# WASHINGTON STATE NONCLINICAL SETTING HIV TESTING GUIDELINES

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



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### **Purpose of Manual**

The purpose of this *Washington State Nonclinical Setting HIV Testing Guidelines* manual is to familiarize HIV 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.<sup>2</sup> 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 <a href="https://www.cdc.gov/hiv/testing/nonclinical/">https://www.cdc.gov/hiv/testing/nonclinical/</a> 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, community-based organizations, mobile testing units, churches, bathhouses, parks, shelters, syringe services programs, health-related storefronts, homes, and other social services organizations.<sup>1</sup>

### **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)
- Certified health care assistants
- Sexually transmitted disease case investigators (DIS)

### **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 fingerstick and venipuncture. Therefore, no additional licensing is required to conduct blood specimen collection for rapid testing.

### **Certified Health Care Assistants**

The Washington State Health Care Assistants Law, Chapter 18.135 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).

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: <u>HSQA DIVISION</u>

### **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 Profession requiring credentialing can be found here:

http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/HealthcareProfessionalCredentialingRequirements

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/

### **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 Health Care Assistants**

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

For the rapid test fingerstick, the supervisor does not have to be physically present, but must be immediately available for consultation. Consultation can take place by any means such as electronically (text, email, cell phone) and other forms of communication within a short period of time. In addition to having this consultation available, the policies and procedures should be in place to direct the health care assistant to call "911" for emergency assistance in the event of an adverse reaction to a fingerstick.

To perform a venipuncture, health care assistants must have the supervising practitioner on the premises and immediately available for consultation and assistance during the procedure to withdraw blood (RCW 18.135.020; WAC 246-826-030). Staffing and supervision policies and procedures for each test should reflect this.

### 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 hereby authorized to perform venipuncture or skin puncture on a person for the sole purpose of withdrawing blood for use in sexually transmitted disease tests.

### **Availability of Phlebotomy Training in Washington**

The Washington State Department of Health, Office of Infectious Disease has partnered with the University of Washington STD Prevention Training Center in Seattle to offer venipuncture and capillary training as part of the Medical Assistant – Phlebotomy certification requirement consistent with WAC 246-827-0400. Classes occur from time-to-time and as need arises. If a partner agency has interest in attending this training, please contact the DOH HIV/STD Testing Coordinator (see below for contact info).

### **Agency License Requirements**

In accordance with **RCW Chapter 709.42**, 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 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 federal CLIA certificate (MTS) through the Washington State DOH Laboratory Quality Assurance (LQA) agency. Refer to the LQA website for additional information. MTS/FAQ

If the site already has a MTS license covering other laboratory testing, CLIA-waived rapid HIV testing can be performed under that license. However, the site must still inform the Department of Health (at the address below) that this testing will be added to their existing license.

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 150<sup>th</sup> 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 a MTS license that covers other laboratory tests, there will be no additional fee for adding the rapid HIV, Syphilis or HCV test.

### Confidentiality

All 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 rapid HIV 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). In recognition of the very sensitive nature of these conditions compounded by associated stigmas, medical record protection for HIV and AIDS, like those for substance abuse and mental health, are protected more rigorously than other medical information. 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/STD/HCV testing and counseling activities with access to testing results and counseling information should sign a confidentiality statement acknowledging their awareness and understanding of 1) the legal requirements under state and federal law not to disclose medical, counseling, and results information, and 2) the legal and agency consequences of such a disclosure.

### **HIV/AIDS Required Training and Education**

### **HIV/AIDS TRAINING REQUIREMENTS:**

You are required to have HIV/AIDS education if you:

- Work as a health care professional or in a state licensed or certified health care facility in Washington State.
- Want to get a license, certification or registration to practice a regulated health care profession in Washington State.

A list of sites providing HIV/AIDS training can be found on DOH's website under HIV/AIDS Training for Licensure (HIV/AIDS Training for Licensure). Classes are offered online or in person and some may require a fee. Classes are usually offered using the KNOW curriculum that was developed and approved by DOH's Office of Infectious Disease (see RCW 70.24.270 and 70.24.310; WAC 246-322-060). The KNOW curriculum is a public domain document and can be found at this site KNOW Curriculum – English. There is a Spanish version available KNOW Curriculum – Spanish. The KNOW curriculum is structured to meet the 4 or 7 hours class requirements. You may find a list of Healthcare Professional Credentialing Requirements on the DOH website (HPCR).

