HIV Counseling, Testing, and Referral Protocol

Wisconsin HIV Program

WISCONSIN DEPARTMENT *of* HEALTH SERVICES

P-00539 (06/2023)

HIV Program Contact List

General HIV Program Number: 608-267-5287

Staff Person	Contact Information	Resource for…
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Syd Robinson HIV Prevention Coordinator	608-886-6197 syd.robinson@dhs.wisconsin.gov	HIV prevention programs and funded agencies, HIV rapid test orders, counseling recommendations, quality assurance, training
Stacy Clark HIV Testing Coordinator	608-266-8427 Stacy.Clark@dhs.wisconsin.gov	HIV testing technical support, HIV/syphilis rapid test orders, counseling recommendations, quality assurance, training
Jamal Perry HIV Biomedical Prevention Coordinator	608-264-8553 Jamal.perry@dhs.wisconsin.gov	HIV biomedical intervention (U=U, PrEP, nPEP, TASP) technical assistance needs, training, education
Vipul Shukla Partner Services Coordinator	608-266-3031 vipul.shukla@dhs.wisconsin.gov	Partner Services questions, training, reimbursement
HIV Case Reporting	Phone: 608-266-2664 Fax: 608-266-1288 DHSHIVsurveillance@wisconsin.gov **Surveillance Supervisor:** Yi Ou **Epidemiologist:** Abby Winkler **Surveillance Coordinator:** Noah Leigh **Surveillance Specialist:** Linda Ziegler, Kayla Johnson	Contact people for HIV confidential case reports or to obtain HIV confidential case report forms

Yi Ou HIV Surveillance Supervisor	608-266-3073 Yi.Ou@dhs.wisconsin.gov	Primary contact for EvaluationWeb database, including obtaining user IDs, passwords, assistance with reports
Wis. State Laboratory of Hygiene – Retrovirus Lab	1-800-862-1013	Status of test results or interpretation of test results
Wis. State Laboratory of Hygiene- Clinical Orders	1-800-862-1088	Blood test collection kits, mailing supplies, questions related to shipping and processing

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Introduction and Background

Common Acronyms

Ag/Ab – Antigen/antibody

ASO – AIDS Service Organization

CBO – Community-based organization

CTR – Counseling, testing, and referral

EDTA – A type of anticoagulant in some blood tubes

DHS – Department of Health Services

DPH –Division of Public Health

LHD – Local health department

MSM – Men who have sex with men

PCR – Polymerase chain reaction

PS – Partner Services

PWID – Person who injects drugs

STD – Sexually transmitted disease

WSLH – Wisconsin State Laboratory of Hygiene

Common Terms

Acute HIV infection: The time between when a person contracts HIV and the person develops an antibody response. During the acute infection stage, the volume of the virus circulating in the person's bloodstream is very high.

Antibody: Proteins *produced by the body* to fight specific viruses.

Antigen: Proteins *produced by the HIV virus* that are detected during the early stages of HIV entering the body.

Discordant test results: Result from a screening test that is reactive or positive, followed by a confirmatory test that is nonreactive or negative.

Invalid: A failure of a rapid test due to operator error or an issue with the device.

Laboratory-based HIV testing: An HIV test that is conducted in a moderate or high-complexity laboratory, typically an antibody or antigen/antibody test.

Rapid HIV testing: An HIV test that is easy to conduct, produces quick results, and can be done on-site by staff without a laboratory degree. Results typically are ready in 20 minutes or less. HIV test results typically must be confirmed by a laboratory-based test.

Window period: The period of time between when someone is exposed to HIV and when a test can detect HIV in their system.

Intended Audience for this Protocol

This protocol is intended for agencies funded by the Wisconsin Department of Health Services, Division of Public Health (DPH) HIV Program, to provide HIV counseling, testing, and referral (CTR) services. These agencies include local health departments (LHDs), community-based organizations (CBOs), and AIDS service organizations (ASOs). Agencies are funded either through a grant or on a fee-for-service basis. Some LHDs only offer CTR services in conjunction with their Partner Services program.

Purpose of this Protocol

This protocol was developed to provide an overview of the Wisconsin HIV CTR Program, identify requirements of agencies contracted to provide services related to counseling, testing, referral, data collection, and record keeping. CTR sites are required

to adhere to this protocol, in addition to the terms and conditions of contractual agreements and memoranda of understanding (MOUs) with the DPH.

Purpose of the CTR Program

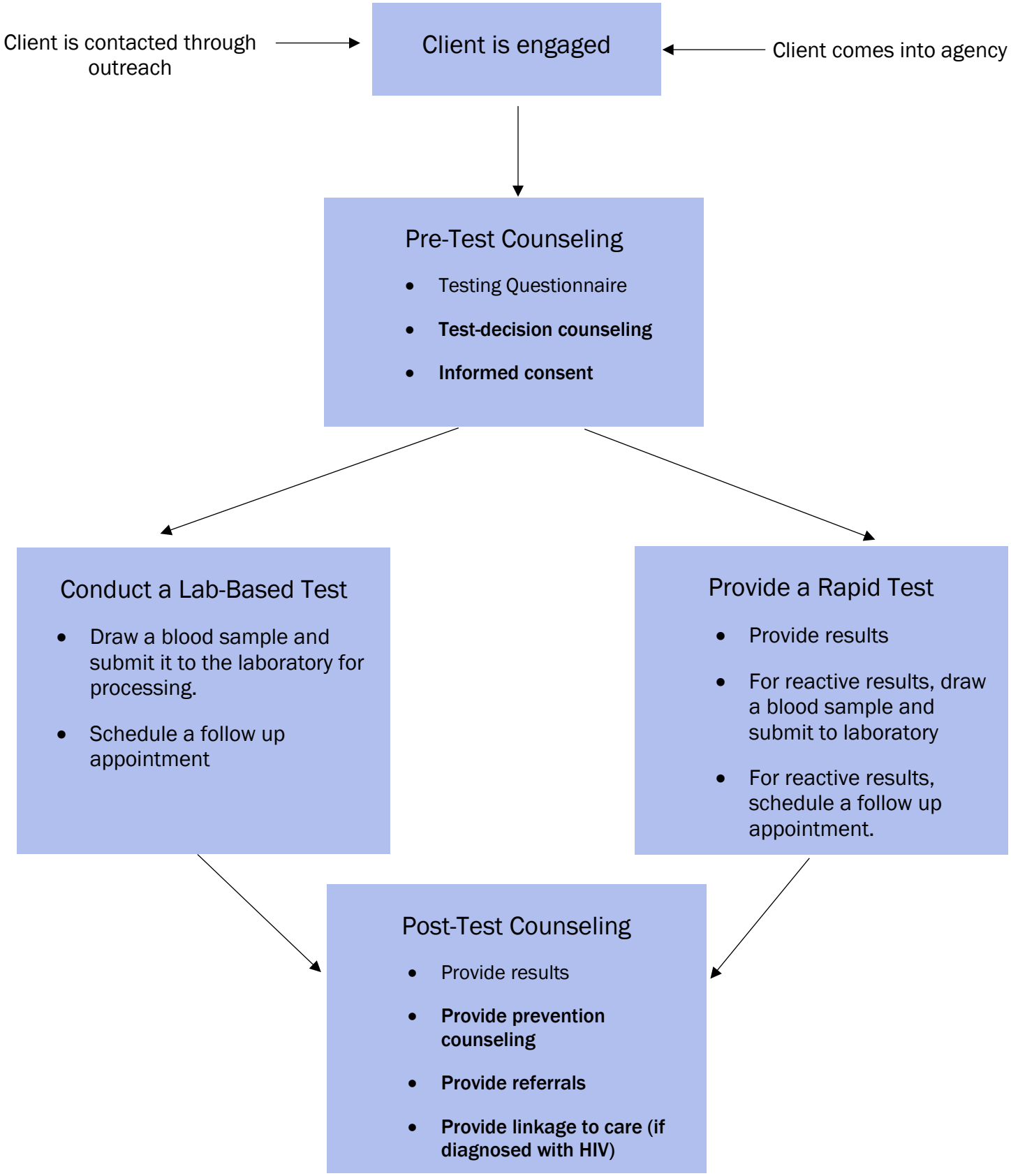
The DPH HIV Program coordinates a statewide program of designated HIV counseling, testing, and referral (CTR) sites to provide the following critical services:

- Readily accessible HIV counseling, testing, and referral services for individuals at increased risk for HIV
- HIV testing at low or no cost to individuals who would not otherwise be able to afford testing
- Anonymous testing for persons with confidentiality concerns that might prevent them from seeking services
- Client-centered counseling designed to reduce risk of acquiring or transmitting HIV
- Appropriate referrals for PrEP, HIV medical services, case management, linkage to care specialists, partner services, social and emotional support, risk reduction interventions, sexually transmitted diseases (STDs) testing, hepatitis testing and vaccination, and resources to meet daily living needs.

Philosophy of Service

HIV CTR services should be provided in a manner consistent with community and consumer norms and values. The quality of services (e.g., accessibility of services, provision of services that are culturally and gender responsive) and the ability to provide services to persons and groups at increased or disproportionate risk of HIV is more important than the number of tests conducted. Services should be provided in a collaborative, cooperative manner among local agencies in a community.

Overview of the HIV CTR Process



Target Audience for HIV CTR Services

The Wisconsin HIV CTR Program is designed to serve those individuals at increased risk for HIV, particularly those persons without resources or a health care provider. Access to HIV CTR is not restricted by residency or ability to pay. With the exception of Partner Services (PS) clients, individuals who have a health care provider with whom they feel comfortable requesting HIV testing and who can afford such counseling and testing should be encouraged to obtain confidential testing from their health care provider. However, if a client comes to your agency seeking an HIV test, they should not be turned away because they don't qualify as being at high risk for HIV.

Populations at high risk for HIV are the primary target audience for CTR services because they comprise the majority of reported cases of HIV in Wisconsin.

Populations at high risk for HIV are defined as:

- Men who have sex with men (MSM)
- Men who have sex with men and inject drugs (MSM/PWID)
- Transgender women who have sex with men
- People who inject drugs (PWID)
- People whose sex partners are living with HIV
- People whose sex partners have a history of injection drug use
- Women whose male sexual partners have had sex with men
- People with a diagnosed or reported sexually transmitted disease (STD) in the past six months

Populations at moderate risk for HIV are an appropriate secondary target audience for HIV CTR services. This is because these individuals may have other unidentified risks or an STD and an active STD can increase the likelihood of contracting HIV.

If someone with low risk of HIV seeks out an HIV test at your agency, they should not be denied services. However, agencies should educate clients regarding risk factors and recommend that persons with no or low HIV risk have a confidential test performed by a primary care or other health care provider in the future, if possible. It's also important to take into consideration if a client is at risk for other STDs. If so, please provide the client with that service or offer a referral to another agency or provider.

Persons Not Appropriate for HIV CTR Services

- Individuals requiring an HIV test due to court order, a condition of insurance, entrance into the military or Job Corp, for immigration purposes, or for any other form of mandatory testing should be referred to their primary care provider or the source requesting the test.
- Individuals requiring or requesting an HIV test as a result of occupational exposure should be referred immediately to their employer to arrange for private provider testing. This will ensure all conditions of Wisconsin statutes addressing possible occupational exposure are properly followed. It also protects the interest and rights of both the exposed employee and the source person.
- People who have been sexually assaulted may be tested, but if they were sexually assaulted within the last 72 hours, they should immediately be referred to a local emergency room that offers Post Exposure Prophylaxis (PEP), if available. PEP can be taken within 72 hours after a possible exposure to HIV to prevent the transmission of HIV. The person should be offered a referral to sexual assault support resources and recommended they visit their primary care doctor. The pros and cons of reporting the assault to the authorities may be discussed. The person should also receive follow up HIV/STD testing one to three months after the assault.

Program Requirements

In this section:

- Agency Requirements
- Staff Training Requirements
- Confidentiality Requirements
- Reporting Requirements
- Record Keeping Requirements
- Material Review Panel Requirements
- Quality Assurance Requirements

Agency Requirements

To assure quality services and to meet state and federal standards, agencies must agree to meet the following core requirements:

Laws and Wisconsin HIV Program Protocols

- Adhere to state statutes (laws) related to HIV, including those concerning confidentiality, informed consent for testing, and HIV case reporting (§ 252). (https://www.dhs.wisconsin.gov/publications/p4/p44295.pdf)
- Comply with state statute and Wisconsin HIV Program's data collection, entry, and reporting requirements, – including mandated quarterly and annual reports.
- Abide by Wisconsin HIV Program's HIV CTR Protocol.
- Provide services to clients regardless of their ability or willingness to pay for these testing and related services.
- Participate in training sponsored by the Wisconsin HIV Program focused on delivering HIV CTR services.

Testing

- Recommend confidential (name-associated) testing to all clients seeking testing.
- Offer anonymous testing to clients with concerns about confidential testing that may prevent them from otherwise seeking services and learning their HIV status.
- Submit samples to the Wisconsin State Laboratory of Hygiene (WSLH) for laboratory processing, as appropriate.
- Confirm rapid reactive test results by submitting a blood sample to the WSLH for laboratory testing.

Additional program requirements for agencies conducting rapid HIV testing are included in the Rapid Testing section starting on page 43.

Referrals

- Coordinate services with other local agencies to facilitate referrals related to HIV and STI prevention, PrEP, hepatitis C testing, general health, and daily living needs for all clients.
- Coordinate services with other local agencies to facilitate referrals for clients who test positive for HIV to access medical care, Partner Services, HIV case management or linkage to care, and other prevention services.

Internal Agency Procedures

- Develop a workflow that includes a written process for how clients will obtain their test results.
- Monitor quality of services through observation of testing sessions, client satisfaction surveys, or other means, within agency limits.
- Establish agency policies and procedures regarding the development and delivery of HIV testing services in a manner consistent with all core requirements, program protocols, and Wisconsin statutes.
- Agencies are expected to provide culturally competent services, to recruit and retain staff members who are reflective of the population served, and to involve a diverse group of individuals in the planning, design, and implementation of services.

- Have a physician currently licensed in the State of Wisconsin provide medical supervision of CTR activities, including review and written approval of CTR agency policies and procedures.

Staff Training Requirements

Wisconsin HIV Program Trainings

Testing staff are required to attend the following Wisconsin HIV Program sponsored trainings in sequential order:

- HIV Basic Facts (online)
    - HIV Basic Facts online training can be accessed at any time during the year. Staff should register for the training online and they will be approved to complete the online modules at their own pace.
    - **HIV Basic Facts online training must be completed before the participant attends the in-person New Provider Training.**

- HIV Counseling, Testing, Referral Services Program New Provider Training (in-person)
    - The in-person New Provider Training includes training on how to perform a rapid test and how to effectively deliver HIV test results.

Agencies may train staff internally under the following conditions:

- Permission is granted by the HIV Prevention Coordinator.
- Internal training guidelines are followed (Appendix A)
- Staff trained internally are required to attend the next available series of HIV Program trainings as identified above.

