. This scenario has been documented in persons on ART and in some person receiving PrEP. However, additional data are needed to determine the extent to which test performance is affected by these factors. HIV testing providers may wish to ask clients if they are currently using ART, nPEP/PEP, or PrEP, in order to determine if additional testing is necessary to rule out a false negative result. False-negative results may occur for other reasons as well, such as test design, improper test procedures, or mislabeling of the specimen.

False-positive test results: False-positive test results occur when someone who is not infected with HIV receives an HIV positive test result. This scenario is not frequent, but can occur in clients who are participating in HIV vaccine trials. HIV vaccine-induced antibodies can cause a rapid HIV antibody test to give a positive result, even though the person does not have HIV. All clients who receive an HIV-positive test result and who are also HIV vaccine trial participants should contact the vaccine trial site for evaluation or to receive a referral to HIV medical care for further evaluation and/or testing. So for clients who question whether their result is "false-positive" in nature, it might make sense to ask them whether they are part of an HIV vaccine trial and provide information on how such can impact results.

False-positive test results also occur in people who have not received the HIV vaccine in the study trial. The number of clients who received false positive test results will vary based on the type of tests you use and the HIV prevalence in your setting. False-positive test results are considered to be very rare.

False-positive results may also occur for other reasons such as those mentioned under false-negative results.

HIV Test Event Testing Steps[10]

Pre-results Steps:

There are 3 pre-results steps for individual HIV testing:

- Step 1: Introduce and orient the client to the test event session
- Step 2: Prepare for and conduct the rapid HIV test
- Step 3: Conduct brief risk screening

Step 1: Introduce and orient the client to the session:

The first thing you will do when conducting an individual HIV testing session is introduce yourself and orient the client to the session. **The key tasks for step 1 are:**

- Introduce yourself and describe your role
- Provide a brief session overview, including:
  - How long the session will take
  - Process for conducting the test
  - How results are returned (i.e., same day or return for results)
- Obtain concurrence/consent to proceed with the session (consult your agency policy regarding consent).

This step is important for building rapport and establishing client expectations for what will happen during the HIV testing session. Generally, this step will take about 1-2 minutes.

Step 2: Prepare for and conduct the rapid HIV test

In step 2, you will provide the client with basic information about the HIV test. Use simple, clear language that the client can understand. Provide information in a language and at a reading level appropriate to the client. Information can be presented verbally, written, or through videos, computers, or other electronic technology. It should only take a few minutes to provide the client with this basic information and answer any questions they might have about the rapid testing process. Then you will collect the sample and conduct the rapid HIV test. **The key tasks for this step are:**

- Explain the process of conducting the HIV test, including:
    - Type of test used (rapid vs. nonrapid; antibody vs combination antibody/antigen test)
    - Sample collected (e.g., fingerstick or venous blood sample)
    - Time until test results are ready
- Explain the meaning of HIV negative and HIV-positive test results, including:
    - Need for retesting if HIV negative
    - Need for and process of conducting follow-up testing if HIV positive
    - Possibility of invalid result
- Obtain consent to test (in accordance with agency protocol and applicable laws/rules)
- Distribute test kit information booklet (required for CLIA-waived tests)
- Collect specimen and conduct rapid HIV test

As you conduct the brief risk screening helping the client assess what may be putting them at risk for HIV, your client may have questions about acute infection, the window period, and retesting for HIV, which can also be addressed while you are waiting for the test results.

Post-results Steps:

The 3 post-results steps for individual HIV testing are:

- Step 4: Deliver results
- Step 5: Develop a care, treatment, and prevention plan based on results
- Step 6: Actively refer and link with medical care, preventive care, and social and behavioral services as appropriate based on risk-assessment, client need and test results.

If you are conducting laboratory testing, remember that you will include 1 additional step before delivering results. When the client returns to your site for his or her result (ideally no more than 1 week after the initial visit), you should first check in with the client to address any HIV risk concerns or issues since the last visit. Then proceed with delivering results.

Delivering HIV Testing Results[11]

If you are conducting a CLIA-waived rapid HIV test, after following the manufacturer's instructions and allowing for the appropriate time for the test to process, you will read the test device and interpret the result. If the test was conducted by another staff at your agency or outside the room where the client is waiting, obtain the result and return to the client. If the

client was in the waiting room, call client back to the HIV testing room to receive their result. If the test result is preliminary and must be confirmed with a follow-up test, you will indicate this to the client and follow your agency's procedure for follow –up testing.

The 2 key steps for delivering results are:

- **Confirm the client's readiness to receive their result**
- **Provide a clear explanation of the client's result**

HIV-Negative Test Results (Non-Reactive): For clients testing HIV-negative, the specific tasks for this step are:

- Explore client's reaction to result
- Discuss need for retesting based on window period of test used and client's risk
- Emphasize key risk reduction strategies that will help the client remain HIV negative:
    - Choose less risky sexual behaviors
    - Get tested for HIV together with partner (s)
    - Use condoms consistently and correctly
    - Reduce number of sex partners
    - Talk to doctor about PrEP (as indicated, according to PrEP screening indicators)
    - Talk to doctor about nPEP (as indicated, within 3 days following a specific exposure to HIV)
    - Get tested and treated for other STDs and encourage partners to do the same
    - If partner is HIV positive, encourage partner to get and stay on treatment
    - Actively refer and make linkages to the above services as needed
- Provide condoms

Clients receiving an HIV negative test result may experience a range of emotions, including relief, shock, joy, or dismay. HIV testing providers should be prepared for any number of responses from clients and should remain neutral as they explore the client's reaction. It is important to reinforce HIV prevention messages, to motivate the client to remain HIV negative, and support them to access medical, social, and behavioral referral services, as indicated based on their risk and specific situation.

HIV Positive Test Results (Reactive): For clients testing HIV positive, the specific steps are:

- Explore client's reaction to result
- Advise on next steps for follow-up testing
- Advise and refer to care and treatment for newly diagnosed clients or those returning to or desiring to establish care

  - Treatment can help people with HIV live long, healthy lives and prevent transmission
  - Explore health benefits status with client (i.e., insured?)
  - Discuss linkage to care options and make active referral as appropriate
  - Other health issues can be addressed
- Discuss disclosure and inform about processes for partner services
  - Advise//Encourage conversation between client and the local health jurisdiction representative or Disease Intervention Specialist (DIS) regarding partner services, including the availability of voluntary partner notification services
- Emphasize key risk reduction strategies that will prevent transmission
  - Discuss and recommend treatment as prevention
    - Discuss the importance of viral suppression and **U=U** (Undetectable = Untransmittable to prevent sexual transmission)
  - Choose less risky sexual and needle-share/substance use behaviors
  - Get tested together with their partners
  - Use condoms consistently and correctly
  - Reduce number of sex partners
  - Encourage partners to be tested
- Provide condoms

Clients receiving a positive test result for the first time might also experience a wide range of emotions, including shock, grief, or other strong feelings. While exploring the client's reaction to his or her result, you can effectively use silence to express empathy and give the client space to absorb this new information. Attend to the client's immediate needs before moving on with other tasks.

Advise the client on their next steps for follow-up testing to confirm the HIV positive test result. Follow-up testing can be addressed in a number of ways:

1. Immediately link clients to medical care for follow-up and confirmatory testing after the initial reactive rapid test result.
2. Collect a specimen to send to a lab for follow-up confirmatory testing after the initial reactive rapid test result; discuss the importance of returning to the agency to get this test result; and schedule a day and time for the client to return to the agency to get the result of the follow-up test.
3. Collect a specimen and run a second rapid test using a different rapid test to confirm the preliminary result as a second preliminary positive test result. If the second test is reactive, follow protocols for a preliminary positive reactive test results. Additional follow up test is required to confirm results through a laboratory level

testing procedure that uses CDC's laboratory testing algorithm. Please note that the existence of successive preliminary positive HIV test results does not serve to confirm an HIV test result. A confirmatory differentiation HIV 1/2 will be necessary to confirm the preliminary test results for all persons other than those previously diagnosed.