### **Age of Consent**

The same laws regarding age of consent for diagnostic HIV testing apply to rapid HIV testing screening technology. A person must be 14 years of age to provide independent consent for a HIV 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 of the time of this writing, new administrative rules (WACs) are being promulgated to clearly define the new rules involving HIV testing. In July of 2018, the legislature passed SB6580 (chapter 158, Laws of 2018), which requires any and all barriers to HIV testing be removed. The purpose of this proposal is to update three state board of health rule sections that contain consent and opt-out options specific to HIV testing to assure alignment with newly revised state law. 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. 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. For further discussion on consent, please refer to the Washington Law Health Manual – 4<sup>th</sup> Edition at <a href="http://www.wsha.org/wp-content/uploads/HLM">http://www.wsha.org/wp-content/uploads/HLM</a> Chapter2A.pdf .

# **HIV Testing Technology<sup>3</sup>**

These guidelines will focus predominately on rapid tests technology used for HIV screenings; not diagnostic confirmation determination. These tests will be divided into two categories which are antibody detecting only and antigen/antibody detecting test. The Washington State Department of Health strongly recommends using blood-based specimen tests. 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. The medical professional should use discretion when determining what tests to use; taking into consideration the health and safety of all parties involved. Your agency should have already determined which tests to use and staff appropriately trained to competently perform test according to instructed procedures. Agencies should also be aware that the DOH Office of Infectious Disease is currently only offering support for blood-based rapid test kits described below.

The tests discussed below use only blood-based specimen (fingerstick).

### Antibody Tests – (i.e. INSTI (BioLytical Labs):

Blood-based 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 are rapid tests, 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.

Oral fluid (i.e., OraQuick) antibody tests have been shown to detect infection a month or more later than blood-based tests because there is a lower concentration of HIV antibodies in oral fluid than in blood. Oral fluid is not ideal for identifying early HIV infection, but may also be appealing in outreach settings because collecting oral fluid does not involve a fingerstick or venipuncture to perform the test. No antigen/antibody or nucleic acid tests are available for use with oral fluid.

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.

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

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.

# Testing Approaches<sup>4</sup>

### **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 is an emerging area of interest among consumers and HIV testing providers because it can be an effective method for reaching people who are not otherwise getting tested. This approach may also be helpful in reaching couples and persons in sexual relationships. Some nonclinical HIV testing sites are finding opportunities to engage with home testing clients by being available for follow-up counseling or by actually distributing the tests and serving as a resource for clients who have completed testing and interpreted their results. Strategies for engaging persons who test positive with a self-test should be explored so they can be linked to medical care quickly. More information on home testing is available at <a href="https://www.cdc.gov/hiv/testing/hometests.html">https://www.cdc.gov/hiv/testing/hometests.html</a>.

### **Laboratory-Based Testing:**

If a blood specimen is drawn for the laboratory, all testing 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 or oral fluid samples from your clients and ship them to the laboratory where the HIV tests 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 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 a 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 <a href="https://stacks.cdc.gov/view/cdc/23447/">https://stacks.cdc.gov/view/cdc/23447/</a>.

# Testing Algorithms<sup>5</sup>

Most HIV testing conducted in nonclinical settings will include an initial HIV test and, if the initial HIV test is reactive, a follow-up HIV test. 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®.

An initial HIV test (sometimes referred to preliminary test) will either be an antibody test or combination antigen/antibody test. It may involve sending blood or oral fluid to a laboratory or obtaining blood or oral fluid for a rapid test.

**Follow-up testing** (sometimes referred to as "supplemental testing" or "confirmatory testing") is performed if the initial test result is positive. HIV tests are generally very accurate, but follow-up testing is import to be sure of the diagnosis of HIV infection.

Rapid/Rapid testing, 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 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 <a href="https://stacks.cdc.gov/view/cdc/23447">https://stacks.cdc.gov/view/cdc/23447</a> and <a href="https://stacks.cdc.gov/view/cdc/50872">https://stacks.cdc.gov/view/cdc/50872</a> (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. 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. Ideally, any reported positive result will have followed one of the above testing algorithms for HIV infection identification.

# HIV Counseling and Risk Assessment<sup>6</sup>

Washington State requires that individuals who are tested for HIV receive an individualized risk assessment. Health care providers and other persons providing pretest or post-test counseling shall assess the individual's risk of acquiring and transmitting human immunodeficiency virus (HIV) by evaluating information about the individual's possible risk-behaviors and unique circumstances, and as appropriate: . . . (WAC 246-100-209).