Confidentiality Requirements

Client confidentiality is essential to the success of HIV testing services. Strict client confidentiality must be maintained to protect the client and to preserve the integrity of CTR services. Client confidentiality is not limited to just protecting the client's name, but also applies to other information that could identify a client, such as where they reside, their age, race or ethnicity, or social connections.

- Client information, regardless of whether testing is anonymous or confidential, should be kept confidential in locked file cabinets—ideally, in a locked room.
- Never share your ID or passwords with anyone and do not allow others to use the computer while you are logged in.
- Use secure shredder bins to dispose of documents containing confidential information.
- Agencies that provide other health services must keep HIV records of clients testing anonymously separate from other medical or social service records containing the client's name, since the client's name or medical record number may be used to link anonymous results to the client.
- When conducting outreach or field-based testing, client testing forms and records should be transported in portable, locked file containers. Ensure this information is securely stored in the vehicle like a locked trunk and not visible in the vehicle. All files should be returned to the agency at the end of the testing event. This should be done in a manner that addresses both staff safety and record security when conducting outreach testing late at night (e.g., testing staff return files to agency while working in pairs). Files should not be left in motor vehicles or staff homes overnight. See page 58 for more information on testing in nontraditional or outreach settings.
- Maintain possession of mobile devices (i.e. laptops, smartphones, USB flash drives, etc.) that are used to store client testing forms and records. Ensure mobile devices that are used to store and transport client information are secure by enabling encryptions, firewalls and secure user authentication on every device.
- Counseling at all designated agencies should be provided in a private, comfortable and nonthreatening environment that will foster open discussion and ensure confidentiality.
- Access to test results and client records must be limited to those with a legitimate need to access these documents (e.g., testing staff, supervisory oversight staff)
- Agencies must provide all testing and program support staff with copies of Wisconsin HIV Program requirements, Wisconsin confidentiality statutes for HIV, and agency policies pertaining to client confidentiality. In addition, agencies must require all testing and program support staff to sign confidentiality agreements at time of hire, which should be maintained in their personnel files. Agencies have their own policies on how frequently their confidentiality agreements are re-signed.
- Agencies should periodically review confidentiality policies and monitor agency procedures to ensure client confidentiality is maintained.

Reporting Requirements

Wisconsin statutes (Wis. Admin Code DHS 145.04(3)(b)) require that persons testing positive on confidential, name-associated tests must be reported to the HIV Program within 72 hours of the result. Agency staff should call the HIV Program Surveillance Unit to report positive HIV test results. See the contact list at the beginning of this protocol for the Surveillance Unit contact information. The agency staff person should let the Surveillance Unit staff know whether the client has been notified of the test result.

Staff may also report the case by using the *Wisconsin Human Immunodeficiency Virus (HIV) Infection Confidential Case Report* form (F-44338). Access the form here: https://www.dhs.wisconsin.gov/forms/f4/f44338.doc.

This form should be completed and faxed to 608-266-1288. This is a secure fax in a locked room. Be sure to fax with a fax cover. If an agency is unable to fax the form, they can mail it in an envelope marked "Confidential" to:

HIV Program Section Manager
Division of Public Health
1 West Wilson Street
PO Box 2659
Madison, WI 53701-2659

If there are questions about reporting requirements, they can be directed to the HIV Surveillance Coordinator or by emailing dhshivsurveillance@dhs.wisconsin.gov. **Please do not include any confidential or personally identifiable information in emails to the HIV Program.**

Record Keeping Requirements

A file should be established for each client tested. The file should retain copes of all Wisconsin HIV CTR Program documents and EvaluationWeb data collection forms used as part of the HIV testing process. These forms will include: client HIV Consent Form (Appendix B), Testing Questionnaire form (Appendix C), Authorization for Release of Confidential Test Results forms (if used) (Appendix D) and a copy of test results received from the WSLH, if applicable.

Also, if a site is funded to provide rapid HIV testing, they will be expected to retain their agency's testing, temperature, and inventory logs for one year.

How Long to Keep Records:

3 Years

- Consent for HIV Testing (English, Spanish) (Appendix B)
- Authorization for Release of Confidential HIV Test Results (English, Spanish), if used (Appendix D)
- Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up to be **kept for duration of employment, plus 3 years.**
- Sharps injury log

18 months

- Wisconsin CTR Testing Questionnaire (English, Spanish) (Appendix C)

1 Year

For Rapid Testing only. Logs that contain personally identifiable information should be shredded:

- Temperature Logs
- Inventory Logs
- Testing and Controls Logs

Material Review Panel Requirements

Grantee agencies receiving funding from DPH for HIV prevention services must document review and approval of HIV-related materials by a program content review panel. Agencies must establish a committee to review materials, document who is on the committee, and keep a list of materials that have been reviewed and the committee approval and/or recommendation for them. Agencies are encouraged to have representation from public health or other health experts and community members on their review committees.

Examples of HIV-related materials that must be reviewed and approved include HIV-related written materials, pictorials, audiovisuals, questionnaires, survey instruments, the content of educational sessions, and HIV-related web-based materials posted on the

internet. This requirement has been established by federal regulation and is enforced by the Centers for Disease Control and Prevention (CDC).

This requirement does not apply to materials the agency uses that were produced or purchased by the CDC or the Wisconsin HIV Program. More details about this requirement can be found in Appendix E.

Quality Assurance Requirements

Written quality assurance policies and procedures should be developed, made available to all testing staff, and routinely implemented.

Quality assurance measures should ensure services and materials are accessible and appropriate to the clients' culture, language, gender, sexual orientation, age, developmental level, and risk activities, such as injection drug use. Quality assurance measures should be developed and implemented for each of the three main components of the *counseling*, *testing*, and *referral* process.

Quality Assurance Program Requirements Checklist

- ☐ Review program materials for cultural appropriateness.
- ☐ Evaluate the physical space and client confidentiality system of in-agency testing services.
- ☐ Evaluate the physical space, client confidentiality system, and client and staff safety in outreach-based testing settings and venues.
- ☐ Review and/or update referral lists **annually**.
- ☐ Review record keeping and security practices **quarterly**.
- ☐ Monitor accuracy of data collection and entry **quarterly**.
- ☐ Confirm completion of all proficiency tests provided by the Wisconsin State Lab of Hygiene.

Here is a list of additional quality assurance measures. Test sites should implement these measures to the extent possible based on agency type, size, and staffing level.

Quality Assurance Additional Recommendations Check List

- ☐ Supervisors should observe staff during CTR sessions.
- ☐ Conduct client satisfaction surveys for testing services and referrals.
- ☐ Host case conferences.
- ☐ Review outcomes by testing site if conducting outreach testing **annually**.
- ☐ Compare surveillance data and testing data if receiving grant funds for CTR services.

The Wisconsin CTR Coordinator may conduct an annual review of individual agencies' quality assurance policies and procedures.

Testing Session

In this section:

- Pre-Test Counseling Components
- Additional Recommendations
- Post-Testing Counseling Session
- Other HIV Testing Scenarios

Pre-Test Counseling Components

Here is a list of key components for each HIV testing session. They do not need to be addressed in order, and some can happen at the same time, but each of these components should take place within a testing session.

A	Test Decision Counseling
B.	Confidential vs. Anonymous Testing
C.	HIV Test Consent Form
D.	Testing Questionnaire
E.	Prevention and Risk Reduction Counseling

A. Test Decision Counseling

Prior to testing, the provider should discuss the client's decision to receive an HIV test that day. To assist the client in making the decision to test or not test, the following topics should be discussed:

- Potential benefits of testing
- Potential concerns associated with testing
- Recommendation for and benefits of using confidential testing

- Potential concerns about confidential testing and the availability of anonymous testing for persons with significant concerns about testing using their name
- The window period of the test
- Anticipated feelings about possible test results
- Benefits and limitations of available testing methods (laboratory-based testing or rapid testing)
- Relationship between testing and future goals

B. Confidential vs. Anonymous Testing

Confidential Testing = Name-Based Testing

Confidential testing uses the client's name on the consent form and lab result (if applicable), the same as all other medical services provided in health care settings. The client's name will be printed on the test result and becomes part of the client's confidential record. The HIV Program expects that most tests will be conducted confidentially. Confidential testing makes it easier to locate individuals who test positive but fail to return for their final results, conduct follow-up on referrals to HIV-related services, and eliminates the need for re-testing when a person is linked to HIV care.

Key Points to Discuss with Confidential Testing

When testing someone confidentially, there are two related points that should be discussed.

1. If the result is positive, a public health staff member at the local health department will contact the client, likely via phone, to ensure the client is able to access HIV care and offer assistance notifying their partner(s) of the result. This is because HIV positive results are required by law to be reported to the state health department, like several other diseases.
2. Availability of HIV-related medical and social services for people living with HIV

Some clients who are anxious or are at high risk for HIV may need to know more about services and treatment available if they test HIV positive. Other clients may not be interested or ready to hear this information.

Benefits of Confidential Testing

- The client will receive a test result with their name. This is particularly beneficial for clients who want to share their HIV status with their partners. They can show their partners a piece of paper with their HIV test result and their name.

- Having a name associated with the test will streamline access to medical services for clients who test positive for HIV. This will allow the testing staff to connect a client directly to care and have linkage to care specialists follow up with the client for support as necessary.

Anonymous Testing = Code-Based Testing

Anonymous testing does not use the client's name, but uses a unique code on the consent form and the lab result. This code can be any combination of letters and numbers that the client chooses. With anonymous testing, the name of the person being tested is not identified, and the result is not linked to a specific person. Because of this, anonymous positive test results cannot be reported to the HIV surveillance unit, and follow-up with the client is impossible. Anonymous testing should only be used with clients who are so concerned about confidentiality that they are not likely to get tested without this option. If a client chooses to test anonymously and the rapid result comes back positive, the testing staff should strongly recommend the client switch to confidential testing for the confirmatory test by discussing the benefits of confidential testing. If a client decides to switch to confidential testing for their confirmatory result, they should fill out the name and contact information section of the consent form. They should check the confidential testing box and note that it is just for the confirmatory test.

Key Points to Discuss about Anonymous Testing

When testing someone anonymously, there are five points that testing staff should discuss.

1. If using a lab-based test, emphasize that the client must return in person for the test result at the appointed time; if they don't, there will be no way for agency staff to contact them.
2. Sometimes barriers arise that prevent clients from returning for their test results, so testing staff should discuss methods with the client to contact them while maintaining their confidentiality.
3. Testing staff should inform the client about the availability of Partner Services.
4. If the result is positive, testing staff should discuss the need for the client to test confidentially in order to access medical care and other services.
5. Once the client accesses HIV medical care, their result will be reported confidentially to the state HIV surveillance program.

There are various ways testing staff might explain the above points, depending upon the client's needs, awareness, and abilities. As with confidential testing, some clients will want to know more about services and treatment available if they test HIV positive,

prior to taking the test. Testing staff should be prepared to offer a detailed description of available services, particularly when testing people at high risk for HIV or partners of people living with HIV.

Expectations for Recommending Confidential Testing

CTR and PS-funded sites that conduct HIV testing are expected to recommend confidential testing to all clients. CTR and PS sites that conduct rapid testing should recommend that clients who test anonymously with rapid reactive results should switch to confidential testing for their confirmatory test. The client should be informed of how the agency and the state protect client confidentiality, and the benefits of confidential testing should be discussed.

Agency staff should then assess if the client has concerns about confidential testing and discuss and address each concern individually. These may include:

- Fear of results
- Who has access to results
- Issues related to insurance or workplace discrimination
- Concerns over others determining their status if PS is initiated

In addition, counselors may need to address cultural issues and issues of trust. For example, there is a long-standing cultural norm in the white MSM community of testing anonymously that has been passed on from generation to generation. Much of this is based on fears of discrimination and how gay men were portrayed in the media and by the government early in the epidemic. Racial and ethnic groups may have similar questions as well as concerns over trust of government-associated agencies. These may include concerns related to immigration status. A major concern of many clients may be others in their social circles somehow learning their status.

C. HIV Test Consent Form

Prior to 2010, Wisconsin statutes required that individuals provide written, informed consent prior to an HIV test. However, this law changed in 2010 to comply with CDC recommendations to reduce barriers to HIV testing by streamlining the testing process.

Wisconsin statute (§ 252.15(2m)) requires that individuals provide verbal consent for HIV testing. However, the Wisconsin HIV Program requires that individuals electing to have an HIV test at a publicly funded CTR site **sign a written, informed consent form prior to HIV testing** (See appendix B for an example of the form). In the case of anonymous testing, the client would initial on the consent form.

The reasons for requiring written, informed consent at the majority of CTR sites are as follows:

- The CDC recommendations are intended for health care settings and meant to increase HIV testing in those settings by making it a routine part of care. The majority of CTR sites are not clinical settings.
- CTR sites offer anonymous testing for clients with significant concerns about confidential (name associated) testing, so the client's consent cannot be documented as required in the statutes. The written consent form documents the client's acceptance of testing, particularly in a nonmedical setting.

Discussion points when obtaining consent

Prior to obtaining consent, the testing staff should provide the client the following information, much of which is on the back of the consent form:

- Simple explanation of the test—benefits and limitations—and the meaning of test results
- Reporting requirements for positive HIV test results
- How and when the client will receive their test results
- Availability of HIV treatment
- Availability of PS and various options for informing partners of potential exposure
- Availability of HIV case management and other supportive services

As part of the process for obtaining written informed consent, testing staff should:

- Assess client literacy and offer assistance reading and understanding the form as appropriate.
- Provide access to translated consent forms—or confidential translation services—for clients with limited English proficiency.
- Review the consent form with all clients and provide the opportunity for clients to ask questions.
- Have available—and be prepared to discuss—circumstances under which agencies and institutions have legal access to confidential test results.
- Ensure individuals electing to be HIV tested sign or initial or write their code, and date the consent form.

Exceptions to obtaining written informed consent:

Clinical CTR sites, such as STI clinics, may obtain verbal rather than written consent from their clients. These sites must maintain patient paper or electronic medical records. Clinical sites must also obtain approval from the CTR Coordinator prior to implementing verbal consent and must submit an updated testing protocol reflecting this change to the CTR Coordinator.

Clinical HIV test sites that adopt verbal consent must do so in accordance with the required statutory process. To obtain verbal consent, the health care provider must:

1. Indicate to the client that HIV testing will be done unless the client declines.
2. Offer a brief oral or written explanation of HIV, HIV test results, requirements for reporting HIV, and services available to people diagnosed with HIV.
3. Notify the client that they may decline to be tested and this fact cannot be used to deny other services or treatment by the health care provider.
4. Offer the client the opportunity to ask questions or decline the HIV test.
5. Verify that the client understands that an HIV test will be performed and their decision to have an HIV test performed is not coerced or involuntary.
6. Document in the client's health care record whether the person consented to or declined the HIV test.