Although it might be difficult in this moment for clients to grasp everything you are telling them, it is important to discuss disclosure to sex and/or needle-share partners, inform them about the processes for partner services and to reinforce the importance of accessing care and treatment. Most clients will be referred for follow-up testing to confirm their result and to be enrolled in HIV medical care, so that they can begin accessing treatment as soon as possible to prevent transmission and help them stay healthy. Remember that this is not the last encounter clients will have with the health care system; your primary goal should be to link clients with medical care and other necessary follow-up services, either directly or through a peer navigator or linkage counselor. HIV test events in Washington State are seen as entryways to either further preventive care or medical care, as the case may be, and any referral to any needed social/behavioral services.

DISCLOSING A POSITIVE (CONFIRMATORY) TEST RESULT: The steps for disclosing a preliminary positive result are the same with the disclosure of a confirmatory result with the exception of the timeframe between the tests and availability of the results. Therefore, if you are conducting laboratory testing, remember that you will include 1 additional step before delivering results. When the client returns to your site for his or her result (ideally no more than 1 week after the initial visit), you should first take a moment to check in with the client to address any HIV risk concerns or issues since the last visit. Then proceed with delivering results and making the appropriate referrals as necessary.

HIV Reporting

In Washington State, AIDS has been reported since 1983, symptomatic HIV infection since 1987, and asymptomatic HIV infection since 1999.

Agencies providing confidential HIV testing should develop policies and procedures (including roles and responsibilities) to ensure the timely reporting of HIV cases to Washington local health jurisdictions and/or DOH.

NOTE: Positive HIV results obtained through anonymous rapid testing are not reportable to local public health or DOH via surveillance. For HIV testing programs that are supported with

Washington State Department of Health funds, anonymous HIV testing is highly discouraged and agencies must individually report to DOH HIV Prevention Staff why a client elected to choose an anonymous HIV test.

However, it is strongly recommended that agencies offer and encourage confidential preliminary and confirmatory testing in order to ensure that clients receive timely confirmatory results, Partner Services, and referral into appropriate case management and care services.

State laws and health department security and confidentiality rules protect the identity of persons reported with HIV or AIDS. Anyone who violates these confidentiality laws may be found guilty of a gross misdemeanor with a fine of up to $5000 and up to 364 days in jail, and may also be subject to civil action for reckless or intentional disclosure up to a penalty of $10,000 for each violation or actual damages, whichever is greater (RCW 70.24.080, RCW 9A.20.021, RCW 70.24.084).

Case report information for individual patients can only be shared on a "need to know" basis for work pertaining to the client's seropositive status. Case reports must be kept in locked rooms with access limited to authorized personnel who are trained in maintaining the confidentiality and security of these records.

Each provider of testing services has a legal obligation under Washington law to report HIV test results to the local health jurisdiction of the client's residence. If the client lives outside of Washington State, then the case report should be sent to WA DOH for communication to the appropriate health jurisdiction. (Please contact the DOH/OID Infectious Disease Testing Coordinator for more information.) For Washington State disease reporting, testing agencies are advised to communicate with their local health department HIV/STD programs to establish an agreed upon method of reporting HIV cases. If you need assistance in establishing a reporting relationship with your local health jurisdiction, please contact the Infectious Disease Testing Coordinator at DOH/OID. For counties outside the location of the testing agency office, please refer to the DOH reporting link on how to report STD cases to other Washington counties - https://doh.wa.gov/YouandYourFamily/illnessandDisease/SexuallyTransmittedDisease/CaseReports

All test events, including anonymous tests that are negative, preliminary positive, or positive, should be entered into Evaluation Web (see below).

Linkage-To-Care[12]

As part of the confirming and delivering results process, special attention should focus on the development of a care, treatment, and prevention plan with the client based on their HIV test results and risk issues identified during the brief risk screening (see LTC steps above; fig. 2). After receiving their test result, whether HIV negative or HIV positive, clients may have a hard time absorbing lots of information so it may be most effective to identify key referral services, make linkages with those services, and schedule follow-up visits if the client has additional concerns. Alternatively, another provider, such as a linkage coordinator or peer navigator, can also address the client's concerns during follow-up visits.

The specific tasks of the follow up care and treatment plan will differ based on the client's results, but there will be some similarities whether the client was negative or positive. The tasks will also vary slightly depending on your agency's process for conducting follow-up testing for clients with an initial reactive rapid HIV test.

As a result, it is crucial that testing programs have in place linkage relationships to a strong network of service providers for care, prevention, navigation, health benefits and social services work in or near their communities. If assistance is needed to establish linkages to the providers of any of these services, please contact the Infectious Disease Testing Coordinator at DOH.

Partner Services (PS)[13]

Partner Services are available for all persons who test positive for HIV and other select sexually transmitted infections. The primary function of PS is to notify the sex and needle-sharing partners of People Living With HIV (PLWH) about their potential exposure to HIV. It is a voluntary service that involves interviewing newly diagnosed persons to elicit names of their current and previous sex and needle-sharing partners who might have been exposed to HIV, then confidentially notifying these partners of their potential exposure. In addition to this notification, Disease Intervention Specialists can offer these partners HIV testing and linkage to HIV medical or preventive care, including PrEP/nPEP services, social services, and behavioral services. Local health departments play a key role in implementing PS, and nonclinical HIV testing providers should be aware of the PS protocol followed by their agency.

Examples of partner services protocols include:

1. **Refer to local health department –** persons newly diagnosed with HIV are referred to the local health department where a Disease Intervention Specialist (DIS) conducts an interview to elicit the names and locating information of current and previous partners who may have been exposed to HIV. The DIS then contacts these partners and offers

HIV testing or testing referral services. In some jurisdictions, the health department initiates PS automatically when it receives an HIV case report form. Clients should be informed that the health department will contact them to discuss PS. **Please note the data question in Evaluation Web for PS18-1802 "was the client's information provided to the health department for Partner Services, yes or no".** The question indicates CDC's view that client information for a newly positive diagnosis should be forward to the health department for that agency to follow up and offer partner services for the client. DOH strongly encourages that PS referrals be made and that the Evaluation Web question on this point should be marked as "yes" when this referral has been made.

2. **DIS onsite –** some agencies have health department DIS staff onsite to interview clients who have a positive HIV test where the partner services process can begin.
3. **DIS on call –** some agencies work with the local health department to have DIS staff on call. When an individual is newly diagnosed with HIV, the DIS can be contacted and can arrive quickly at the agency to interview the client, set a time for the interview, or otherwise meet the client agreeable to both the client and DIS staff-person.
4. **CBO elicitation –** some CBOs have authorization from the health department to interview newly diagnosed clients and elicit their partner names and locating information. This information is provided to the health department to locate and notify partners of their potential exposure to HIV and provide HIV testing.

Outreach/Event Testing[14]

Prioritizing and Recruitment: Prioritizing and recruitment is the process by which persons from your focus population are located, engaged, and motivated to access HIV testing services. Regardless of whether HIV testing providers are directly involved in prioritizing and recruitment, they should be aware of how their HIV testing services are messaged in the community and how clients reach them for testing.

Prioritizing is the process for defining how you will direct your HIV testing services to identify persons who are unaware of their HIV status and who are at greatest risk for HIV infection. Appropriately prioritizing your HIV testing services to these highest-risk populations is necessary for maximizing resources, and for identifying undiagnosed HIV-positive persons in need of HIV medical care, treatment, and prevention services. Prioritizing can also help you identify high-risk HIV-negative persons needing important HIV prevention services, such as PrEP, non-occupational post-exposure prophylaxis (nPEP), and other social and behavioral interventions.