HIV Counseling 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. Counseling and risk assessment should be client focused but counselor driven. Counseling 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 counseling tailored to the client's needs. This strategy is recommended in rapid HIV testing environments. 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<sup>7</sup>

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 counselor, navigator or medical provider 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 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 you have delivered their results. 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 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 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.<sup>7</sup>

# **Specimen Collection and Preparation<sup>8</sup>**

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 <a href="https://effectiveinterventions.cdc.gov/en/2018-">https://effectiveinterventions.cdc.gov/en/2018-</a>

<u>design/TrainingCalendar/EventList/2013/04/01/default-calendar/Rapid HIV Testing Online</u>. 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).

# **Interpreting Results<sup>9</sup>**

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 are infected 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 infection. If you've had a recent exposure, it may be too early to tell if you are infected. 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.

Indeterminate (Invalid) Results: On occasion, testing with a rapid test or laboratory level technology, tests 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 tests." We can help you set up those appointments for additional tests.

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 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 flulike symptoms, they should be referred immediately to their doctor or other local clinic for acute infection 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 after their potential exposure.

False-negative test results: False-negative test results occur when someone who is infected with 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.

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

### Pre/Post HIV Testing Steps<sup>10</sup>

### **Preresults Steps:**

There are 3 preresults steps for individual HIV testing:

- Step 1: Introduce and orient the client to the 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

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 take approximately 1-2 minutes to provide the client with this basic information and answer any questions he or she might have about the rapid testing process. Then you will collect the sample and conduct the rapid HIV test. **The key tasks for step 2 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 (blood vs. oral)

- 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 (oral or written)
- Distribute test kit information booklet (required for CLIA-waived tests)
- Collect specimen and conduct rapid HIV test

As you conduct the brief risk screening, 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.

### **Postresults Steps:**

The 3 postresults steps for individual HIV testing are:

- Step 4: Deliver results
- Step 5: Develop a care, treatment, and prevention plan based on results
- Step 6: Refer and link with medical care, social and behavioral services

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**<sup>11</sup>

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 Clients (Non-Reactive):** For clients testing HIV-negative, the specific tasks for step 5 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
  - o If partner is HIV positive, encourage partner to get and stay on treatment
- 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 Clients (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 to access care and treatment for HIV
  - 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 referral if appropriate
  - Other health issues can be addressed
- Discuss disclosure and inform about processes for partner services
  - Advise//Encourage conversation between client and local health jurisdiction representative or DIS regarding partner services, including the availability of partner notification services

- Emphasize key risk reduction strategies that will prevent transmission
  - Choose less risky sexual and drug-using 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 an HIV positive 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 testing after the initial reactive rapid test result.
- 2. Collect a specimen to send to a lab for follow-up testing after the initial reactive rapid test result; discuss the importance of returning to the agency to get the 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 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.

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 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.

**DISCLOSING A POSITIVE (CONFIRMATORY) TEST RESULT:** The same steps for a preliminary positive are same 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.

### **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 the 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.

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.

For the address of the local health department in your county, assistance in developing a reporting policy, or information on HIV/AIDS report, call the state office:

Toll free number: (888) 367-5555

Department of Health: 360-236-3464

All test events, including anonymous tests that are negative or positive, should be entered into Evaluation Web.

### Linkage-To-Care<sup>12</sup>

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 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.

# Partner Services (PS)<sup>13</sup>

Partner Services is implemented with all persons who test HIV positive. The primary function of PS is to notify the sex and needle-sharing partners of HIV positive individuals about their potential exposure to HIV. It is a voluntary service that involves interviewing newly diagnosed HIV positive persons to elicit names of their previous sex and needle-sharing partners who might have been exposed to HIV, then confidentially notifying these persons of their potential exposure and offering them HIV testing and linkage to HIV medical care (including PrEP services), social, 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 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.
- **2. DIS onsite** some agencies have health department DIS staff onsite to interview clients who test HIV positive.
- **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.
- **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<sup>14</sup>

**Targeting and Recruitment:** Targeting 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 targeting and recruitment, they should be aware of how their HIV testing services are messaged in the community and how clients reach them for testing.

**Targeting** 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 targeting 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 preventions services. Targeting can also help you identify high-risk HIV-negative persons needing important HIV preventions services, such as PrEP, non-occupational post-exposure prophylaxis (nPEP), and other social and behavioral interventions.

In nonclinical settings, it is important to target your 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 subpopulation). 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.