Sites that obtain verbal consent must inform clients that anonymous testing is not an option since consent for testing will be documented in their medical record. However, they must still offer anonymous testing for a client either through referral to a nonclinical testing site or through use of a written consent form provided by the Wisconsin HIV Program. This also means maintaining all HIV testing documents separate from the patient's confidential medical record(s).

D. Testing Questionnaire

The testing questionnaire collects demographic and risk information about the client. This questionnaire should be used to guide your counseling and risk reduction conversations with the client. The questionnaire can be completed before a testing session or while the test is running and the client and the testing staff are waiting for the rapid result. Either way, the agency staff member should offer to complete the questionnaire with the client as needed. The questionnaire should also be reviewed with the client to ensure it was completed correctly and is legible.

The testing questionnaire must be entered into the online database, EvaluationWeb. Data from the questionnaire is used by the HIV Program to comply with federal reporting requirements and to evaluate program utilization.

The questionnaire provides significant information on the client's risk of HIV, but should not be considered a complete risk assessment.

E. Prevention and Risk Reduction Counseling

HIV prevention counseling provides a critical opportunity to assist the client in identifying whether they are at risk for HIV, and to negotiate and reinforce a plan to reduce or eliminate risk. HIV prevention counseling should be offered to all clients. It should be provided in an interactive manner responsive to individual client needs. The focus of client-centered counseling is on developing prevention goals and strategies with the client rather than simply providing information. CTR staff should engage in prevention counseling using the evidence-based practice of motivational interviewing, which all new HIV testing staff will learn in the required in-person HIV Counseling, Testing, and Referral (CTR) New Provider training.

According to the founders of motivational interviewing, it is a "collaborative, goal—oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion." Miller & Rollnick (2013, p. 29).

The core processes of motivational interviewing are:

- Engaging: The relational foundation. Efficiently establish then maintain a caring and productive working relationship with the client.
- Focusing: Collaboratively select change target (behavior, substance, or condition).
- Evoking: Explore the client's motivation regarding the change target by cultivating change talk while softening sustain talk.
- Planning: Collaboratively develop a change goal and plan. Build confidence for change.

Ultimately, HIV prevention counseling using motivational interviewing should help the client move from ambivalence towards behavior change, and establish clear, realistic goals to prevent HIV transmission.

To support the accomplishment of these goals, staff should address any of the client's confidentiality concerns at the beginning of the session.

Risk assessment is an essential component of HIV prevention counseling because it provides the basis for assisting the client in formulating a risk reduction plan. An assessment of risk can begin with a review of information provided on the Testing Questionnaire.

In addition, assess the client's prevention, social, and clinical needs by asking open-ended questions on the following topics:

- Reason for visit and other relevant concerns
- History of HIV testing and results
- Knowledge of HIV
- Risk activities and awareness of risk
- STD and hepatitis risk
- Steps taken to reduce risk
- Knowledge, awareness, and experience with PrEP
- Desire and readiness to alter risk activities
- Resource and support systems
- Benefits of annual HIV screening for persons at high risk
- Receptiveness to available services and referrals

Listen for and address the following information:

- Sexual activity: type of sexual activity, sexual or gender identification, gender of partners, number of partners, frequency of activity, and how sexual activities may vary depending upon type of partner or situational influences
- Sex with a partner known to have HIV
- Needle-sharing history and other drug use activities
- STD history
- Sex in exchange for drugs or money
- History of sexual assault
- Use of alcohol, cocaine, etc., in connection with sex
- Interest in PrEP

Based on the assessment, agency staff should work with the client in an interactive manner to develop a realistic, incremental plan to reduce their risk for HIV and support and affirm all behavior changes that the client has already made in their life. The HIV Program provides condoms to CTR agencies to distribute to their clients, at no cost, in order to support safer sexual behavior.

Providing HIV prevention counseling in the pre-test session is a high priority; however, providing that counseling should never be a barrier to providing HIV testing to clients.

HIV prevention counseling should not be promoted:

- When the client declines
- When the circumstances or setting may affect confidentiality
- When the client or setting does not have sufficient time to enable this type of counseling.

If agency staff are unable to provide prevention counseling based on the above circumstances, agency staff should attempt to support the client in reducing their risk in whatever way possible (e.g., acknowledging positive steps already taken, clarifying critical misconceptions, and/or negotiating one concrete, obtainable risk reduction goal, assessing STD, hepatitis risk). Providing one or more of the critical aspects of prevention counseling can often take just a few minutes. Agency staff should also plan to offer prevention counseling during the post-test counseling session after the client receives their results.

Deferring Testing

Testing staff have authority to defer testing for any client. Deferral should be based on a determination that testing the individual is not in their best interest. Examples of reasons to defer include client is unable to consent (mental illness, intoxication or high, cognitive problems, may be too young to understand the impact of the test); has been coerced to seek testing; or has expressed intent to harm themselves or others.

Additional Recommendations

CDC promotes additional recommendations for people accessing HIV testing. Testing staff should include the following recommendations when providing prevention counseling with clients:

- HIV testing: The CDC recommends that men who have sex with men who are sexually active be tested at least once a year. More frequent testing should be recommended based on an individual's own risk and other factors identified during the risk reduction counseling session. Based on HIV prevalence in the Milwaukee area, HIV testing is recommended every three months for sexually active men of color in Milwaukee who have sex with men.
- STD testing: Anyone who is sexually active with multiple partners or partners who have had an STD should receive regular STD testing.

CDC Recommendations for STD Testing (https://www.cdc.gov/std/prevention/screeningreccs.htm)

- Hepatitis A & B vaccination for all MSM: Assess whether MSM have been vaccinated for hepatitis A and B, provide information on the risks for hepatitis A and B, identify the benefits of being vaccinated, and have referral systems in place for vaccination.
- Annual HIV and hepatitis C testing for people who inject drugs (PWID): Assess whether a person who injects drugs receives annual testing, identify the benefits of annual testing, and assist the client with developing a plan to be tested annually. Have referral systems in place for hepatitis C testing if not provided by your agency.
- Sexually active females between adolescence and 25 years of age should receive annual chlamydia screens regardless of symptoms: Assess whether young females have had a recent chlamydia test, inform clients that chlamydia often displays no symptoms in young females, provide information on the chlamydia rates and the benefits of being tested, have referral systems in place for chlamydia and other STD screening.
- Women over 25 who exhibit symptoms should also be referred for chlamydia screening: Provide information on symptoms of chlamydia, rates of chlamydia, and the benefits of testing and treatment.
- Syphilis testing: The CDC recommends at least one annual screening for syphilis in sexually active Same Gender Loving (SGL) cis gender men and people of trans-experience per year. Those who have multiple or anonymous partners should be tested more frequently (e.g., every 3-6 months). Recommendations extend to pregnant women or women who suspect pregnancy.

Post-Test Counseling Session

The post-test counseling session occurs when CTR staff provide HIV test results to the client. This session may happen on the same day as the pre-test session for rapid tests, and 7 -10 days after the initial session for laboratory-based test results. The purpose of the post-test session is to:

- Notify the client of their test results
- Assess need for repeat testing
- Provide referrals as needed
- Reinforce the existing plan for reducing risk, as appropriate

Post-test Counseling and Referral for Rapid Results

What is discussed during the post-test counseling session depends on whether the rapid test was reactive or nonreactive.

Nonreactive Results

The following information should be covered when counseling someone with a nonreactive result:

1. Interpret the result and discuss possible need for re-testing: A nonreactive result is interpreted as negative unless the client has engaged in risk behavior within the last month. If the client has engaged in risk behavior during this time, staff should recommend retesting one month after their last exposure.
2. Assess need for referrals: Staff should assess any need for additional client services, such as substance use disorder treatment, financial assistance, domestic violence services, housing, STD testing and treatment, hepatitis testing and vaccination, and other testing in accordance with CDC guidelines.

Reactive Results

The following information should be covered when counseling someone with a reactive result. Throughout this process, staff should provide emotional support to assist the client while waiting for confirmatory testing to be done.

1. Interpret the result and assess client understanding of the result.
2. Explain confirmatory testing.
3. Obtain commitment from client to return for confirmatory results.
4. Discuss what client intends to do during waiting time, including disclosure issues.
5. Encourage client to take precautions to avoid potentially transmitting the virus to others.
6. Assess need for referrals.

1. *Interpret the result and assess client understanding of the result:* Reactive results are defined as "preliminary positives" by the CDC. However, this term may be confusing since some clients may not understand the word "preliminary," and

"positive" has intense associations with it. By hearing the word "positive," clients may believe they have HIV, regardless of how the staff person describes the screening result. To more accurately convey that this result is an initial screen and requires confirmatory testing, staff should explain the result in the following manner:

- "Your test was reactive. We need to do another test to find out whether you have HIV."
- "Your test result shows that we need to do another test to check whether you are HIV-positive."
- "Your test result indicated that you may have HIV. We need you to have another test done to confirm whether or not you are positive."

Ideally, the client will understand the meaning of the result and the process of confirmatory testing based on your pre-test counseling and explanation during the informed consent process. However, clients with a reactive result may require more explanation of the next steps in the testing process.

Although a reactive result is a screening test, the majority of confirmatory results will come back HIV positive, especially when the client has been at risk. Therefore, although the client does not have a confirmed result, it is appropriate for the client to discuss their feelings and begin to deal with the possibility of being HIV positive.

Staff should provide the client with written documentation of their result.

2. *Explain confirmatory testing*: A blood sample for supplemental laboratory testing should be obtained immediately. Test results should be available from the WSLH in 3-7 days.

3. *Obtain commitment from client to return for confirmatory result*: Staff should set an appointment with the client in one week to receive the confirmatory test result.

   If the rapid test was done anonymously, staff should **strongly encourage** the client to have a confidential confirmatory test. If the client refuses to do this, the client may be willing to give the staff person some identifying information (e.g., a first name) and a phone number to reach them in case the result arrives early or the client cannot return for their result. If the client provides this information, staff should verify that the client is willing to have the agency contact them regarding the result if the client does not return.

If the client is willing to have a confidential confirmatory test, the client should sign their original consent form—now checking the confidential box and dating it—noting on the form that it applies to the confirmatory test.

All confirmatory results should be provided in person to facilitate linkage to further services and to offer emotional support. If it is impossible for the client to return for the confirmatory result, staff should make a strong effort to obtain contact information to follow up with the client at another site or by phone as a last resort.

4. *Discuss what the client intends to do while waiting for the confirmatory result, including disclosure concerns*: Waiting for the confirmatory result will create anxiety for many clients. Staff should discuss how clients intend to cope during this waiting period and whom—if anyone—they intend to tell about their rapid test result. As with someone who has just received a confirmed positive result, staff should discuss with the client who they will trust with the result, and the potential ramifications of disclosing their result widely. If their confirmatory result is negative, the client may also have to contend with people who mistakenly believe that they are living with HIV.
5. *Encourage the client to take precautions to avoid potentially transmitting the virus to others*: Staff should encourage and support the client in using risk reduction behaviors to avoid potentially passing HIV to others. This includes examining the client's possible risk behavior while waiting for the testing result and developing a plan with the client for modifying this behavior.
6. *Assess need for referrals*: The client may need emotional support during this waiting period. Minimally, staff should offer to support the client by phone or in person. In addition, the client may need referrals to a mental health counselor, or crisis line. Staff should assess the need for referrals based on the steps defined in the HIV Counseling, Testing, Referral Services Program New Provider Training (in-person), HIV Basic Facts Training (online), and in this protocol.

   Staff should also mention the services that are available to them if their confirmatory test is positive. These services include Partner Services, medical care, case management, linkage to care support (if applicable in your area), legal services, and financial programs for medication and health insurance.

Scheduling a Post-Test Appointment

Agency staff should provide clients with an appointment to return for their result, as needed. Clients who test negative with a rapid HIV test will receive their result on the same day. All clients who have a laboratory test should have an appointment scheduled to obtain their result 3-7 days after their initial visit. The agency staff member should assess potential barriers to returning for test results and develop both a plan to overcome barriers and locate the client in the event of a missed appointment. It is important to obtain contact information, such as a phone number, from the client to help with follow-up.

Some individuals may be anxious during this period while they are waiting for their result. Agency staff should assess each client's ability to cope with the wait and provide, as appropriate, the telephone numbers of support and resource persons they can contact in the interim.

Other HIV Test Scenarios

Providing Test Results by Phone

Providing HIV test results over the phone is highly discouraged. The primary reason for this is because it is hard to confirm that you are speaking to the client directly. The CDC guidelines stress that providing HIV test results in person is important for people with a positive result and for those who have a negative result, but are at high risk for HIV. However, the guidelines acknowledge that providing test results over the phone to persons testing negative who are not at increased risk for HIV may be appropriate under certain circumstances, if the provider can ensure client confidentiality. Providers and clients should identify a secure and confidential method for delivering results acceptable to both people. Agencies should also follow their own guidelines for HIPPA-compliant communication regarding secure messaging systems and electronic medical records.

Agencies must seek approval from the HIV CTR Coordinator prior to developing and implementing policies and procedures for providing HIV test results over the phone.

See the CDC *Implementing HIV Testing in Non-Clinical Settings: A Guide for HIV Testing Providers* (https://www.cdc.gov/hiv/pdf/testing/cdc_hiv_implementing_hiv_testing_in_nonclinical_settings.pdf) for more information.

Failure to Return for Results

If a client received a lab-based HIV test and did not receive the result the same day as the test, there are a variety of reasons why people do not return for their HIV test result. The individual may have simply forgotten, the clinic hours may be inconvenient or incompatible with their schedule, or they may have decided they are not ready to know their result. A client may assume that if there was a problem someone from the site would call them, or they may have received the test as part of a family planning or STD visit and may not have much invested in learning their result.

Whatever reasons clients fail to return, agency staff should discuss at the initial, pre-test, session:

- Any barriers to returning for their result
- Personal motivators to return
- A plan to receive results if the client misses their return appointment

Efforts should be made during the initial pre-test counseling session to motivate the client to return for their result. Most agencies lack the personnel and resources to follow up on all clients who fail to return for results. However, strong efforts must be made to contact clients who test HIV positive.

If a client tests positive for HIV and agency staff are unable to locate the client, local PS staff will attempt to locate them to provide the test result and offer them services. Agency staff should report the case to the HIV Surveillance Program, either by phone or fax, indicating that the client did not return for their result. Surveillance staff will provide this information to the state PS Coordinator, who will connect with local PS staff.

Agencies should develop policies and procedures identifying how they will work with clients to locate them should they fail to return for their results. Separate approaches will be needed to return test results for clients testing confidentially and anonymously.

Previously Positive Clients Seeking Testing

In some circumstances, clients who already know they are living with HIV will seek an HIV test from a CTR site. There are various reasons this may happen. The client might not share with the agency staff prior to testing that they already know their status. This is an important opportunity to educate the client on HIV and assist the client with getting reconnected to care services, as needed.