In nonclinical settings, it is important to prioritize your testing services to identify high-risk individuals who do not access health care services or who may not otherwise have access to HIV testing in clinical settings; these are the persons who may benefit most from HIV testing services in nonclinical settings, and so these are the persons you should attempt to recruit into your program. Additionally, in defining your focus population and how to reach them, your program should consult multiple data sources, including local epidemiologic and surveillance data, recent programmatic monitoring and evaluation data, and your health department's Comprehensive HIV Prevention Jurisdictional Plan. Members of your focus population, agency staff, and other service providers can also be important sources of information for identifying high-risk populations, where they congregate in the community, and the best ways of reaching them. Key informant interviews, which are brief interviews to obtain feedback from these groups, can be used for this purpose.

Each agency will need to define or segment their focus populations, which should include both their primary focus population and their secondary focus population (or sub-population). In order to narrow your overall focus population to reach persons most at risk for HIV infection, you will need to know what high-risk behaviors and other factors are related to increased risk in your community, who is engaging in these behaviors or is affected by these factors, and where to identify these populations. This will help you tailor your messages and services in a way that resonate with your focus population and plan for how to reach them.

In many cases, your HIV testing program's focus population will be determined by your funder, state or local health department, CDC, or agency management.

Washington State Department of Health has identified the following as priority testing populations based on available data, determinants of health and considerations involving equitable health outcomes:

- Men who have Sex with Men (MSM)/Trans women who have Sex with Men (TSM)
- Black (US Born and Foreign Born)/Hispanic (US Born and Foreign Born)
- Persons Who Inject and/or Use Drugs (PWID/PWUD)

This list is not meant to be exhaustive and is no way intended to preclude agencies from working with identified at-risk groups within their communities.

Recruitment: Recruitment begins once you have defined your focus population and identified where and how to reach them (i.e.., prioritizing). Community assessment or formative evaluation can provide valuable information on recruitment, given the dynamics

of different communities, and the potential for certain strategies to work better than others with high-risk groups.

Your agency should develop a recruitment plan that outlines when, where, and how recruitment of the prioritized populations should be done. The plan should include ideas about where your reach your priority populations, as well as the specific recruitment strategies and messages that will be used for reaching them and engaging them in HIV testing. You might find that your focus population is accessible at a physical location (e.g., a particular neighborhood, bar, or weekly meeting) or in a virtual space (e.g., Internet chat group, social media).

Once you have defined the recruitment strategies you will use to engage your focus population and outlined these in your plan, you should pilot these strategies and make refinements based on your results. Even after you begin implementing your recruitment strategies, you routinely monitor your HIV testing services to determine if you are meeting your targets, and make adjustments to your recruitment strategies as needed. For example, if you find over the course of 6 months that you have not tested anyone who is HIV positive, you might need to revise your recruitment strategies to better reach persons with undiagnosed HIV infection or at high-risk for acquiring HIV infection.

Recruitment Strategies: Agencies should aim to deliver strategic, culturally competent, client centered, community-based recruitment strategies that engage the focus population and motivate them to access HIV testing services. Organizations should collaborate with other organizations that have a history of working with and recruiting the priority population. They should seek input from community stakeholders, such as the advisory boards to select the most appropriate program promotion and recruitment strategies. Community stakeholders can also be useful for crafting recruitment messages, which may focus on increasing public awareness of the agency's services, destigmatizing HIV and HIV testing, and providing key information about HIV and HIV testing.

The 6 primary categories of recruitment strategies are the following:

1. **Street-based and venue-based outreach**
2. **Internet outreach**
3. **Internal referrals**
4. **External referrals**
5. **Social networking**
6. **Social marketing**

Street-based and **venue-based** outreach are done by engaging the priority population in their own environment, such as a particular street, neighborhood, hot spot, or venue (e.g., a bar,

hotel, bathhouse or community center). Outreach workers, who may include HIV testing providers, aim to reach the focus population with key messages about HIV and HIV testing. HIV testing services may also be offered in conjunction with street and venue-based outreach, if appropriate, and some agencies will bring a mobile testing unit, such as a van or tent, to provide HIV testing for the priority population.

Internet outreach involves reaching the focus population through online venues, such as chat rooms, social networking sites, and mobile applications. Agencies can promote HIV testing services including couples or partner testing through these approaches; provide information about HIV prevention, care, and treatment; or schedule appointments for clients seeking HIV testing. Internet-based outreach may be especially useful for reaching young people and MSM who do not identify as gay or who cannot be found in traditional outreach settings.

Internal referrals means accessing the focus population through other services offered at the HIV testing agency, such as through case management services, syringe services programs, substance use programs, mental health services, evidence-based HIV prevention interventions, sexually transmitted infection (STI) testing and treatment programs, and HIV medical care (for partners of people already in care). This approach can be successful, but persons with high-risk behaviors may not access these services independently, so additional recruitment strategies should also be used.

External referrals mean that persons from the priority populations are referred to HIV testing services by agencies outside the specific HIV testing agency. External agencies may include syringe services programs, substance use programs, mental health services, evidence-based HIV prevention interventions, STI testing and treatment programs, HIV medical care, and agencies that serve those who are houseless or unstably housed. These offsite programs identify high-risk clients who are accessing their services and send them to your agency for HIV testing. Building strong partnerships with external agencies that tend to serve high-risk clients is important, as is sharing information with them about how to make appropriate referrals to your program. DOH encourages the recruitment of these referral agencies by our testing partners to create and enhance testing linkage work for priority populations wherever they may engage with service delivery programs.

Social Networking Strategy (SNS) is a peer-driven approach to recruitment that involves identifying PLWH or high-risk HIV-negative persons from the community to serve as “recruiters” for your agency. Recruiters deliver key messages and encourage HIV testing among high-risk persons in their social, sexual, or substance-using networks. They may use coupons or invitations as a way of documenting that they have delivered these messages to potential clients. The recruiters are trained or “coached” on the best approaches to reach their peers, including who should be reached through this approach and what messages can motivate their

peers to be tested for HIV. Partner referral is a type of social networking that involves recruiters referring their sexual partners and/or needle-share partners to an HIV testing program. Recruiters may refer these sexual or needle-share partners to be tested alone, or recruiters may accompany their partners and be tested together.

Social marketing is the use of media (e.g. digital flyers and brochures, posters, print advertisements and materials, radio and television advertisements, or Internet advertisements) to recruit clients into HIV testing programs. Organizations can develop their own social marketing campaigns but are encouraged to use existing resources, such as those available from CDC, and tailor them to their jurisdiction's specific requirements.

Implementing Recruitment: Agencies should consider staff safety, agency capacity, and availability of resources when selecting a recruitment strategy. Recruitment of priority populations is essential to the success of your high-impact HIV testing program. In order to have an effective and innovative program, resources should be dedicated to carrying out your recruitment plan. You may have the most success if you:

- hire and train specific recruitment staff who are separate from HIV testing staff
- build partnerships in the community to ensure multidirectional referrals and expand your reach
- use innovative approaches for reaching priority populations through Internet and social media
- offer incentives to reach previously unreached populations, generate interest in new services, or obtain buy-in for testing at high-risk venues (e.g., bathhouse or bar) where clients might need extra motivation to access HIV testing

Culturally Appropriate: When conducting on- and off-site testing, attention to offering culturally appropriate services using an equity lens should be a priority for all organizations. Not doing so could result in the inability to recruit and retain client base, establish meaningful relationships; negatively impacting short- and long-term testing outcomes. Cultural appropriateness/equity will be defined by several factors such as:

- Priority population/demographics
- Cultural norms
- Location of testing organization
- Location of population seeking services
- Workflow of the organization

- Familiarity with client base
- Historical Relationships
- Socioeconomic Status
- Perceived status of privilege/underprivileged
- Both current and historical issues of client stigma

All of these factors and more can influence how services are accessed and rendered.