**Recruitment**: Recruitment begins once you have defined your focus population and identified where and how to reach them (i.e.., targeting). 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 focus population should be done. The plan should include ideas about where your reach your focus population, 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 3 - 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 focus 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, destignatizing 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 focus population in their own environment, such as a particular street, neighborhood, hot spot, or venue (e.g., a bar, hotel, 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 focus 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 syringe services programs, substance use programs, mental health services, evidence-based HIV prevention interventions, sexually transmitted disease (STD) 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 focus population are referred to HIV testing services by agencies outside the HIV testing program. External agencies may include syringe services programs, substance use programs, mental health services, evidence-based HIV prevention interventions, STD testing and treatment programs, HIV medical care, and homeless shelters. 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.

Social Networking Strategy (SNS) is a peer-driven approach to recruitment that involves identifying HIV-positive 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. flyers and brochures, posters, print advertisements, 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 the focus population 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 the focus population 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 should be a priority for all organizations. Not doing so could result in the inability to recruit and retain customer base, establish meaningful relationships; negatively impacting short and long term testing outcomes. Culturally appropriate will be defined by several factors such as:

- Target 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
- Stigma

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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 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 mode 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 about do's and don'ts and what to expect prior to setting up a testing site. Testers must be flexible and willing to recognize 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**





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.

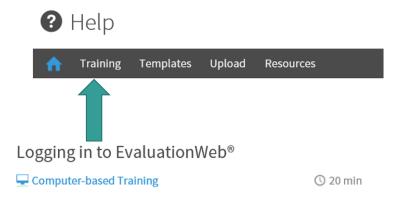
# Training Module

• Training modules are available on the Evaluation Web user site. Click the "?" in the upper right hand corner of the sign-on screen for help and additional training tools. The user should see the Washington State name and picture to the left of the screen. This means that you are in the right place!



# Training Module Cont'd

 Click Training tab and select training module "Logging into Evaluation Web". This will open up a 20 minute computer-based training presentation.



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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)

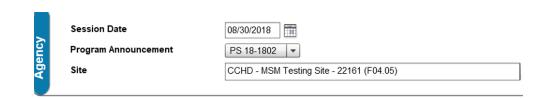
# Form ID

If the client tests positive, the auto-generated form ID from Evaluation Web will be used for the confidential report form to report the positive result to DOH.



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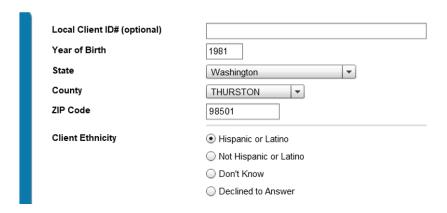
# Enter Client Session Date and Site



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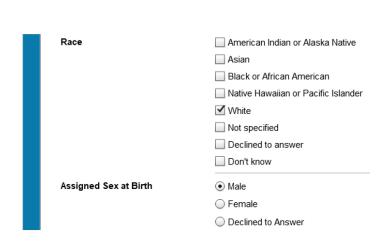
DOH 430-015 Revised 09/2018 Office of Infectious Disease
DOH PUB: 430-015 Rev. 09/2018 OID

# Enter Client Basic Demographics



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# Enter Client Race and Sex at Birth



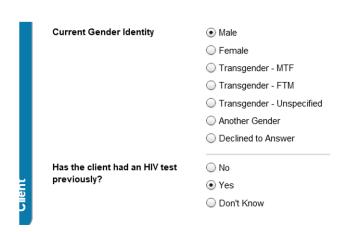
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Revised 09/2018

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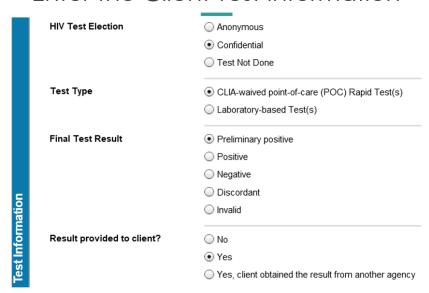
Office of Infectious Disease

# Enter the Remaining Client Info



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# Enter the Client Test Information



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DOH 430-015 Revised 09/2018 Office of Infectious Disease DOH PUB: 430-015 Rev. 09/2018 OID

# Positive Test Result

Did the client attend an HIV medical care appointment after this positive test?	<ul><li>Yes, confirmed</li><li>Yes, client/patient self-report</li><li>No</li><li>Don't Know</li></ul>
Date attended	08/30/2018
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

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# Positive Test Result Cont'd