Testing Of Children and Adolescents

The CTR Program discourages testing of young children at CTR sites. Parents of children should be encouraged to have HIV testing performed by the child's pediatrician or regular primary care provider. Additionally, Determine™ HIV rapid tests cannot be used with children under age 12. However, if the parent indicates there is no primary care provider or they lack resources to obtain testing, sites should either test the child or be prepared to provide referral to a site that can test young children. If a site decides to test, CTR personnel must be capable of obtaining a blood sample from a child.

If agency staff determines that the person is 14 or older and has sufficient maturity to understand what the test is and the implications of testing, then they can provide informed consent for testing and should be offered testing and counseling services. Wisconsin statutes (§ 252.15(2m)(c)) allow youth ages 14 and older to consent to HIV

testing without a parent or guardian's consent. The statutes do not specifically address consent for youth under the age of 14.

Testing at Health Fairs and Community Events

Agencies funded by the Wisconsin HIV Program to provide point-of-care testing should not provide testing at health fairs, school or university events, or community events intended for a general audience because these events do not identify persons at increased risk for HIV. When requested to provide CTR services at these events, agencies may offer the option to provide health education materials and resource lists instead of testing.

HIV testing can be conducted at community events aimed at persons who are at *high risk* for HIV, such as at LGBTQ Pride festivals.

The exception to testing at health fairs and community events is limited to events designated by the CDC as "National Testing or Awareness Days" for various populations. These include the following:

- National Black HIV Awareness Day: February 7th
- National Women and Girls HIV Awareness Day: March 10th
- National Native HIV Awareness Day: March 20th
- National Youth HIV Awareness Day: April 10th
- National Transgender HIV Testing Day: April 18th
- HIV Vaccine Awareness Day: May 18th
- National Asian & Pacific Islander HIV Awareness Day: May 19th
- National HIV Testing Day: June 27th
- National HIV and Aging Awareness Day: September 18th
- National Gay Men's HIV Awareness Day: September 27th
- National Latinx HIV Awareness Day: October 15th
- World AIDS Day: December 1st

When agencies do offer testing on these days, they should inform the CTR Coordinator 30 days before the scheduled event for review and approval. Similar to standard HIV outreach testing protocol, agencies must have a plan in place to ensure client confidentiality is not negatively impacted when testing at public events.

Additionally, agencies should make every effort to be inclusive and promote the event through advertisements in LGBT publications, promotion among IDU and syringe exchange clients, and in neighborhoods with high HIV prevalence.

Testing at Short-Stay Correctional Facilities

HIV CTR sites are discouraged from offering testing in city and county jails. Historically, testing at city and county jails doesn't result in identifying very many new, undiagnosed HIV cases. A strategy for testing in jails often involves providing a brief education presentation and then inmates have the opportunity to decide whether they want to receive testing or not. Because inmates are self-selecting for testing, this generally results in the lowest risk inmates opting in for testing.

The length of incarceration is brief for people in short-stay correctional facilitates, which can also make it hard to follow up on results from laboratory tests. This same follow up challenge is also true if a rapid test is used and then a confirmatory blood draw is needed, it can also be hard to locate the client if they have left the facility.

The preferred approach to testing in jails is to work directly with the jail's medical provider to refer inmates to CTR providers for possible on-site, voluntary testing based on an inmate's medical history and specific medical indicators.

Local health departments interested in offering testing in short-stay correctional facilities should use this referral-based approach. CTR sites receiving grant funds from the HIV Program must seek permission from the HIV CTR Coordinator to initiate or continue offering testing in short-stay correctional facilities. A determination will be made if jail testing fits the agencies' approved service delivery plans targeting high-risk populations.

HIV statutory issues also affect testing in short-stay correctional facilities. The primary example of this is that medical providers of a jail have the right to know if an inmate tests positive. This allows them to make decisions on how to medically treat inmates if they develop any type of illnesses during their incarceration. Any site providing testing in a jail must first determine if the medical provider wants access to results of inmates testing positive. In these instances, anonymous testing is not an option and inmates must be informed that results will be shared with the jail's medical provider should they test positive.

Please note that CTR Program services must be voluntary in any setting and therefore CTR services cannot be used for court-mandated testing.

HIV Test Technology and Procedures

In this section:

- Types of HIV Tests
- Window Period
- Testing and WSLH Services
- Antigen/Antibody Testing
- Laboratory HIV Testing Algorithm
- Algorithm

Types of HIV Tests

The HIV Program uses tests within each of these categories:

- *Laboratory-based Antigen/Antibody Testing (Ag/Ab):* This test requires a blood sample to be sent to the laboratory for processing. The test identifies both HIV antigen and HIV antibodies in a blood sample. Antigens are proteins produced by the HIV virus that are detected during the early stages of HIV entering the body. Antibodies are proteins produced by the body to fight specific viruses. At Wisconsin CTR sites, a blood sample is sent to the Wisconsin State Laboratory of Hygiene (WSLH) to test the specimen for HIV antigens and antibodies. If the test is positive, the same blood sample will receive additional testing. See the laboratory-based antigen/antibody testing algorithm on page 42.
- *Fourth Generation Rapid Antigen/Antibody Testing:* Rapid antigen/antibody tests are *screening tests* that can be run easily and quickly at a testing site ("point-of-care") without the equipment or expertise of a dedicated laboratory. If the test is reactive, this result must be confirmed by collecting a blood sample to be sent to the laboratory for further testing. If the rapid result is negative and the client has not had a risk exposure in the past month, the client is considered negative for HIV. Various rapid tests range in time from 1-20 minutes. The Wisconsin HIV Program uses a test that takes 20 minutes, called the Abbott Determine HIV ½ Ag/Ab Combo Test.

- *DNA PCR testing:* Laboratory-based tests or PCR tests that detect viral genetic material, not antibodies, and are effective at detecting HIV in the very early stages, also known as an acute or early infection. It is in a classification known as nucleic acid amplification tests (NAAT).

The Wisconsin HIV Program no longer supports oral fluid specimen testing.

Window Period

The period of time between a possible exposure to HIV and when a test is capable of identifying HIV in a person's body is called the "window period." For antigen/antibody tests, the window period is about one month. For an antibody only test, the window period can be as much as three months after exposure, although some individuals will test positive earlier. Clients who have risk within the window period of the test should be re-tested. It is very important for testing staff to communicate the window period of the test to all clients receiving HIV testing.

Testing and the WSLH Services

Testing at the Wisconsin State Lab of Hygiene is supported financially by the HIV Program. Local health departments and individual agencies funded to provide HIV counseling, testing, and referral services are not charged for this lab-based testing.

Labeling Specimen Collection Devices Sent to the WSLH

All **specimen containers** sent to the WSLH for HIV testing must be labeled with **TWO** unique patient identifiers. The same two identifiers must be on the laboratory slip accompanying the specimen. All CTR sites are required to follow the steps below when submitting samples to the WSLH for HIV testing:

1. Place the pre-printed Test ID sticker on the laboratory slip. Test ID stickers are supplied by the Wisconsin HIV Program.
2. Place an identical Test ID sticker on the specimen collection vial or device.
3. Write the client's date of birth (MM/DD/YYYY) in the designated section on the top of the laboratory slip.
4. Use the client's date of birth from the laboratory slip as the **second** patient identifier on the specimen collection device. You can either write the date of birth on the test ID sticker—above the pre-printed test ID number—or use a separate

blank sticker to write the date of birth and attach it to the specimen collection device along with the test ID sticker.

5. **DO NOT use the client's name as the second identifier on specimen collection devices or write the client's name anywhere on the specimen collection device. This applies regardless of whether the client is testing anonymously or confidentially.**

Questions Related to Testing and Results

Questions related to shipping and processing of specimens may be directed to WSLH Customer Service, 800-862-1031. All calls or questions related to interpretation of tests results should be directed to the HIV CTR Coordinator.

Antigen/Antibody Testing

The Abbott Diagnostics HIV 1/2 Ag/Ab Combo test is the first FDA-cleared laboratory-based test that detects both HIV-1 p24 antigen (Ag) and HIV-1 and HIV-2 antibody (Ab) simultaneously in the same test. HIV-1 p24 Ag is a protein that is produced by the virus immediately after infection, while antibodies develop days or weeks later as the body works to fight off the HIV virus. Because of this, the Ag/Ab test can identify a client who has acute HIV—the initial stage of HIV prior to antibody response. **The window period for the Ag/Ab test is up to one month post-exposure.** The test is able to detect both HIV-1 and HIV-2. To test a client, agency staff draws a tube of blood from the client and sends it to the WSLH.

Specimen Collection and Submission to the WSLH

Supplies are available from WSLH at no charge and can be ordered by calling WSLH Clinical Orders at 800-862-1088. To send a specimen to the WSLH, sites can use http://www.slh.wisc.edu/clinical/diseases/supplies/. For sites that conduct a high volume of tests, all of the components of the test can be ordered in bulk from the WSLH.

See Appendix F for the Blood Sample Guidelines for HIV, Hepatitis C, and Syphilis Tests by the Wisconsin State Lab of Hygiene.

Staff should collect one tube of blood to be sent to the WSLH:

- Collect 10 mL of whole blood in an EDTA (lavender top) anticoagulant tube. If the staff person is unable to obtain the needed volume of blood, as much specimen should be submitted as can be obtained and the WSLH will attempt to test it. See

Blood Sample Guidelines for HIV, Hepatitis C, and Syphilis Tests, Appendix F, for more information.

- Invert the tube 8-10 times to be certain that the entire specimen has contact with the anticoagulant.
- **Do NOT centrifuge the blood specimen.**
- The specimen should be refrigerated if it is not sent immediately to the WSLH
- Complete the Laboratory Requisition by checking HIV-1/HIV-2 Antigen/Antibody (SS00099). This is necessary to properly bill the test.
- The specimen tube should be labeled with a Test ID sticker and the client's date of birth, wrapped in absorbent material, and individually bagged with the Laboratory Requisition.
- Package the tube in the Styrofoam mailer with a cold pack. The exterior of the mailer must have the "Biological Substance, Category B / UN3373" label affixed to it. Mailer can be addressed to:

  Wisconsin State Laboratory of Hygiene
  Communicable Disease Division
  2601 Agriculture Dr. PO Box 7904
  Madison, WI 53718

Results are generally reported back to sites in 3-7 days depending on agency location and the length of time it takes for specimens to reach WSLH. Post-test counseling appointments should be scheduled accordingly. The WSLH will maintain a record of all test results, and a copy of the results will be sent or securely faxed to the testing site.

HIV Testing Algorithm

- Specimens that are negative on the HIV Ag/Ab combo laboratory-based test are reported by the WSLH as "Nonreactive -HIV p24 Ag and HIV-1/HIV-2 Ab not detected."
- Blood that is initially reactive in the HIV Ag/Ab combo laboratory-based test will be tested again by repeating the Ag/Ab combo test several times.
- See Laboratory HIV Testing Algorithm on page 43 for more details.

Meaning of HIV Test Results

Negative Result: Samples are considered negative if the Ag/Ab combo test is nonreactive. If the client engaged in risk behavior less than one month from the date of the test, the client should test again one month after their last exposure to be certain they do not have HIV.

Positive Result: Specimens are considered positive if the Ag/Ab combo test is repeatedly reactive and a Geenius antibody test is reactive for HIV-1 or HIV-2.

Positive for Acute HIV Infection: Specimens are positive for acute HIV infection when the following is true:

Ag/Ab result is repeatedly reactive

+

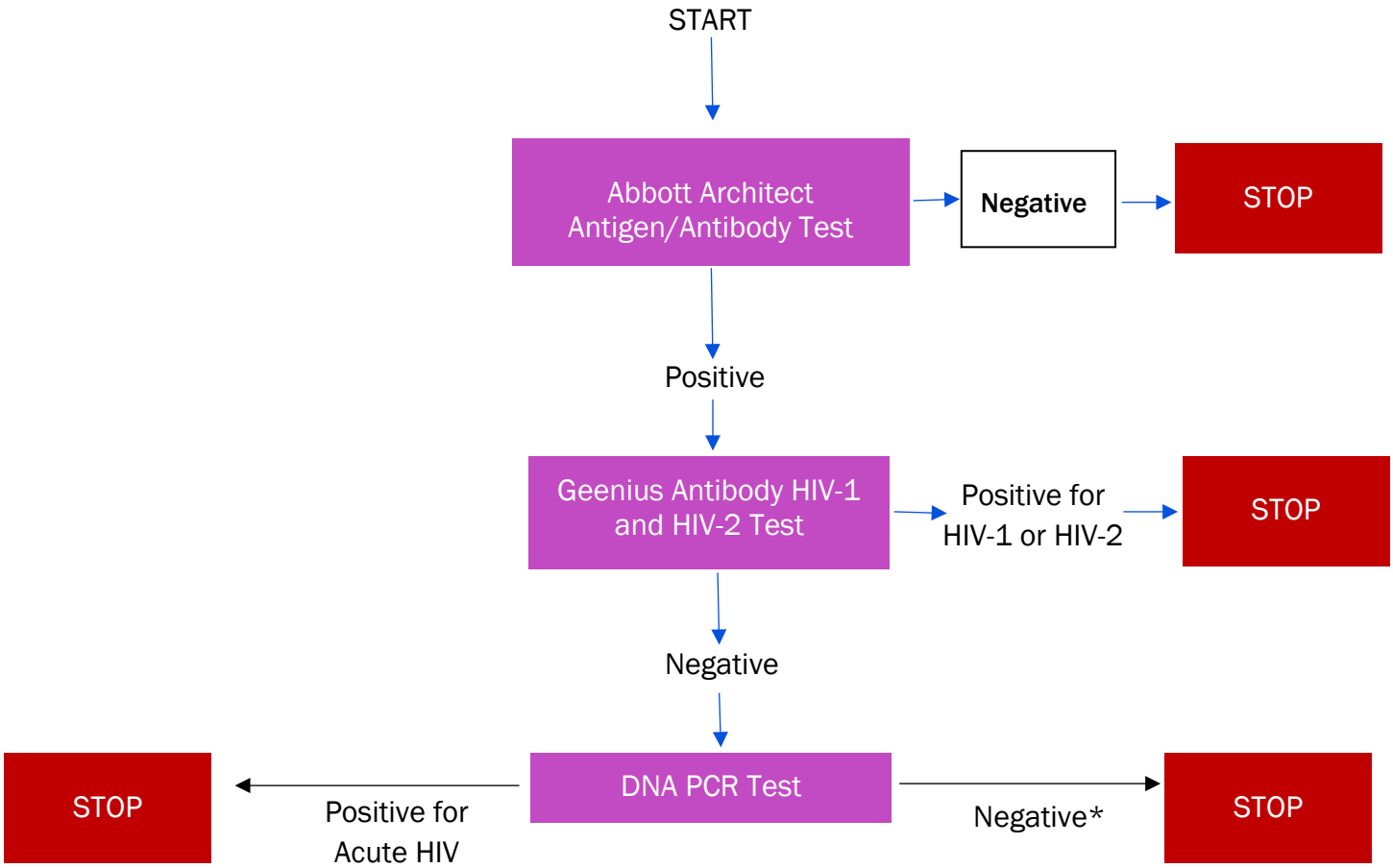
Geenius antibody HIV-1 and HIV-2 test is nonreactive or indeterminate

+

DNA PCR is reactive

This set of results indicates that the client has acquired HIV recently (i.e. less than 1-2 months), because virus has been identified by the Ag/Ab and DNA PCR tests, but antibody has not been produced sufficiently to show up on the Geenius™ antibody test. It is important that the client is connected immediately to medical care, Partner Services, and, if appropriate, case management or linkage to care services.