Environment Sensitivity: When testing in locations that cater to a specific population or activity, it is important to understand a site-specific cultural code of ethics, especially if your organization is new to the environment. It may take time to build rapport with clients and understanding modes of operation helps towards building long and trusting relationships with your testing audience and testing facility. Having testers who are familiar with the space and comfortable working in such spaces would also help to establish rapport with the client base. Discuss with management the do's and don'ts and what to expect prior to setting up a testing site. Testers must be flexible and willing to recognize their own possible biases in order to create a friendly and inviting testing environment. Professional ethics should be maintained by testing staff in order to minimize risks and liabilities.

Adapting: It is not uncommon for agencies to modify or change testing strategies based on the discovery of information that was unknown prior to implementing testing strategies. Programs may have to redirect, scale up or scale back, and incorporate a higher level of flexibility in order to achieve desired outcomes.

Reporting HIV Test Events – Evaluation Web

Washington State Department of Health

NEW NHM&E VARIABLES EVALUATION WEB

Reporting HIV Test Events

Overview Evaluation Web

- Evaluation Web is the database used for reporting HIV negative and positive test events.
- User: One who enters the record. Each user must be authenticated by CDC/DOH in order to obtain access to Evaluation Web.
- Tester: One who is listed in Evaluation Web as a test provider and may or may not be a user.
- Contact your designated administrator to begin the User authentication process. Currently, the person designated for this activity is the DOH HIV/STD Testing Coordinator.

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Overview Cont'd

- HIV testing event data is anonymous. No names are attached to the test event records.
- Client's information collected by the user/agency for each testing event is entered into Evaluation Web.
- Each testing event produces one record. Records cannot be cross-referenced as each record is treated as a separate event.

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Evaluation Web Test Template

- The following slides will show portions of the test template that users will see when entering data. This is a basic view as some of the responses have a parent/child relationship. This means that if the user clicks a parent variable (e.g., positive result), the user will be prompted to respond to more related questions such as linkages to care (children)

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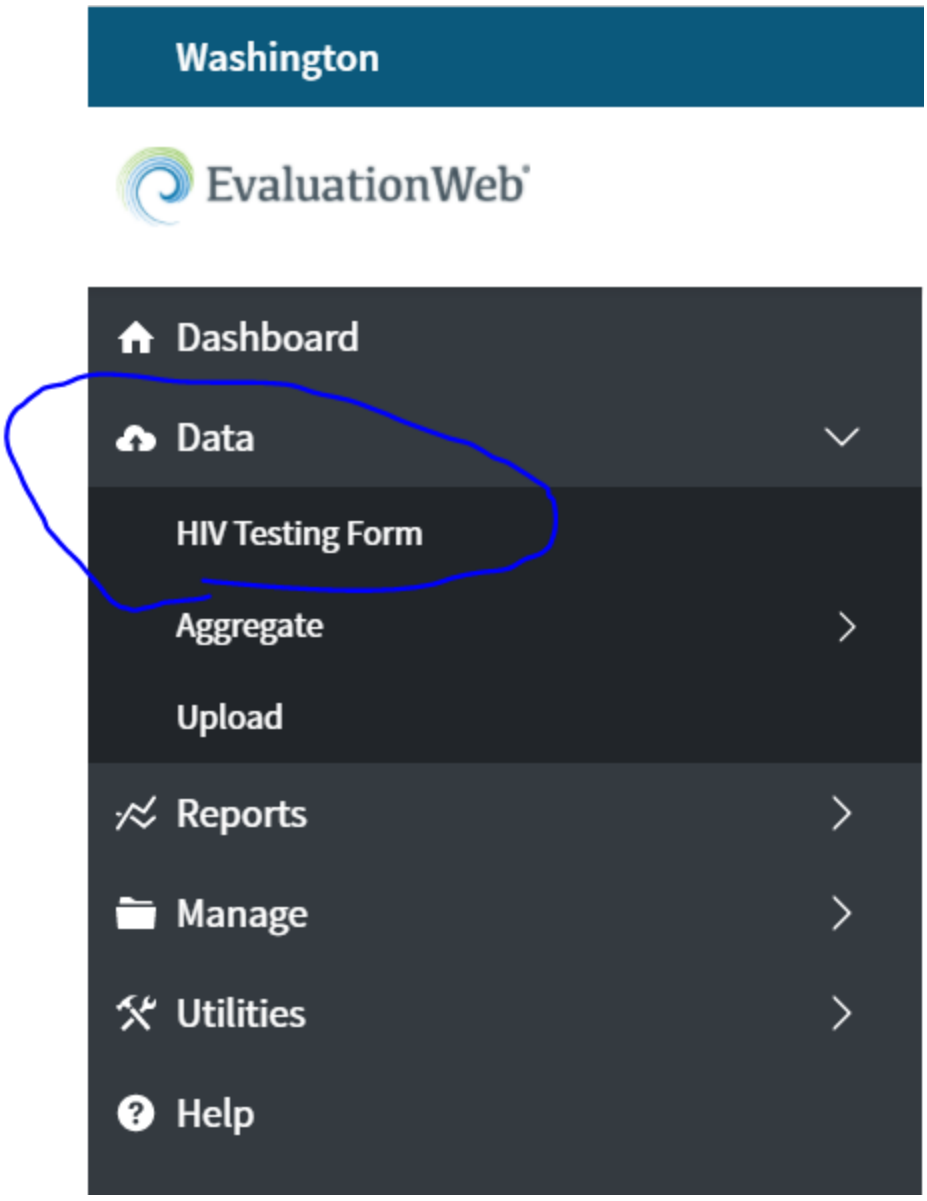
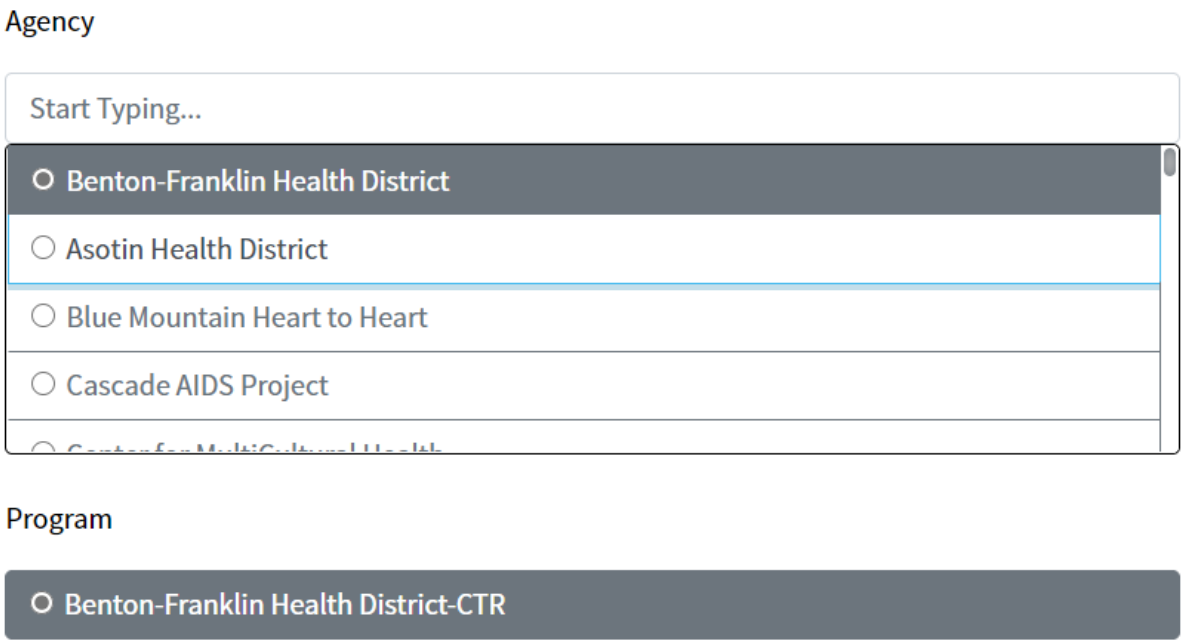
To begin the Data Entry Process, log into Evaluation Web as instructed by going to sams.cdc.gov. Once logged in, go to Data – HIV Testing Form