		Was the client's contact information provided to the health department for Partner Services?	○ No
# 10		What was the client's most severe	C Literally Homeless
What was the client's most severe housing status in the last 12 months?	Unstably housed and at-risk of losing housing		
to		months:	○ Stably housed
٥			○ Not Asked
į			O Declined to answer
ě	3		O Don't know
"	•		

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#### Negative Test Result ○ No Is the client at risk for HIV infection? Yes Risk Not Known O Not Assessed Was the client screened for PrEP ○ No • Yes eligibility? Is the client eligible for PrEP O No Yes, CDC criteria Yes, by local criteria or protoco Was the client given a referral to a ○ No ● Yes PrEP provider? Was the client provided with services to assist with linkage to a $\bigcirc$ No $\odot$ Yes PrEP provider?

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# Was the Client Tested for Additional Infections?



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## Additional Infections - YES

Was the client tested for co- infections?	○ No
Was the client tested for Syphilis?	○ No ○ Yes
Was the client tested for Gonorrhea?	○ No ○ Yes
Was the client tested for Chlamydial infection?	○ No ○ Yes
Was the client tested for Hepatitis C?	○ No ○ Yes
	infections?  Was the client tested for Syphilis?  Was the client tested for Gonorrhea?  Was the client tested for Chlamydial infection?  Was the client tested for Hepatitis

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# Syphilis Testing



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# Gonorrhea Testing



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# Chlamydia Testing

Was the client tested for Chlamydial infection?	○ No • Yes
Chlamydial infection Test Result	O Positive
	<ul> <li>Negative</li> </ul>
	Not Known

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# Hepatitis C Testing

Was the client tested for Hepatitis C?	○ No • Yes
Hepatitis C Test Result	O Positive
	<ul> <li>Negative</li> </ul>
	Not Known

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# PrEP Awareness

	Has the client ever heard of PrEP (Pre-Exposure Prophylaxis)?	○ No • Yes
Priority	Is the client currently taking daily PrEP medication?	● No ◯ Yes
PrEP Awareness and Use/Priority	Has the client used PrEP any time in the last 12 months?	● No ○ Yes
ness ar	In the last 5 years, has the client had sex with a male?	○ No
Aware	In the last 5 years, has the client had sex with a female?	○ No • Yes
불	In the past 5 years, has the client injected drugs or substances?	○ No • Yes

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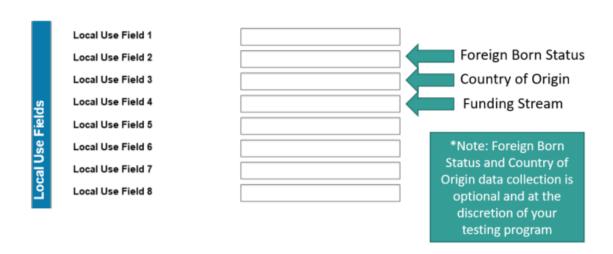
# Essential Support Services

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Health benefits navigation and enrollment	Screened for need  No Yes	Need determined  No Yes	Provided or referred  No  Yes
Evidence-based risk reduction intervention	○ No	○ No	● No
	<ul><li>Yes</li></ul>	<ul><li>Yes</li></ul>	O Yes
Behavioral health services	○ No	○ No	● No
	<ul><li>Yes</li></ul>	<ul><li>Yes</li></ul>	O Yes
Social services	○ No	<ul><li>No</li></ul>	● No
	<ul><li>Yes</li></ul>	○ Yes	O Yes

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# Local Use Fields



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### Current Local Use Codes

Local U	se Fields			
FORM ID:				
Local Use 1- Open for agency use	Local Use 2- Foreign Born Status (if applicable)			
	□ US Born		□ Foreign Born	
	Enter 'O' in <u>EvalWeb</u>		Enter '1' in EvalWeb	
Local Use 3- Country of Origin	Local Use 4- Funding Stream (if applicable)		)	
Abbreviate county of origin to fit in allocated spaces	□ GFS	□ EIS	□ Other	
	Enter 'GFS' in EvalWeb	Enter 'EIS' in EvalWeb	Enter 'Other' in EvalWeb	
Local Use 5- Open for agency use	Local Use 6- Open for	agency use		
Local Use 7- Open for agency use	Local Use 8- Open for	agency use		

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## Referral Source

	Referral Source	HIV Partner Services
		HIV clinic / DIS
a)		Community outreach or prevention program
2		Social media
Referral Source		Needle Exchange     ■
20		Community based organization / AIDS service organizatio
ē		Private medical provider
쮼		Other

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## Submit Form

This will enter the data into Evaluation Web. Failure to click "submit" will result in the test event not being recorded.