Laboratory HIV Testing Algorithm



*The DNA PCR Test is the final test. If the Ag/Ab test was positive, but the PCR test was negative, then the Ag/Ab test was a false positive.

Rapid Testing

In this section:

- Summary
- Deciding if Rapid Testing is Right for your Agency
- Rapid Testing Program Requirements
- Rapid Testing Quality Assurance
- What to do when a Rapid Test is Invalid
- What to do when External Controls Fail
- Rapid Testing in Non-Traditional or Outreach Settings
- Abbott Determine HIV-1/2 Ag/Ab Combo Rapid Test
- Rapid HIV Testing Algorithm
- Dual Rapid Testing

Summary

All rapid HIV tests are screening tests. A reactive result on a rapid test must be confirmed by supplemental tests. A nonreactive result is interpreted as negative and means that the client either does not have HIV or it is too early since a recent exposure for the rapid test to identify HIV in their body. If the client has had a risk exposure within the last month, the rapid HIV antigen/antibody test should be repeated one month after exposure. Some clients mistakenly believe that the term "rapid test" refers to identifying HIV rapidly—that the test can accurately determine whether a risk exposure last night resulted in living with HIV today. **Staff must be clear that rapid HIV testing only refers to obtaining results rapidly.**

The Wisconsin HIV Program is currently using one rapid test for HIV CTR sites: Abbott Determine HIV-1/2 Ag/Ab Combo Test. This test is a rapid, finger-stick test that takes 20 minutes to complete. See page 60 for more information on how to use this test.

Deciding if Rapid HIV Testing is Right for your Agency

Rapid HIV testing may not feel "rapid" to the client being tested. Since the pre-test counseling, sample collection, testing, and post-test counseling all occur in one visit, a client can expect to be at an agency at least 30–60 minutes before receiving their test result. Some clients may feel this is too long and opt for laboratory HIV testing requiring them to return one week later for their result. Some agencies may decide to perform a rapid test and arrange for the client to return later in the day or the next day. However,

under these circumstances the risk of the client not returning for their test result remains. The Wisconsin HIV Program does not encourage adopting the practice of returning for a rapid result, except in special circumstances.

Rapid testing typically requires more personnel for conducting the same quantity of tests since agency staff must now perform the rapid test in addition to the counseling. Agencies should consider how to use their staff most effectively in order to provide efficient client services. Some agencies may use two or three staff to conduct rapid testing services—one or two to provide the counseling and referral and the other to process the test. Other agencies may decide to "overlap" clients: while one client is waiting for their test to develop, the staff person may begin counseling and testing another.

Each site will need to review how site flow is established based on their personnel resources and other logistics of their setting. Agencies should assure that staff members are available to assist and support the client receiving a reactive rapid test. Persons with reactive rapid results will typically require much more time for post-test counseling and referrals than those with nonreactive (negative) results.

Rapid Testing Program Requirements

In order to provide rapid HIV testing, sites must meet the following requirements.

Laboratory and Bloodborne Pathogen Requirements Checklist

- ☐ Valid CLIA certification for conducting waived tests (see more below)
- ☐ Refrigeration to store controls, and provision for monitoring refrigerator temperatures (Per bloodborne pathogen standards – the refrigerator must not store food or beverages)
- ☐ Compliance with bloodborne pathogen standard requirements listed below:
    - ☐ Exposure control plan including documentation of review and use by staff of safer devices
    - ☐ Exposure determination record
    - ☐ **Initial and annual staff training in bloodborne pathogen control standard precautions (c.)**
    - ☐ Availability of hepatitis B vaccine to all employees conducting testing, at no cost to the employee
    - ☐ Availability of post-exposure evaluation and follow-up, including prophylaxis, at no cost to the employee

- ☐ Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up—to be kept for duration of employment plus 3 years (d.)
- ☐ Training records to be kept for three years from the date of training (d.)
- ☐ Sharps injury log
- ☐ Warning labels affixed to all containers containing blood or other infectious materials, (including refrigerators) or red containers
- ☐ Biohazardous waste containers, gloves, decontamination materials
- ☐ Access to hand washing facilities or appropriate antiseptic hand cleanser as indicated
- ☐ Arrangements for biohazardous waste disposal

Here is more detailed information related to the checklist. For additional technical support and resources, agency staff may contact the HIV CTR Coordinator using the contact list.

a. CLIA Requirements

- The rapid tests used by the Wisconsin HIV Program are classified as "waived" by the FDA when used with whole blood samples. CLIA requires that all sites offering these tests have laboratory certification allowing them to conduct waived testing.
- Sites must minimally hold a CLIA Certificate of Waiver or Provider Performed Microscopy Procedure (PPMP) certificate. For more information on CLIA and how to apply for a certificate, view the federal Centers for Medicare & Medicaid Services website at www.cms.gov/clia. Staff in the Clinical Laboratory Section of the DHS Division of Quality Assurance is also available to answer questions.
- The CLIA application should be mailed to:

  Wisconsin Department of Health Services
  Division of Quality Assurance Clinical Laboratory Section
  1 West Wilson Street
  PO Box 2969
  Madison, WI 53701

  Phone: 608-261-0654
  Fax: 608-283-7462
  Contact: Charise Mancheski
  Email: dhsdqaclia@wisconsin.gov

- When submitting the application, please add the email address for the person who is completing the application and identify the State of Wisconsin License Number (e.g. MD, RN, Certified Social Worker, etc.) for the person who will be the laboratory director.

b. OSHA Requirements

- All sites must also adhere to the Occupational Safety and Health Administration (OSHA) *Occupational Exposure to Bloodborne Pathogen* standard. (www.osha.gov/SLTC/bloodbornepathogens/index.html.) OSHA published this standard to prescribe safeguards to protect workers against health hazards related to bloodborne pathogens. Under the OSHA standard, an employer must develop and implement a worksite exposure control plan that describes detailed steps to protect employees.
- Since the external controls used with rapid tests are derived from plasma, all sites must develop an exposure control plan and implement the bloodborne pathogen controls standard.

- Exposure control plans are required to cover the following areas:
    1. Determination of employee exposure
    2. Methods of compliance addressing exposure control (including standard precautions, engineering and work practice controls, personal protective clothing and equipment.)
    3. Vaccination and antibody testing for hepatitis B
    4. Post-exposure evaluation and follow-up
    5. Communication of hazards to employees
    6. Utilizing biohazard signs, labels, and waste disposal methods
    7. Keeping of records, including a sharps injury log
    8. Annual training

- Resources for developing and implementing a bloodborne pathogen control plan and additional infection control information are available at https://www.dhs.wisconsin.gov/ic/index.htm.
- Also available is a copy of a multiple-ply form entitled *Determination of Exposure to Blood/Body Fluids* (Form WKC-8165). This form is to be completed by a health care provider to certify that a staff person has been significantly exposed to the blood or body fluids of a patient or client. This form may also be used for the purpose of Worker's

Compensation. **Form WKC-8165 is available for purchase** from the Bureau of Document Services at: 608-243-2441, doadocumentsalesinformation@wisconsin.gov, https://docsales.wi.gov/.

c. In addition, all staff must be trained annually in bloodborne pathogen control ("standard precautions") through their employer. Staff who conduct rapid testing with whole blood must be trained and competent in finger-stick collection of whole blood specimens. The Wisconsin HIV Program will provide opportunities for training on bloodborne pathogen control and finger-stick specimen collection, as needed. It is the responsibility of the agency to assure that staff are proficient and are using standard precautions.

d. To comply with OSHA standards, the agency should document training of staff in bloodborne pathogen control and finger-stick specimen collection. All relevant training and results of any competency assessment should be documented in the personnel file.

Administrative Requirements Checklist

The following policies and procedures must be in place:

- ☐ Pre-test counseling information to be provided to clients during rapid testing.
- ☐ Use of gloves and other personal protective equipment.
- ☐ Safe disposal of biohazardous waste (e.g. used lancets, external controls).
- ☐ Maintaining sufficient inventory and checking new lots and shipments.
- ☐ Maintaining and documenting environmental temperature control.
- ☐ Describing in writing testing steps and activities for both in-house and outreach settings.
- ☐ Written procedure on how to collect a blood sample.
- ☐ Written test procedure and how to read the results.
- ☐ Written procedure explaining how to perform quality control testing and identify what to do when controls fail.
- ☐ Participate in external quality assessment (proficiency testing) as required.
- ☐ Written procedure on how to report test results as contracted to do so by the HIV Program.
- ☐ Specimen collection and submission for confirmatory testing.
- ☐ Document client and control test results.
- ☐ Post-test counseling and provide referrals.
- ☐ Record review, storage, and disposal.
- ☐ Troubleshooting activities—what to do when things go wrong.

- ☐ Staff training, competency assessment, and documentation of training.
- ☐ Supervisor or lead worker assuring that procedures are being followed to ensure high-quality testing.
- ☐ Supervisor or lead worker assuring that bloodborne pathogen control standards are being implemented.
- ☐ Confirmatory testing (serum) is provided to confirm reactive rapid tests.
- ☐ Participation in the state's quality assurance (QA) activities and compliance with its QA plan.
- ☐ Referral systems for reactive rapid results.

This HIV CTR protocol may serve as an agency's basic policies and procedures related to rapid HIV testing. However each agency should have **site-specific** policies and procedures that include a description of how the test is conducted in both clinic and outreach settings.

Staff Training and QA Requirements Checklist

- ☐ Attend the Wisconsin HIV Program training courses, including the HIV Counseling, Testing, and Referral New Provider Training (in-person) (b.)
- ☐ Participate in online HIV Basic Facts course (online) (b.)
- ☐ Demonstrate competence in conducting fingerstick blood draws.
- ☐ Establish knowledge of and adherence to package insert instructions for the rapid test (c.).
- ☐ Complete a competency assessment by testing samples and accurately reading the results prior to testing clients
- ☐ Demonstrate accurate test administration and interpretation of test results for both positive and negative controls prior to testing clients
- ☐ Participate in the state proficiency program to assure staff competency in testing at each agency.
- ☐ Assigning a lead staff person responsible for overseeing rapid testing and all QA activities on-site.
- ☐ Using external controls as required in the protocol.
- ☐ Documenting testing process and results.
- ☐ Recording the storage temperature of test devices and external controls.
- ☐ Communicating testing problems to the on-site lead staff person (#1 above), the WSLH, or the Wisconsin HIV Program, as appropriate and taking action to ensure that the test is providing valid and reliable results.

a. Personnel providing rapid testing should possess the following qualities.

- Commitment to following procedures and precision in work habits.
- Literacy – the ability to read instructions and document testing activities, including reading results
- The ability to resolve problems and discern when further help is needed
- Organizational skills

b. All site staff intending to offer rapid HIV antibody testing must first attend the following foundation courses conducted by the Wisconsin HIV Program.

- HIV Basic Facts (Online)
- HIV Counseling, Testing, and Referral New Provider Training (in person)

An exception to the above requirement is for laboratory staff working in a moderate complexity laboratory. If these staff will not be conducting counseling, they may conduct the test by following the instructions in the package insert and program protocols without attending the Wisconsin HIV Program in-person training. Typically, the HIV CTR Coordinator will meet with the lead staff person in a moderate complexity laboratory to review rapid testing procedures and forms for the program and to assure that the testing process is consistent in all CTR sites.

c. Prior to testing client specimens all staff **must** read and understand the rapid test's package insert, in addition to this protocol. Also, staff **should review the revision date** of the package insert, included with each test shipment, to find out whether the instructions have been updated, and to review them if they have been changed.

How Long to Keep Records:

3 Years

- Consent for HIV Testing (English, Spanish) (Appendix B)
- Authorization for Release of Confidential HIV Test Results (English, Spanish), if used (Appendix D)

- Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up to be **kept for duration of employment, plus three years.**
- Sharps injury log

18 months

- Wisconsin CTR Testing Questionnaire (English, Spanish) (Appendix C)

1 Year

For rapid testing only: Logs that include personally identifiable information should be shredded.

- Temperature logs
- Inventory logs
- Testing and controls logs

Rapid Testing Quality Assurance

Lead QA Staff

Each agency must designate a lead staff person responsible for assuring quality of their agency's rapid testing. This person will be responsible for assuring that:

- Storage and site temperatures are monitored and documented.
- Site testing log is completed accurately.
- Testing devices and controls are used prior to expiration.
- The agency has sufficient test devices and controls to provide efficient services to clients.
- Staff are trained and following the protocol.

The lead QA staff person will be the first person notified by other testing staff when a test is invalid or external quality controls fail. This person will work with agency testing staff to determine the basis of the problem and to notify additional agency personnel as needed. Some large agencies will have a hierarchy of administrative staff who oversee quality assurance of testing. Each agency should develop communication mechanisms to assure that staff are made aware of testing problems and problem solving.

When problems arise, the lead QA staff or other administrative staff should contact the HIV CTR Coordinator. The HIV CTR Coordinator will provide technical assistance on resolving problems regarding rapid HIV testing. It may be necessary to contact the test manufacturer to report defective devices or controls.

Training

As stated previously, all staff conducting rapid testing must participate in the following training sessions conducted by the Wisconsin HIV Program through the Wisconsin HIV Training System:

- HIV Basic Facts (online)
- HIV Counseling, Testing, and Referral New Provider Training (in-person)

The lead QA staff person should assure that staff are competent in rapid testing procedures by observing them in the various steps required for conducting a rapid test, see the Determine Rapid Ag/Ab Training Checklist, page 76.

Competency Assessment

At the completion of Wisconsin HIV Program rapid testing training, all participants who intend to conduct rapid testing must successfully complete a competency assessment to assure that they can run tests and interpret results properly. Each participant must conduct tests on five samples provided by the WSLH Proficiency Testing Program.

Staff identifying less than 4 of the 5 samples must participate in remedial training related to problems in conducting or interpreting the test. This may involve one-to-one discussion with the trainer, attending another training, or repeating the competency assessment.

In addition to the competency assessment, the Wisconsin HIV Program recommends that the lead QA person at each agency completes the training checklist (see Determine Rapid Ag/Ab Training Checklist on page 76) to assure that staff accurately conducts rapid HIV testing. Lead QA staff should observe the newly trained staff when initially conducting rapid testing with clients.