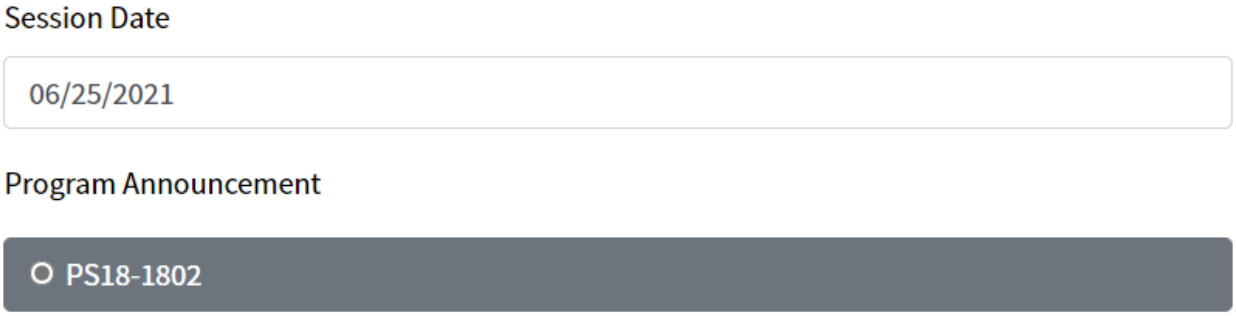


A new testing form will open. Complete the agency you work for if your agency does not automatically populate this field. For all fields, you can start typing or scroll down and make the appropriate selection

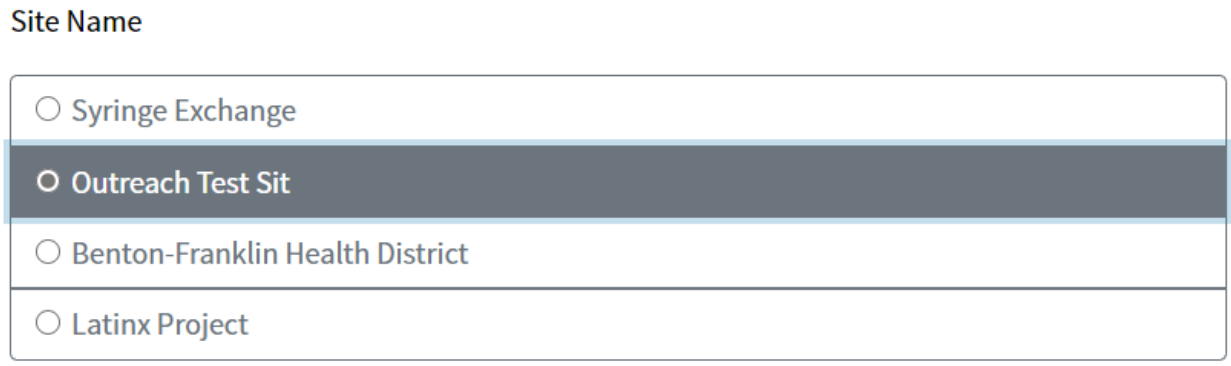


Once you have selected your agency, an Evaluation Web Form ID will be automatically generated for this test event. It is highly recommended that you note that Form ID on your client paperwork that you house/store at the agency's office. This will allow you to return to the test form later for reference and/or to update testing information such as with "additional tests".

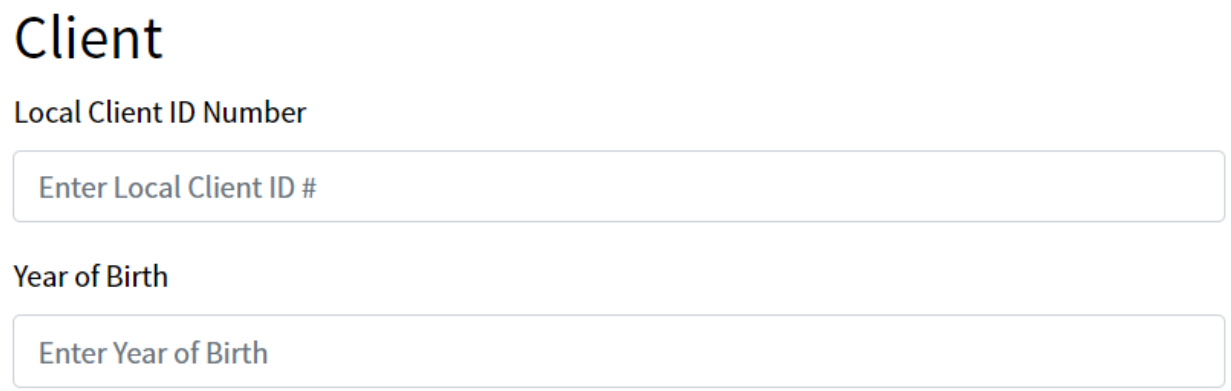
Next, you will select the "session date", which is the date the test actually happened. The program announcement during this current grant cycle is PS18-1802, so please select announcement for most testing situations. Agencies that are working on other grants may have other selections. Check with the DOH-OID Infectious Disease Testing Coordinator for more information.



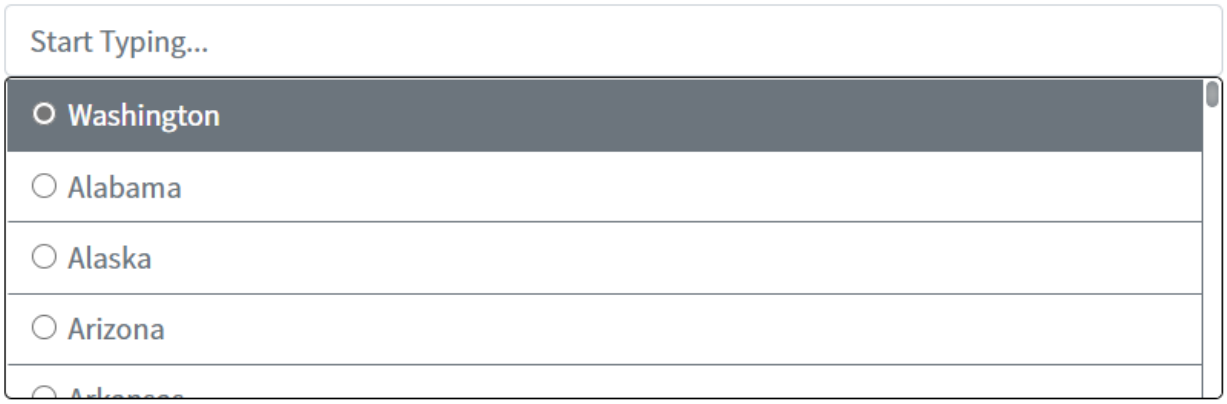
For Site Name, please select the site where your agency conducted the test. All agencies have at least two sites: agency test site and outreach test site. If you would like to add a test site to your agency's profile to better track your agency's test activities, please contact the DOH-OID Infectious Disease Testing Coordinator.