Submit Form

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### Form Submission

- The user must click the "submit form" button to commit the form to record it to the database. Failure to do so will result in loss of information after logging off or when the system routinely logs off users automatically for prolonged inactivity.
- If there are errors in the record, the user will be alerted upon clicking the "submit form" button. All errors must be corrected before record will upload.

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### To View and/or Edit the Test Event Form ID Form ID **Session Date Date Entered** 981040 08/30/2018 08/30/2018 View ID 981006 07/15/2018 07/16/2018 View ID 981005 07/16/2018 07/16/2018 View ID Please enter Form ID Be sure to click on the matching value in the lookup box before clicking the "Submit Form ID" button. If the form you're looking for doesn't appear, please check the other DDE section in the navigation menu. Type to filter Submit Form ID Washington State Department of Health | 28

### Testing and Reporting Processes

- Obtain consent from client to perform test and inform client that DOH will be notified of all positive results.
- Washington State no longer requires separate and written consent for HIV testing as of Spring 2018 due to the repeal of RCW 70.24.335. However, client consent to test for any disease or condition is generally required, so general consent procedures should be followed for HIV and STD/Hepatitis C testing.
- Complete the required information in Evaluation Web.
- Complete and send the Positive Confidential Report Form to DOH as described below.

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# 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.

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### **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

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### REPORTING HIV POSITIVE TEST EVENT FORM AND INSTRUCTIONS

- **1.** Enter and submit the required information in EvaluationWeb to create a record for the HIV positive test event.
  - a. Locate the unique FORM ID (i.e. WA0004A000000000 **3087099**)1
  - **b.** and record in the "Confidential Report Form" attached below
  - c. only the numbers to the right of the underscore symbol are used on the CRF: 3087099
  - d. You must complete step one in order for this unique ID to attach to client's EW record.
- **2.** To report the positive test results, complete the attached "Confidential Report Form" below with client's information.

#### **MAILING INSTRUCTIONS**

- Use two envelopes (inner #1/outer #2)
- Place the "Confidential Report Form" in the inner (#1) envelope, mark envelope #1 confidential and seal with tape. DO NOT MAIL INSTRUCTIONS WITH CONFIDENTIAL REPORT.
- Place envelope #1 into envelope #2. Seal #2 with tape and mark confidential.
- DO NOT PLACE YOUR AGENCY'S NAME ON ENVELOPE #2. USE ONLY STREET ADDRESS, CITY, STATE, ZIP
- MAIL TO:

Washington State Department of Health Assessment Unit 310 Israel Road MS – 47838 Tumwater, WA 98501

3. **Secure File Transfer Reporting:** Agencies may submit "CONFIDENTIAL REPORT FORM" electronically using the Secure File Transport (SFT) system. Contact <a href="mailto:Luke.syphard@doh.wa.gov/360-236-3428">Luke.syphard@doh.wa.gov/360-236-3428</a> to have this option evaluated for your agency's use.

# **CONFIDENTIAL REPORT FORM**

	CLIENT INFORMATION	
EvaluationWeb FORM ID (i.e.	3087099)	
Client's Name: First MI	Last	
(PLEASE PRINT)	MM DD YYYY	
Date of Birth: MM/DD/YYYY		
Session Date: MM/DD/YYYY  (record same session date entered o	on client's EvaluationWeb Form)	/

#### FORM/INSTRUCTION CODES:

**CRF:** Confidential Report Form

**EW:** EvaluationWeb **ID:** Identification **DOB:** Date of Birth

MM/DD/YYYY: Month/Date/Year

**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.

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

<sup>&</sup>lt;sup>1</sup> The new form will automatically generate a FORM ID; located at the top of the form.

### **Contact Information**

OID Data Coordinator/Evaluation
Web Administrator

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HIV Testing/Community Engagement
Consultant

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**HIV/STD Testing Coordinator** 

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360-688-8084



#### References:

**1-13 CDC**: "Implementing HIV Testing in Nonclinical Settings – A Guide for HIV Testing Providers" <a href="https://www.cdc.gov/hiv/pdf/testing/CDC">https://www.cdc.gov/hiv/pdf/testing/CDC</a> HIV Implementing HIV Testing in Nonclinical Set <a href="mailto:tings.pdf">tings.pdf</a>

#### 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

WAC – Washington Administrative Code

RCW – Revised Code of Washington

### WAC/RCW References:

Health Care Assistants Law - Chapter 18.135 RCW