Proficiency Testing

Proficiency testing (PT) is another way to "test the tester." The WSLH sends agencies specimens to test and interpret results three times a year. Their performance is scored based on how many tests were interpreted correctly. The goal is for all sites to obtain a score of 100% for each PT event.

The Wisconsin HIV Program enrolls sites in the WSLH PT Program, and pays for its cost. Staff at the agency test the samples and send WSLH the results, which are scored on accuracy. Ideally, each staff person performing rapid testing will test and interpret at

least some of the specimens each year. The lead QA staff at each agency will document that proficiency testing was completed and the name of the staff person who tested and interpreted each sample. When completed, the specimens should be disposed of in a biohazardous waste container.

The results from each PT event will be sent to both the agency and the Wisconsin HIV Program. If an agency fails a PT event, the HIV CTR Coordinator will contact the lead QA staff person to assess the situation. Rapid testing may be halted at the site until the problems with testing or interpreting test results are resolved.

Use of External Quality Controls

Using external quality controls on a consistent basis is important to maintain quality testing. Please find additional information on how to run Determine HIV 1/2 Ag/Ab Combo Test controls on page 62.

Documentation

To assure that conditions and key elements of the testing process are in place for quality testing, each site is required to complete the following documentation:

1. Testing Log—documentation of key information related to each test and control run at the site.
2. Inventory Log—documentation of when test kits and control kits are received by the agency, their lot numbers, expiration dates, the number of tests within each box, and the date that tests from this box were first used.
3. Storage Temperature Logs—documentation of temperature where controls **and** tests are stored.

Examples of each of these logs are at the end of the Determine rapid testing section starting on page 77. Each log is described below.

1. Testing Log: Each time a test is run on a client specimen **or** an external control, the information regarding the test must be documented on a testing log. This documentation should occur at the same time the test is conducted. Staff should *not* wait to document tests on the log at a later time (e.g., waiting until back in the office after an outreach event), since it increases the potential for error. For each test, the following must be documented:

- Date of test
- Test ID number and code/initials or positive or negative control
- Initials of staff performing test
- Current temperature of testing area
- When the test was started
- When the test was read
- Whether the internal control on the test device was valid
- Whether the result was reactive or nonreactive
- Whether a client specimen was sent for confirmatory testing
- Confirmatory test result
- Comments (e.g., why external controls were run, troubleshooting for invalid results, whether client received confirmatory results, venue where test was done)

In addition, the lot numbers and expiration dates of both the tests and external quality controls must be documented at the top of the log.

All tests and controls must be logged chronologically, so that the log provides an accurate history of testing at that location. **A new log should be started every time a new lot of tests or external controls are used**.

2. Inventory Log – Each time a shipment of tests or external quality controls is received by the agency, it should be documented on the log. The log should indicate when the item was received, the lot number, and the expiration date. The log should also indicate the date when devices from this box were first used. Items with the earliest expiration dates should be used first.

3. Storage Temperature Logs - Staff must document storage temperatures of both test kits and the controls on each day tests are performed. The Sample Temperature Log on page 77 specifies a column for the high and low temperatures since the last reading as indicated on a min/max thermometer. If the temperature falls out of the specified range, staff must document what corrective action was taken.

   When temperatures fall out of the required range for storing test kits, staff should run a set of external quality controls. If the expected results are obtained, the tests may be used. If either the tests are invalid or the expected results are not obtained, the tests should be disposed.

   When temperatures fall out of the required range for storing external control kits, staff should use that set of controls to run a positive and negative control on test devices that have been stored properly. If the expected results are obtained, the controls may be used. If not, the controls should be disposed. This process should be done for each set of controls exposed to the out-of-range temperatures.

Troubleshooting

Troubleshooting is a problem-solving process. When a test fails, staff must attempt to determine the source of the problem. The problems may rest with the testing process or conditions, the test device, or the specimen.

The lead QA staff person should be involved in the problem-solving process. If the testing process and conditions met all specified requirements, staff must assess if there was a problem with the test device. In a rare event, something about the sample may have caused the failure. A process described on the next two pages can assist staff in evaluating reasons why an invalid test result occurred, or external controls failed.

Whenever a site has an invalid result, this test should still be logged on the Testing Log and entered into EvaluationWeb. Staff should also email the HIV CTR Coordinator (see contact list) regarding the invalid result, possible reasons for it, and whether a repeat test yielded a valid result. If the invalid result does not seem to be due to human error, agency staff should contact the manufacturer.

Similarly, whenever a site has a discordant or false-positive result (a reactive rapid, but negative supplemental testing), staff should contact the HIV CTR Coordinator.

What to do when a Rapid Test is Invalid:

1. Identify the problem using the following list of potential problem areas:
   - ☐ Were the tests **stored** within the proper temperature range?
   - ☐ Was the temperature of the **testing area** within the proper range?
   - ☐ Was the test used prior to the expiration date?
   - ☐ Was the test kit at room temperature prior to testing?
   - ☐ Was the lighting in the testing area adequate for proper testing?
   - ☐ Was the desiccant present in the test pouch?
   - ☐ Was the first drop of blood wiped away and testing performed on the second drop?
   - ☐ Was all of the blood from the pipette added to the sample pad?
   - ☐ Was the test device properly placed on a flat surface?
   - ☐ Was the buffer solution added to the test device?
   - ☐ Was the test result read between 20 and 30 minutes after the test was completed?
2. If it is determined that any of the above conditions caused the invalid test result, staff should document on the *Testing Log* in the "Comments" section - the troubleshooting process; actions taken; and how staff verified that the corrective action taken addressed the problem. Staff should use the other side of the log if more space is needed.
3. If it is determined that none of the above conditions caused the invalid result, perform a second rapid test either with another client specimen or with a set of external quality controls.
4. Take a picture of the test strip and email it to the HIV CTR Coordinator. This may help with troubleshooting.
5. If a client specimen was used and the second test is also invalid - run a set of external quality controls.
6. If the control tests come back invalid, discontinue testing. Report the problem to the test manufacturer, (Abbott – 1-800-257-9525) and to the HIV CTR Coordinator.

What to do if the External Quality Controls Fail:

1. Identify the problem using the following list of potential problem areas.

   - ☐ Were the tests **stored** within the proper temperature range?
   - ☐ Was the temperature of the **testing area** within the proper range?
   - ☐ Were the controls stored between 35°F and 46°F?
   - ☐ Were there controls brought to room temperature prior to use?
   - ☐ Were the tests used prior to the expiration date?
   - ☐ Were the controls used prior to the expiration date?
   - ☐ Was the test brought to room temperature prior to testing?
   - ☐ Was the lighting in the testing area adequate for proper testing?
   - ☐ Was the desiccant present in the test pouch?
   - ☐ Was a new pipette used with each control vial?
   - ☐ Were the tests labeled correctly? (i.e. positive on a positive control and negative on a negative control)?
   - ☐ Was buffer added to the tests? (Do not use the buffer for controls).

2. If it is determined that any of the above conditions caused the external controls to fail, staff should document on the *Testing Log* in the "Comments" section - the troubleshooting process; actions taken; and how staff verified that corrective action taken addressed the problem. Staff should use the other side of the log if more space is needed.
3. If it is determined that none of the above conditions caused the external controls to fail, perform a second rapid test on another set of controls.
4. Take a picture of the test strip with the control bottle used and send the picture to the HIV CTR Coordinator.
5. If the problem resolves with the second set of controls, dispose of the first set of controls.
6. If the problem remains with the second set of controls, contact the test manufacturer, (Abbott – 1-800-257-9525) and the HIV CTR Coordinator.

Record Review

The lead QA staff person at your agency should review all testing documentation at least once per month to assure that testing practices meet the requirements indicated in the manufacturer's package insert and this protocol. The lead staff should also review whether the number of test kits left in inventory is consistent with the number of tests used as documented on the *Testing Log*.

Wisconsin HIV staff will review testing documentation (testing logs, temperature logs, and inventory logs) of grantee agencies at annual site visits.

Rapid Testing in Non-traditional or Outreach Settings

The Wisconsin HIV Program approves of conducting rapid HIV testing in non-traditional or outreach settings as long as specific conditions are met. The following conditions must be present for rapid HIV testing in non-traditional settings:

- *Lighting*: Sufficient lighting to safely and accurately conduct the test and read the result. If the natural or room lighting is not bright enough to read the result, staff should use a lamp to improve the lighting – not a flashlight.
- *Temperature*: The temperature of the testing environment should be within the operating temperature for the test specified in the package insert and this protocol. Staff must use a thermometer in the field to assure that the temperature is within the proper range. The temperature during each test should be documented on the Rapid Testing Log. Test kits should be stored at all times within the storage temperature range listed in the package insert and this protocol.
- *Surface area*: The test must be performed on a level, clean surface. Consistent with bloodborne pathogen control procedures, no food or drink should be consumed in the area where testing is performed. Staff should set up their workspace as recommended under "Testing Steps" in the Determine section of this protocol on page 65.
- *A confidential, private space for testing, counseling, and providing results*: Since the test is actually conducted in the outreach setting, staff must be certain that tests develop in a private place where only the testing staff can view results. A confidential space must also be used to provide pre-test and post-test counseling to clients. Testing staff must be particularly conscious of the confidentiality issues of clients with a reactive result. For instance, if a client meets with staff for a longer period of time than those clients with a nonreactive result, this may inadvertently break their confidentiality, since others may assume the client had a reactive result. Staff must consider all the ways that confidentiality may be broken and develop strategies to protect the client's privacy.
- *Testing staff prepared to provide a reactive result*: A reactive rapid test result is provided in a short time frame, which limits staff's ability to prepare for providing this difficult news. A reactive result also is not definitive, limiting the type of referrals the staff person can provide and leaving the client in a state of uncertainty. In outreach, these difficulties are compounded by the inability of

staff to access on-site agency resources and support that are usually available in the clinic setting.

For these reasons, staff providing rapid testing in an outreach setting must be adept at interpreting a reactive result, prepared to support a client through the confirmatory process, and ready to respond to a client in crisis. Staff must know what referrals can be immediately accessed for the client and be ready to link the client to these services. If outreach testing is being done late in the evening or on the weekend, staff must have a plan of how to emotionally support clients who receive a reactive result.

- *Linkage to referrals available*: Although a reactive result is not definitive, clients may need resources to help them understand and cope with the news of possibly being diagnosed with HIV. Staff must have their referral lists available, and immediately link clients to services if possible. If staff are offering rapid testing outside of business hours, they must have a plan of how to refer clients to needed services—including mental health or crisis intervention services—during those hours.
- A supportive setting for clients to respond to their test result: Certain settings may make it harder for a client to emotionally respond and accept their test results. Bars, street fairs, and public sex environments—where the setting is primarily social, alcohol or drug use is typical, and privacy is difficult to maintain—may be settings where rapid testing may be difficult to implement. Testing staff must review the above conditions as well as the social atmosphere to determine whether rapid testing is appropriate in such a venue.

Obtaining Devices and Controls

Agencies should contact the HIV CTR Coordinator through email to obtain more tests and external quality controls. Agencies should order needed tests and controls at least two weeks before current inventories run out. Agency staff should maintain sufficient inventory of both tests and controls so that rapid testing services are not interrupted.

If an agency cannot use all of their tests prior to the expiration date the lead staff person should contact the HIV CTR Coordinator to find out whether another site can use the tests prior to expiration so that these tests are not wasted. Shipments with the earliest expiration dates should be used first. Tests should be kept in a secure area, and inventory should be reviewed to assure that the number of tests that remain are consistent with the number of tests that have been used.

Abbott Determine HIV-1/2 Ag/Ab Combo Rapid Test

Introduction

The Abbott (formerly "Alere") Determine HIV-1/2 Ag/Ab Combo test involves collecting a small amount, 50mL, of finger-stick blood in a capillary pipette. The blood is then released onto a pad on a test strip. After one minute, a drop of a buffer solution is added to the test pad to promote the movement of the sample through the test device. The test result is read between 20 and 30 minutes after the drop of buffer was added.

Determine is FDA approved to identify both HIV-1 and HIV-2 antibodies and p24 antigen for HIV-1 infection. It is CLIA-waived for whole blood finger-stick specimens only. Determine is a CLIA-moderately complex test when used with venous whole blood, plasma, and serum specimens.

In clinical studies by the manufacturer, Determine had a sensitivity of 99.9% and a specificity of 99.8% with finger-stick whole blood samples. This means that the test correctly identified 99.9% of the people in the trial who had HIV, and 99.8% of those who did not have HIV-1. Determine is unique compared to other rapid tests because it is capable of identifying an acute HIV infection. When the p24 antigen test line is present in the absence of an HIV antibody test line, it suggests that the client has acute HIV.

Some individuals who do not have HIV will have reactive results with Determine. This is called a false positive. The number of false positives with Determine may be slightly higher than with other rapid antibody HIV tests. When staff encounters a false positive result, which is a reactive Determine result but a negative laboratory result, contact the HIV CTR Coordinator. Reactive results are not considered definitive until the results are confirmed by laboratory testing. A small number of people who are living with HIV and taking antiretroviral therapy (ART) will have negative test results on Determine. These results are false negatives.

Determine is FDA-approved for individuals 12 years of age and older. This test should **not** be used on individuals younger than 12 years of age.

Materials required for Testing

The following materials are provided to the site by the HIV Program:

- Aluminum zip lock package containing Abbott Determine HIV-1/2 Ag/Ab Combo test cards. Each card consists of 5 or 10 test strips, which can be separated from each other by tearing along the perforated lines. Each test strip has a cover that is to be removed for sample application and visualization of test results.
- Desiccant package in the aluminum zip lock package
- Chase Buffer: one in the 25 test box; two in the 100 test box
- Disposable capillary pipettes, one pipette for each test in a box
- Disposable workstations, one plastic workstation for each test in a box
- Quick reference card
- Package insert
- Subject information notices, one notice per each test in a box
- Customer letter

The HIV Program also provides Determine™ HIV–1/2 Ag/Ab Combo external controls. Each package contains:

- HIV-1 p24 reactive antigen control
- HIV-1 reactive antibody control
- HIV-2 reactive antibody control
- Nonreactive control
- 40 disposable pipettes—for use in testing the external controls only. The disposable pipettes are not to be used for testing patient samples.
- Package insert

The following materials are not provided to the site but are required:

- ☐ Blade finger-stick lancet (Suggested: BD blue microtainer or Surgilance blue)
- ☐ Two timers (one capable of timing up to 30 minutes)
- ☐ Disposable latex, vinyl, or nitrile gloves
- ☐ Sterile gauze
- ☐ Alcohol wipes
- ☐ Biohazardous waste container for controls and sharps container for used lancets
- ☐ Clean, disposable, absorbent workspace cover
- ☐ Trash bags
- ☐ Surface disinfectant to clean up accidental spills (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide)

- ☐ Alcohol-based waterless hand cleanser
- ☐ Laboratory grade thermometers to measure storage temperature of test devices and controls and temperature of testing location. Ideally, minimum/maximum thermometers should be used that record the high and low temperature since the last reading.
- ☐ Refrigerator dedicated to the storage of biohazardous materials

Also, a lamp may be helpful to illuminate the test device in case the result is difficult to read.