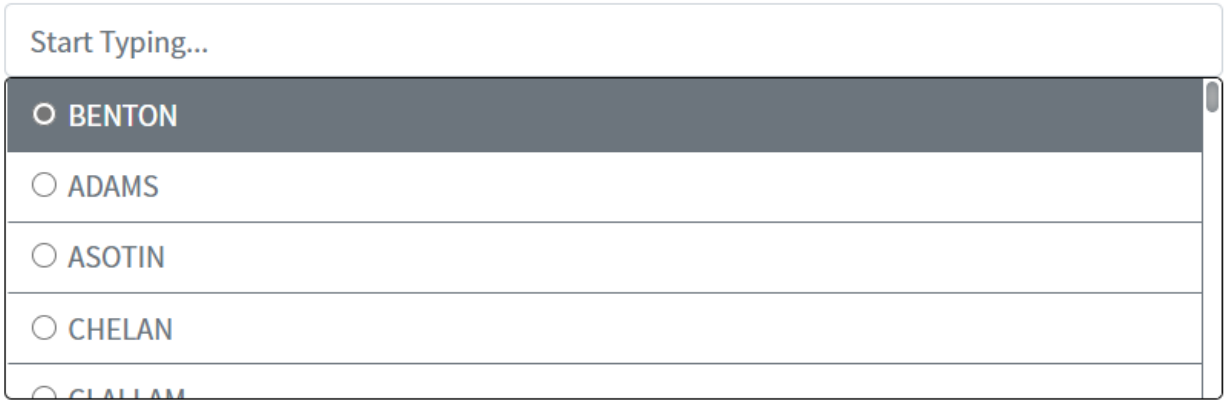
Next, the user will complete the client information section. Please note that the Local Client ID# only needs to be completed if your agency assigns a local client ID to the client for identification/record management purposes. Please enter all other fields, including the client year of birth, state, county and zip code of residence.



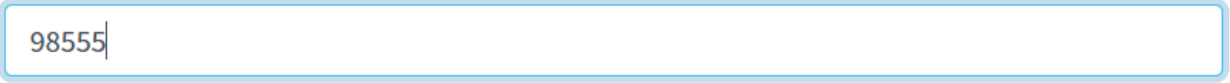
State



County



Zip Code



Next, the user will find the client race, ethnicity and gender identity section to complete.

Client Ethnicity

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Don't know
- ○ Declined to answer

Race *(check all that apply)*

- ✓ White
- ✓ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American

Sex at Birth

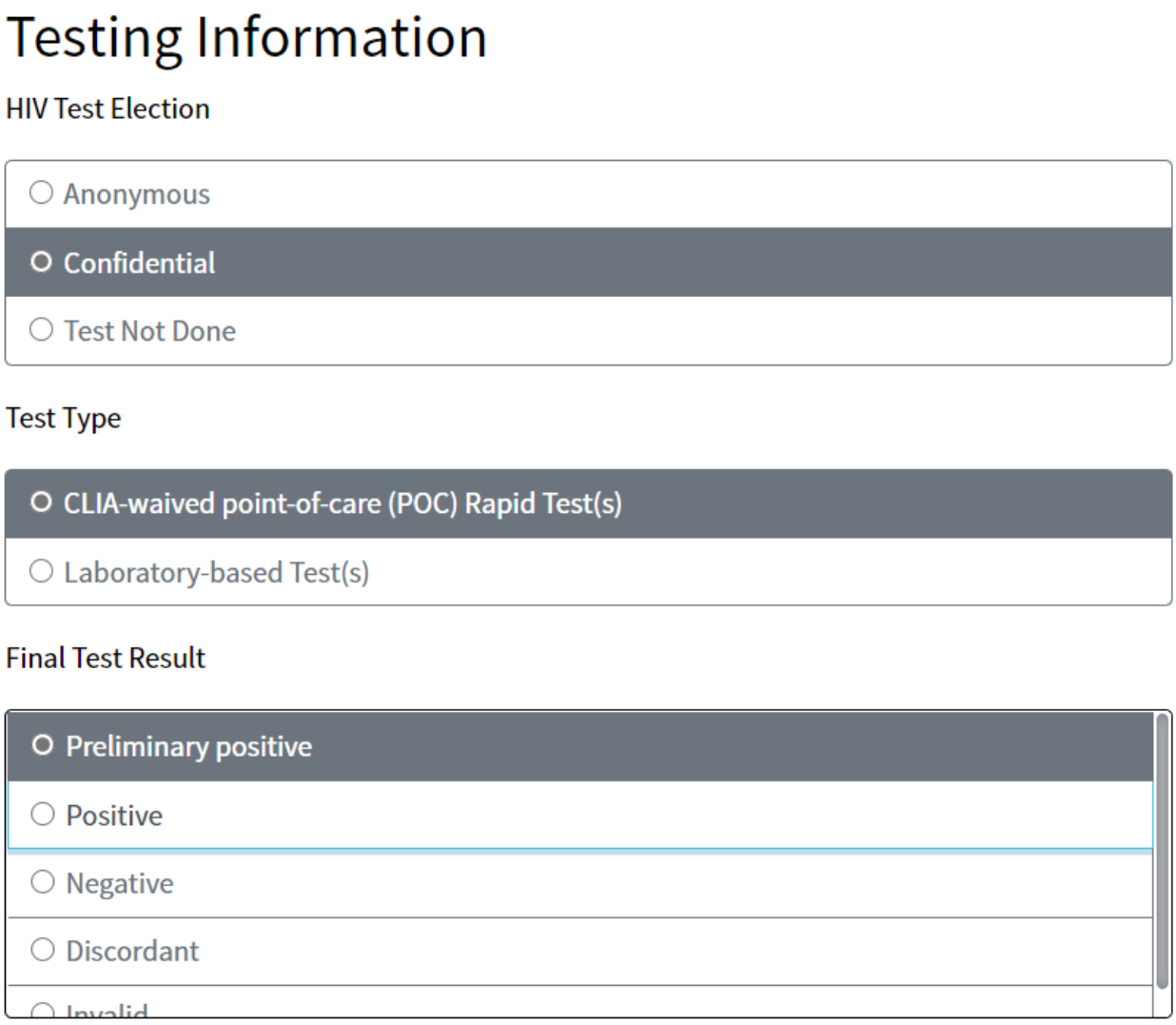
- ○ Male
- ○ Female
- ○ Declined to Answer

Current Gender Identity

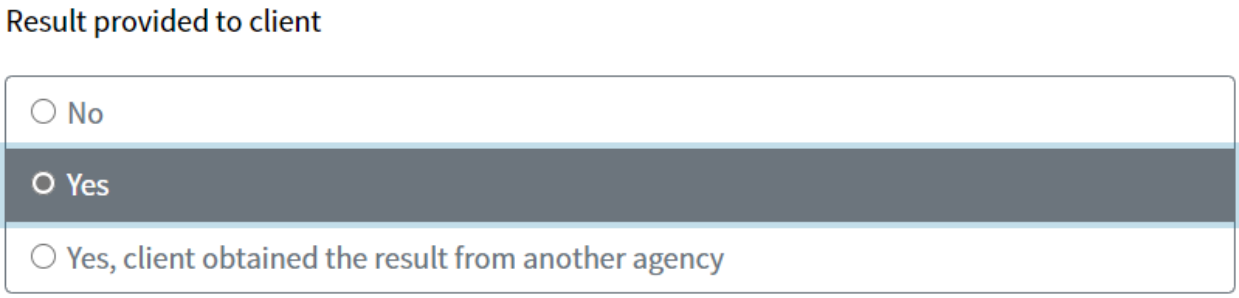
- ○ Transgender - MTF
- ○ Male
- ○ Female
- ○ Transgender - FTM

Once all of this basic information is completed, we can move to completing testing information. Please note that DOH-supported testing programs are highly encouraged to

offer "confidential" HIV testing as the default test election. Currently, most community testing partners are using rapid, point-of-care test kits for HIV testing. Positive test results for these kits should be marked as "preliminary positive". However, if a confirmatory test is reported to the testing agency, then the final test result should reflect the confirmatory test result, usually "positive". In most cases, "preliminary positive" or "negative" will be chosen for the final test result among non-clinical testing partners.



Please note whether the client was provided the test result from this test event.



Next, the user will see a parent-child relationship in the data collection system involving "positive" test results and "negative" test results. The below example tracks a "positive" test result. Please note that the question involving partner services can be answered yes if the testing agency reports the HIV test result to the local health jurisdiction as required by rule. Please visit https://www.doh.wa.gov/DataandStatisticalReports/DiseasesandChronicConditions/HIVData/HIVReporting for more information. To find LHJ information to file reports, please see here: https://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/SexuallyTransmittedDisease/CaseReports. HIV case reports for positive or preliminary positive HIV test results must be made to the client's local health jurisdiction within 3 business days.

Positive Test Result

Did the client attend an HIV medical care appointment after this positive test?

- ○ Yes, confirmed
- ● Yes, client/patient self-report
- ○ No
- ○ Don't Know

Date attended

06/25/2021

Has the client ever had a positive HIV Test?

- ● No
- ○ Yes
- ○ Don't know

Was the client provided with individualized behavioral risk-reduction counseling?

- ○ No
- ● Yes

Was the client's contact information provided to the health department for Partner Services?

- ○ No
- ● Yes

What was the client's most severe housing status in the last 12 months?

- ● Unstably housed and at-risk of losing housing
- ○ Literally Homeless
- ○ Stably housed
- ○ Not Asked
- ○ Declined to answer

Here, the user will enter any additional test information for possible “co-infections” (syphilis, gonorrhea, chlamydia and hepatitis c. Please complete all fields in the parent-child format as appropriate.

Additional Tests

Was the client tested for co-infections?

○ No ● Yes

Was the client tested for Syphilis?

● No ○ Yes

Was the client tested for Gonorrhea?

○ No ● Yes

Gonorrhea Test Result

● Positive
○ Negative
○ Not Known

Was the client tested for Chlamydial infection?

● No ○ Yes

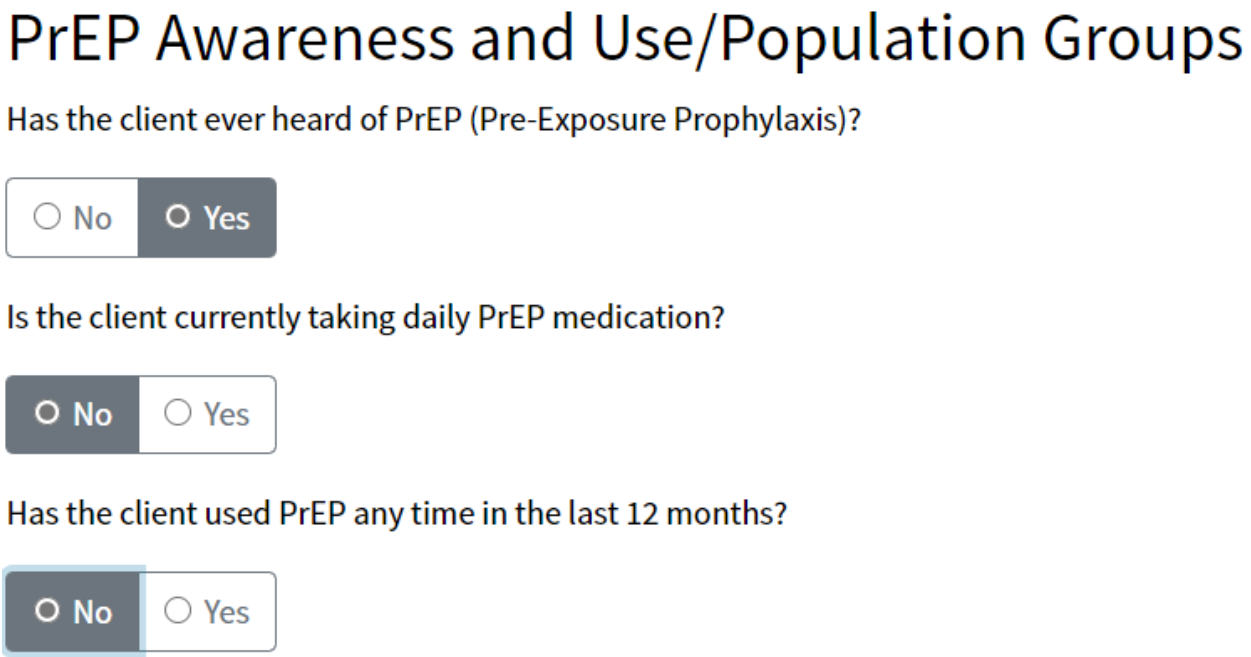
Was the client tested for Hepatitis C?

○ No ● Yes

Hepatitis C Test Result

○ Positive
● Negative
○ Not Known

Next, CDC would like to assess PrEP awareness for clients and will collect data on PrEP eligibility and referrals for those clients who test negative (example not pictured here).



CDC no longer collects copious risk information, but to the extent that risk info is still being collected based on your risk assessment with the client, please complete the following fields:

Priority Populations

In the past 5 years, has the client had sex with a male?

○ No ● Yes

In the past 5 years, has the client had sex with a female?

● No ○ Yes

In the past 5 years, has the client had sex with a transgender person?

○ No ● Yes

In the past 5 years, has the client injected drugs or substances?

○ No ● Yes

The next sections go through Essential Support Services. If your agency is funded by DOH to conduct this work, please fill out these fields completely and accurately.

Essential Support Services

Navigation services for linkage to HIV medical care

Screened for need

○ No ● Yes

Need determined

○ No ● Yes

Provided or referred

○ No ● Yes

Linkage services to HIV medical care

Screened for need

○ No ● Yes

Need determined

○ No ● Yes

Provided or referred

○ No ● Yes

Medication adherence support

Screened for need

○ No ● Yes

Need determined

● No ○ Yes

Provided or referred

● No ○ Yes

Health benefits navigation and enrollment

Screened for need

○ No ● Yes

Need determined

● No ○ Yes

Provided or referred

● No ○ Yes

Evidence-based risk reduction intervention

Screened for need

○ No ● Yes

Need determined

○ No ● Yes

Provided or referred

○ No ● Yes

Behavioral health services

Screened for need

○ No ○ Yes

Need determined

○ No ○ Yes

Provided or referred

○ No ○ Yes

Social services

Screened for need

○ No ○ Yes

Need determined

○ No ○ Yes

Provided or referred

○ No ○ Yes

Local Use Field Keys are as follows:

1 – Open for Agency Use

2- Foreign Born Status – 0 for US born; 1 for foreign born [This is an optional field]

3 – Country of Origin (enter country) [This is an optional field]

4 – Home Collected Specimen Kit (MTL) – Enter "MTL" if home test kit; leave blank if traditional rapid test or other lab-based test

5 – Open for Agency Use

6- Open for Agency Use

7 – Open for Agency Use

8 – Open for Agency Use

Local Use Fields

(Optional)