Conditions for Testing

The following conditions must be present to use Determine:

- Sufficient lighting to safely and accurately perform the test and read the result
- A level, clean surface where testing can be performed
- Storage temperature of the test kit between **36° and 86° Fahrenheit**
- The temperature during testing must be between **59° and 86° Fahrenheit.**
- Space that ensures confidentiality for both testing and counseling. Ideally the test is set up in an area apart from the client and where no other individuals can read the result.

Use of External Quality Controls

The Wisconsin HIV Program supplies each site with external quality controls that verify whether the tests are working properly or the staff person is properly performing the test. Staff should run tests on samples that are manufactured to create a specific result.

Each set of external controls consists of four vials that produce the following results:

- HIV-1 reactive p24 antigen (lavender cap control)
- HIV-1 reactive antibody (red cap control)
- HIV-2 reactive antibody (green cap control)
- Nonreactive (white cap control)

The external controls must be refrigerated at temperatures between 36° and 46°F (2° to 8°C). The controls must be warmed prior to use. Take the controls out of the refrigerator 15 minutes before you run the controls.

To run controls:

1. Remove a test card from the zip lock package. Tear four tests off of the right side of the card. Return the rest of the tests to the zip lock package and close.
2. Remove the protective foil cover from each test and place each test in a workstation.
3. Label each test with the control solution you will use with that test (for example: Ag +; HIV-1 Ab +; HIV-2 Ab+; or neg).
4. Open a control vial and draw up the solution to the marked line in the pipette provided with the controls.
5. Hold the pipette vertical above the sample pad, approximately one-half inch above the pad. Squeeze the control substance onto the pad. **Do not apply the buffer.**
6. Start timing the test.
7. Conduct the same procedure for the remaining controls. **Use a new pipette for each control.** Note the time when each test is started.
8. All tests must be read within 20-30 minutes of their starting time. Do not read any of the tests after 30 minutes.
9. Document the control results on the test log.
10. Discard the used pipettes, tests, and workstations in the trash.

If the test does not show the expected result of the control used, either the testing process was not performed correctly or the test is defective. Staff should thoroughly review all of their testing procedures prior to assuming that the device is defective, see page 57 for more information.

When to Run External Controls:

- When a staff person has been newly trained to use Determine, prior to testing clients.
- When opening a new lot of test kits.
- Whenever a new shipment of test kits is received by the agency
- If the temperature of the test storage area falls outside of 36° to 86°.
- If the temperature of the testing area falls outside of 59 ° to 86°F.

When controls are run, these tests should be documented on the Testing Log. External controls do not need to be run in different outreach locations provided the testing temperature conditions have been met.

- Controls have a designated expiration date.
    - Controls can be used repeatedly, but must be disposed of by the expiration date.
    - Controls must be disposed of in a biohazard waste container.
- If the results are not as expected, staff must assess all possible reasons for the failure of the controls, see page 57.
    - If you have not determined the reason for the failure, run the controls again using a new box of tests.
    - If the controls fail again, open a new set of controls and run them.
    - If the controls fail again, discontinue testing and contact the HIV CTR Coordinator for further guidance.

When controls fail, all results prior to the last control run are suspect.

Shelf-Life of Test and Control Kits

Sites will receive tests approximately one year prior to the expiration date. The expiration date on the outside of the testing box and the on the pouch holding the tests should be checked. Whichever expiration date is shortest is the one that should be referenced. Additionally, external quality controls have a designated expiration date on the outside of the box.

Ensuring Proper Temperatures for Tests and Controls

Tests must be stored between 36°and 86° Fahrenheit. If tests were stored in the refrigerator, they must be warmed to room temperature prior to use.

External controls must be stored in a refrigerator between 36°and 46° Fahrenheit, and also warmed to room temperature prior to use.

Staff should place a thermometer in the storage areas for the tests and controls to assure that the materials are kept at the proper temperature. Ideally the thermometer should identify the high and low temperatures from the last reading. Agency staff should document storage temperatures on a log each day that testing is performed. See the sample Temperature Log on page 77.

The location where tests are performed must be within the temperature range of 59°-86° Fahrenheit. Staff must use a thermometer to determine whether the

temperature is within the specified range, particularly in outreach venues. If the temperature is out of this range, staff should not conduct any tests.

Testing Steps for Conducting the Determine Rapid Test

Below is a summary of the required steps for conducting a Determine test with a finger-stick whole blood sample. The package insert provides detailed instructions. The *Abbott Determine HIV-1/2 Ag/Ab Combo Quick Reference Card*, included in the test box, also provides a convenient reference. Staff must read and understand both of these documents prior to testing clients.

Preparation

1. Cover the area with a workspace cover and set up the materials needed for blood collection.
2. When opening a new box, document the lot number written on the test box and revision date of the package insert (at the end of the package insert) on the Rapid Testing Log.
3. Check expiration date on the box and zip lock package. Whichever expiration date is shortest is the one that should be referenced. Do not use expired tests.
4. The test should be at room temperature between **59° - 86° Fahrenheit**.
5. Put on disposable gloves.
6. Remove a test card from the zip lock package. Tear the test off of the right side of the card. Return the rest of the tests to the zip lock package and close.

> **Store the unused test units only in the aluminum zip lock package containing the desiccant.** Carefully close the zip lock, so that the tests are not exposed to ambient humidity during store.

7. Remove the protective foil cover from the test. Lay the test flat in the workstation or directly on a flat surface. Use of the plastic workstation is optional.
8. Label the workstation or back of the test with the test ID sticker.
9. The test should be initiated within two hours after removing the protective foil cover.
10. Do NOT touch the sample pad with your fingers. Dispose of the test if the pad is touched.

Finger Stick Blood Collection:

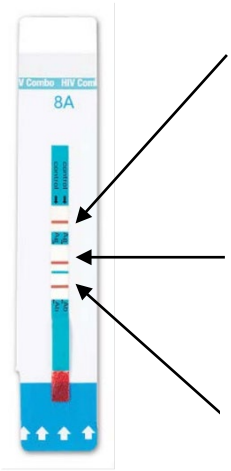
1. Use the disposable capillary pipettes included in the test box to collect the blood sample.
2. To increase blood flow, encourage the client to rub their hands together below their heart or hold their hand under warm water.
3. Clean the patient's finger with an alcohol wipe and allow it to dry thoroughly.
4. To collect an adequate sample, squeeze the client's finger closer to their palm or have the client squeeze their finger. Keep pressing the finger to encourage blood flow to the tip.
5. Using a blue blade lancet, puncture the skin just off the center of the finger pad.
6. Discard lancet in a sharps container.
7. Wipe away the first drop of blood with a sterile gauze pad. Continue to squeeze the finger. Allow a new drop of blood to form.
8. Collect the second drop of blood by holding the capillary pipette *horizontally*, and touch the tip of the pipette to the blood sample. Do not squeeze the bulb of the pipette.
9. The blood will draw into the pipette automatically. Continue to squeeze across the entire finger stopping before the fingertip until you obtain enough blood to fill the pipette to the black mark.

Testing

1. Touch the tip of the filled pipette to the sample pad. With the other hand, cover the small opening at the black line on the pipette with a gloved hand. Squeeze the bulb of the pipette to release the specimen directly onto the pad.
2. Do not lift the pipette until the entire specimen is released.
3. Set a timer for one minute. After one minute, release one drop of the buffer on the sample pad.
4. Set a second timer to read the result between 20 and 30 minutes. Do not read the result after 30 minutes.

Reading the Result

When the Determine test is properly performed, pink/red lines become visible in certain areas of the test strip. A faint pink background may also be visible.

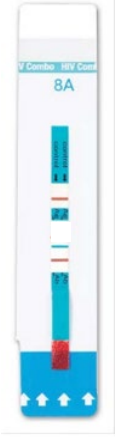


The ***control line*** appears in the section closest to the top of the test strip. This line indicates the test is running properly. The control line will become visible within 20 minutes after starting the test regardless of the result

The ***antigen test line*** appears in the middle section the test strip, below the control line section, and indicates the presence of p24 antigen.

The ***antibody test line*** appears in the lower section, closest to where the sample is applied, and indicates the presence of HIV antibody.

Results for Determine are interpreted based on the following descriptions:



Antibody Reactive (Two lines: control and antibody line)

A **pink/red** control line is present in the control section AND a **pink/red** antibody line is present in the lower test section of the test strip. The intensity of the antibody and control lines may vary. Any visible **pink/red** color in both the control and lower test areas, regardless of intensity, is considered reactive. A reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the sample.

The test result is interpreted as **preliminary positive for HIV-1 and/or HIV-2 antibodies.**

Antigen (HIV-1 p24) Reactive (Two lines - control and antigen line)

A **pink/red** control line is present in the control section AND a **pink/red** antigen line is present in the middle section of the test unit. The intensity of the antigen and control lines may vary. Any visible **pink/red** color in both the control and antigen sections of the test strip, regardless of intensity, is considered reactive. A reactive test result means that HIV-1 p24 antigen has been detected in the specimen.

The test result is interpreted as **preliminary positive for HIV-1 p24 antigen.**

*NOTE: A test result that is **preliminary positive for HIV-1 p24 antigen** in the absence of reactivity for HIV-1 or HIV-2 antibodies **may indicate that the client has acute HIV-1**. In this case the acute HIV-1 is distinguished from an established HIV-1 in which antibodies to HIV-1 are present. **Please contact the HIV CTR Coordinator to report an antigen only reactive result.***

Antibody Reactive and HIV-1 p24 Antigen Reactive (Three lines - control, antibody and antigen lines)

A **pink/red** control line is present in the control section AND a **pink/red** antibody line is present in the lower section AND a **pink/red** antigen line is present in the middle section of the test strip. The intensity of the antibody, antigen, and control lines may vary. Any visible **pink/red** color in the control section, middle, and lower sections of the test strip, regardless of intensity, is considered reactive. The test result is interpreted as **preliminary positive for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen.**

NOTE: A *test result that is preliminary positive for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen may indicate that the client is seroconverting, meaning they are in early infection.*

Nonreactive (One line – control line)

A **pink/red** control line appears in the control section of the test strip, and no **pink/red** antibody or antigen lines appears in the middle and lower sections of the test strip. A nonreactive test result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were not detected in the specimen.

Invalid (No control line)

If there is no **pink/red** control line in the control section of the test strip, even if a **pink/red** line appears in the middle or lower sections of test strip, the result is invalid, and the test should be repeated. If the problem persists, contact Abbott Technical Support at 1-877-866-9335.

White or clear lines may show up on the test strip. These lines should not be interpreted as a result. ONLY **pink/red** should be read as a result.

Typically, only one staff person should read the test result. However, in the event that one staff person identifies a reactive test and another staff person does not see a line in the test area and identifies the test as nonreactive—the test should be considered reactive and confirmatory testing should be done.

Assessing an Invalid Result:

An invalid test result cannot be interpreted. Invalid results are due to human error or a problem with the test device.

A test is invalid when:

- There is no **pink/red** line present in the control area after 20 minutes
- The test is read before 20 minutes or after 30 minutes.

To assess why a test may be invalid, staff should review their procedures to identify if the test was conducted properly, see page 56. After an invalid result, staff should conduct a second test. If this test is also invalid, external quality controls should be run. If the expected results are not obtained, staff should contact the HIV CTR Coordinator. If the invalid result is not due to human error, contact the manufacturer, Abbott, at 1-877-866-9335.

Clean up

1. Dispose of the lancet in a sharps container, and dispose of all other used test materials (test device, workstation, used gauze, gloves, etc.) in a trash bag.

2. Clean any spills with a surface disinfectant (EPA-registered, hospital grade, intermediate-activity disinfectant such as Dispatch, Virex TB, or Cavicide).
3. Remove gloves and wash hands after every test is performed. Use new gloves for each client.

Documentation of the Result:

1. Check the Test ID sticker on the test. Be certain that it matches with the person to whom you are about to give results.
2. Complete documentation on the Testing Log including read time and results.
3. Record the date of the test and the client name or anonymous code on the agency *Determine HIV Rapid Result* form, see sample on page 82, printed on the agency letterhead. This form should also be printed with the name of an agency staff person to contact in case the client has questions regarding their result after leaving the agency.
    a. Place a checkmark next to the appropriate paragraph indicating whether the result was nonreactive or reactive.
4. Provide the client with the written result.

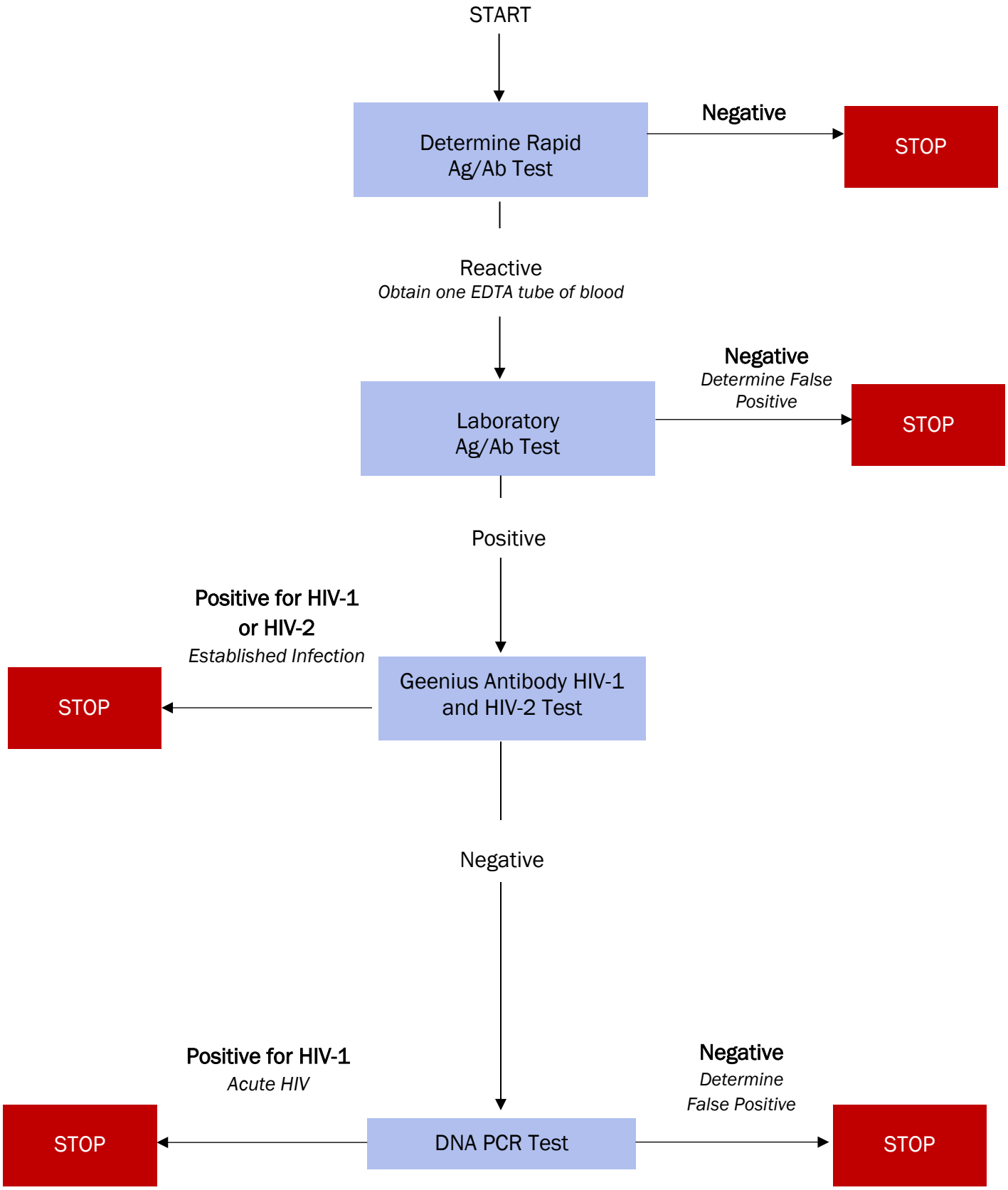
Confirmatory Testing

All clients who receive a reactive result should immediately have a blood specimen collected and sent to the laboratory to confirm their HIV status.