Local Use Field 1

Local Use Field 2

Local Use Field 3

Local Use Field 4

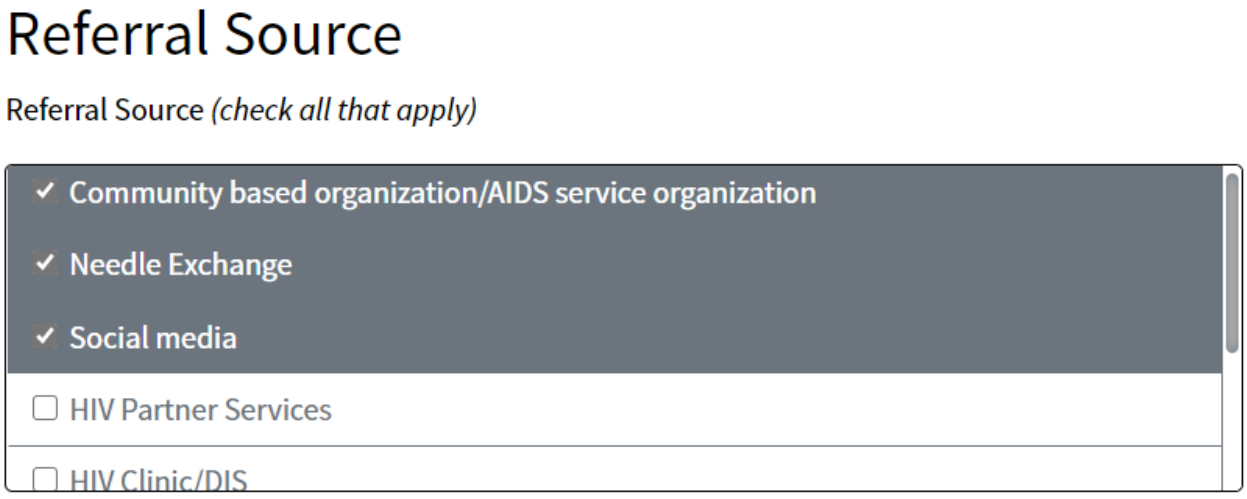
Local Use Field 5

Local Use Field 6

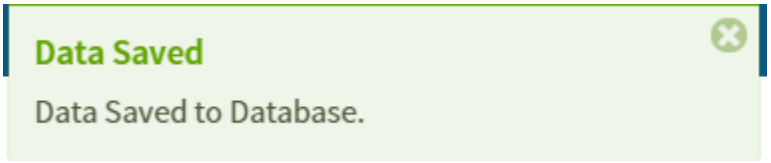
Local Use Field 7

Local Use Field 8

For Referral Source, please complete how the client came to your organization for testing and services (mark all that apply)

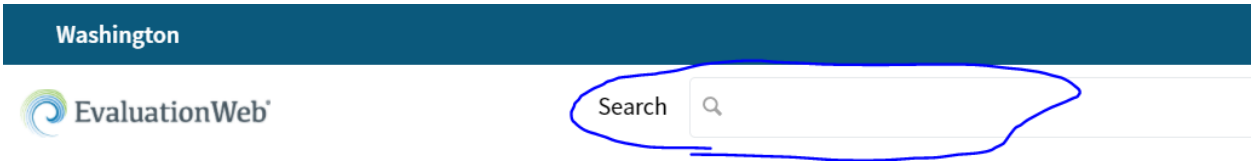


Once data entry is complete, click "save". Please note that the data will not save until you click "save" and get the "data saved" message, which will appear in the upper right corner of the page. If you do not see "data saved", the test event did not save and you may need to re-enter the information. Also note that after a fairly short period of inactivity, Evaluation Web will time out. Unfortunately, the system does not notify the user that it has timed out until the user attempts to save the data.



To go back in and view the test form, you will need the test Form ID, which is why it is important to record this number when entering the test event on the agency client form or in another local place designated by the testing agency. When searching for a record in

Evaluation Web, the search bar appears on any page in the system. Enter the AGF Form ID record number here and press "enter" on your keyboard:



The completed test record should load and is now available for editing, including adding "additional test results", etc.

Confidential Report Form - Overview

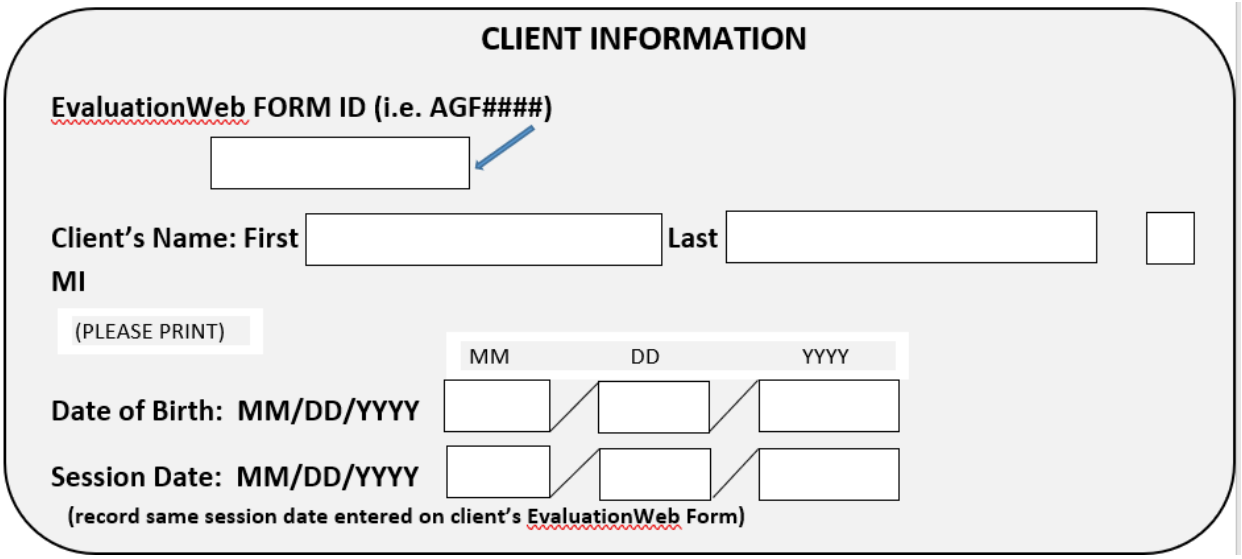
- DOH has developed a Confidential Report Form (CRF) to report HIV positive test results
- This confidential, name-based HIV positive reporting process has been developed to provide an essential data "link" with Evaluation Web anonymous records.

REPORTING HIV POSITIVE TEST EVENT FORM AND INSTRUCTIONS

DOH reporting is under revision at this time. An update will be available in the next revision of this document, which is expected to occur no later than July 1, 2022. During this interim period, agencies should contact the Infectious Disease Testing Coordinator at DOH to make a direct report via phone at 360-688-8084. The form below illustrates the information that should be reported to the Testing Coordinator. Reports should be made within 3 business

days of the positive test result if at all practical. HIV case reports MUST be made to Local Health Jurisdictions within 3 business days by rule. (Please see above.)

CONFIDENTIAL REPORT FORM



FORM/INSTRUCTION CODES:

MI: Middle Initial (leave blank if not available)

If you are filling out the Confidential Report on a computer, click white box first to enter information.

Previous Positives

- Once a Confidential Report Form has been submitted to DOH (see below) to report a positive HIV test event for a client, DOH Staff will:
  - Determine if client was previously reported in eHARS,
  - Will contact CBO testing sites to notify them of a previously diagnosed case on an aggregate, de-identified basis

THE INFORMATION CONTAINED IN THIS CONFIDENTIAL REPORT IS SUBJECT TO WASHINGTON STATE PRIVACY AND CONFIDENTIALITY LAWS.

Contact Information

OID Data Coordinator/Evaluation Web Administrator	HIV Testing/Community Engagement Consultant
Luke Syphard	**Michael Barnes**
Luke.Syphard@doh.wa.gov	Michael.Barnes@doh.wa.gov
(360) 236-3428	(360) 810-1880/(360) 236-3579

Infectious Disease Testing Coordinator

Patrick Dinwiddie

patrick.dinwiddie@doh.wa.gov

360-688-8084

References:

1-13 CDC: *"Implementing HIV Testing in Nonclinical Settings – A Guide for HIV Testing Providers"* https://www.cdc.gov/hiv/pdf/testing/CDC_HIV_Implementing_HIV_Testing_in_Nonclinical_Settings.pdf

Acronyms:

AIDS – acquired immune deficiency syndrome

CDC – U.S. Centers for Disease Control and Prevention

CLIA – Clinical Laboratory Improvement Amendments

DOH – Department of Health

HCV – hepatitis C virus

HIV – human immunodeficiency virus

LQA – Laboratory Quality Assurance

MTS – Medical Test Site

PLWH – Persons or People Living With HIV

SSP – Syringe Service Program

WAC – Washington Administrative Code (State Rules)

RCW – Revised Code of Washington (State Statutes)

WAC/RCW References:

Health Care Assistants Law – Chapter 18.135 RCW