Agency staff should draw one EDTA tube (lavender top) of blood to send to the WSLH. The tube should be mixed by inverting 8—10 times and should not be centrifuged. See page 31 and Appendix F for more information.

The blood specimen will be confirmed with the standard laboratory algorithm, testing the specimen with the laboratory Ag/Ab test, and, if needed, the Geenius Antibody HIV-1 and HIV-2 Test and DNA PCR. Samples that have a positive final result on confirmatory testing indicate that the client has HIV and is either in acute or established infection depending on the results. Specimens that have a negative result indicate that the client **does not** have HIV, and instead had a false positive result on the Determine test.

Rapid HIV Testing Algorithm



Dual Rapid Testing

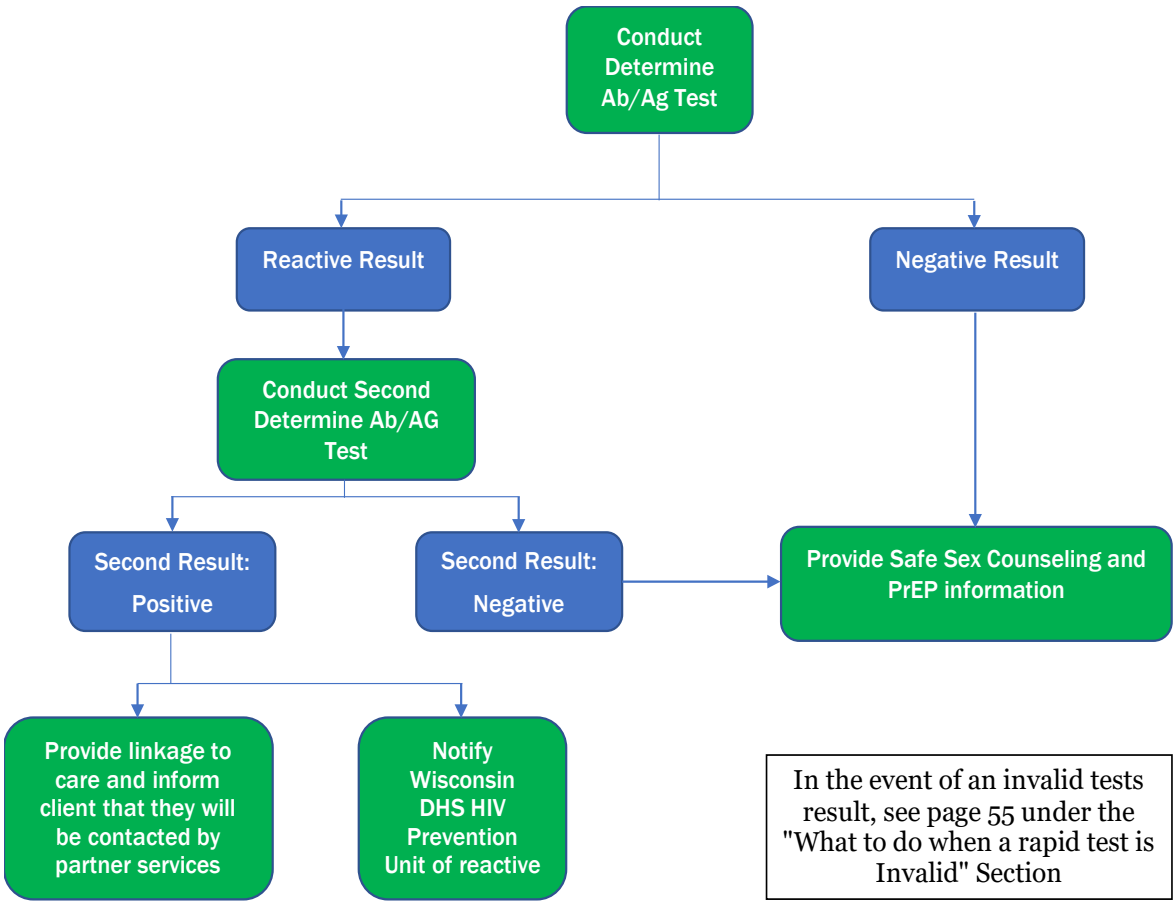
Dual Rapid testing serves as an option for same-day confirmation of a client's reactive HIV rapid test. Agency staff will utilize one Point of Care (POC) test to detect antibodies and a second comparable POC test, using the Determine Ab/Ag Rapid test, to confirm this detection at a 100% positive-predictive-value.

Positive Initial Test Result

- Agency staff will conduct rapid testing using Determine Ab/Ag rapid tests. In the event of a positive result, staff would perform a second POC test using the same manufacturer to gather a confirmed result.
- In the event of a second reactive test, staff will provide linkage to care and inform client that they will be contacted by partner services.
- Agency staff will notify Wisconsin DHS HIV Prevention Unit of reactive result.

The Dual Rapid test option allows clients to receive same-day confirmation of their positive HIV test result and further advances the engagement of populations infected with HIV while removing common barriers including the need for additional laboratory testing and losing clients to follow-up.

Dual Rapid HIV Testing Algorithm



Rapid Testing Program Requirement Checklists

Laboratory and Bloodborne Pathogen Requirements Checklist

- ☐ Valid CLIA certification for conducting waived tests (see more below)
- ☐ Refrigeration to store controls, and provision for monitoring refrigerator temperatures (Per bloodborne pathogen standards – the refrigerator must not store food or beverages)
- ☐ Compliance with bloodborne pathogen standard requirements listed below:
    - ☐ Exposure control plan including documentation of review and use by staff of safer devices
    - ☐ Exposure determination record
    - ☐ **Initial and annual staff training in bloodborne pathogen control standard precautions (c.)**
    - ☐ Availability of hepatitis B vaccine to all employees conducting testing, at no cost to the employee
    - ☐ Availability of post-exposure evaluation and follow-up, including prophylaxis, at no cost to the employee
    - ☐ Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up - to be kept for duration of employment plus three years (d.)
    - ☐ Training records to be kept for three years from the date of training (d.)
    - ☐ Sharps injury log
    - ☐ Warning labels affixed to all containers containing blood or other infectious materials, (including refrigerators) or red containers
    - ☐ Biohazardous waste containers, gloves, decontamination materials
    - ☐ Access to hand washing facilities or appropriate antiseptic hand cleanser as indicated
    - ☐ Arrangements for biohazardous waste disposal

Administrative Requirements Checklist

The following policies and procedures must be in place:

- ☐ Pre-test counseling information to be provided to clients during rapid testing.
- ☐ Use of gloves and other personal protective equipment.
- ☐ Safe disposal of biohazardous waste (e.g. used lancets, external controls).
- ☐ Maintaining sufficient inventory and checking new lots and shipments.
- ☐ Maintaining and documenting environmental temperature control.
- ☐ Describing in writing testing steps and activities for both in-house and outreach settings.
- ☐ Written procedure on how to collect a blood sample.
- ☐ Written test procedure and how to read the results.
- ☐ Written procedure explaining how to perform quality control testing and identify what to do when controls fail.
- ☐ Participate in external quality assessment (proficiency testing) as required.
- ☐ Written procedure on how to report test results as contracted to do so by the HIV Program.
- ☐ Specimen collection and submission for confirmatory testing.
- ☐ Document client and control test results.
- ☐ Post-test counseling and provide referrals.
- ☐ Record review, storage, and disposal.
- ☐ Troubleshooting activities—what to do when things go wrong.
- ☐ Staff training, competency assessment, and documentation of training.
- ☐ Supervisor or lead worker assuring that procedures are being followed to ensure high quality testing.
- ☐ Supervisor or lead worker assuring that bloodborne pathogen control standards are being implemented.
- ☐ Confirmatory testing (serum) is provided to confirm reactive rapid tests.
- ☐ Participation in the state's QA activities and compliance with its QA plan.
- ☐ Referral systems for reactive rapid results.

Staff Training and Quality Assurance Requirements Checklist

- ☐ Attend the Wisconsin HIV Program training courses, including the HIV Counseling, Testing and Referral New Provider Training (in-person) (b.)
- ☐ Participate in online HIV Basic Facts course (online) (b.)
- ☐ Demonstrate competence in conducting finger-stick blood draws.
- ☐ Establish knowledge of and adherence to package insert instructions for the rapid test (c.).
- ☐ Complete a competency assessment by testing samples and accurately reading the results prior to testing clients
- ☐ Demonstrate accurate test administration and interpretation of test results for both positive and negative controls prior to testing clients
- ☐ Participate in the state proficiency program to assure staff competency in testing at each agency.
- ☐ Assigning a lead staff person responsible for overseeing rapid testing and all QA activities on-site.
- ☐ Using external controls as required in the protocol.
- ☐ Documenting testing process and results.
- ☐ Recording the storage temperature of test devices and external controls.
- ☐ Communicating testing problems to the on-site lead staff person (#1 above), the WSLH, or the Wisconsin HIV Program, as appropriate and taking action to ensure that the test is providing valid and reliable results.

How Long to Keep Records:

3 Years

- Consent for HIV Testing (English, Spanish) (Appendix B)
- Authorization for Release of Confidential HIV Test Results (English, Spanish), if used (Appendix D)
- Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up to be **kept for duration of employment, plus three years.**
- Sharps injury log

18 months

- Wisconsin CTR Testing Questionnaire (English, Spanish) (Appendix C)

1 Year

For rapid testing only: Logs that include personally identifiable information should be shredded.

- Temperature logs
- Inventory logs
- Testing and controls logs

Training Checklist for the Determine Rapid Ag/Ab Test

Employee Name: _____

Instructions: Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable.) The trainee should initial when they feel the objective or procedure has been mastered and the trainer thinks the trainee has met the objective or performs the specific procedure competently.

Objective or Procedural Step	Date Observed by Trainee	Date Performed by Trainee	Trainee's initial and date	Trainer's initial and date
Read Determine package insert and CTR Protocol.	N/A			
Read Biohazard Exposure Control Plan.	N/A			
Identify if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space).				
Practice rapid test with external controls.				
Give person getting tested the "Subject Information" brochure.				
Label test device and appropriate paperwork				
Obtain finger-stick specimen and transfer specimen onto test strip. Time for one minute.				
Apply one drop of buffer on the test strip, time test, read result.				
Dispose of lancet and other biohazardous waste appropriately.				
Record results on Testing Questionnaire and Determine Testing Log.				
Record internal and external quality control (QC) results on Determine Testing Log.				
Explain what to do if result is invalid with no control line.				
Report test result to the person being tested (one negative and one preliminary positive).				
Collect specimen for confirmatory testing.				
Complete lab requisition form, send confirmatory test specimen to laboratory, and document submission.				
Receive laboratory results and record results on Testing Questionnaire and Determine Testing Log.				
Explain what to do if results of external controls show a problem.				

Rapid Testing Temperature Log

Thermometer location: _____
Acceptable temperature range*: _____
Month/Year: _____

Day	Initials	High Temp	Low Temp	Corrective action taken when temperature is out of range
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

*The acceptable range for **Determine test kit** storage is 2 to 30° C or 36 to 86° F and the acceptable range for control storage is 2 to 8°C or 36 to 46° F. The acceptable range for the **Rapid Syphilis Health Check Test** is 4 to 30 °C or 39 to 86 °F and the acceptable range for syphilis control storage is 2 to 8°C or 36 to 46° F.

Reviewed by: _____

Date reviewed: _____

Rapid Test and Controls Inventory Log

Log each box of tests or external controls received at your agency

Item Received (Tests or Controls)	**Date Received**	**Lot No #** (on box)	**Exp. Date**	**Date when item first used**

Rapid Testing Log

Agency: _____ **Location:** _____

Determine Tests and Controls	
Device Lot Number:	
Device Expiration Date:	
Package Insert Revision Date:	
Control Lot No.	
Control Exp. Date	

Other Test/Manufacturer:	
Device Lot Number:	
Device Expiration Date:	
Package Insert Revision Date:	
Control Lot No.	
Control Exp. Date	

Other Test/Manufacturer:	
Device Lot Number:	
Device Expiration Date:	
Package Insert Revision Date:	
Control Lot No.	
Control Exp. Date	

Date	Testing I.D. sticker or +/- Control	Staff Initials	Temperature	Start Time	Read Time	Internal control valid?	Result* Pos/Neg /Inv (If Pos: Ag+, Ab+, or Ag/Ab+)	Confirmatory Result** pos/neg	Comments -Indicate reason for running control -If test is invalid, indicate next steps -If rapid test is reactive, indicate whether client received confirmatory test results

***Indicate whether positive result is Ag+, Ab+, or Ag/Ab+ **Indicate whether confirmatory positive result is Acute/Early Infection or Established Infection**

Instructions for Rapid Testing Log

Agency	Fill in name of Agency.
Location	Fill in location of testing: e.g. Smith Clinic or outreach.
For each rapid test fill out…	
Other Test/Manufacturer	Fill in the type of test (RST or HCV) and the manufacturer of the test.
Device Lot # and Expiration Date	Fill in Lot Number (on outside of box for Determine) and Expiration Date of test devices. For Determine, the expiration date is determined by the shortest dated test kit component, on box or pouch.
Package Insert Revision Date	Fill in the revision date of the package insert for this box of tests. Revision date is **typically listed at the end of the package insert**.
Control Lot No. and Expiration Date:	Fill in Lot Number (on box for Determine) and Expiration Date of most recent control performed.
Date	Fill in date of rapid test.
Test ID Sticker or +/- Control	• If testing a Positive Control, fill in "+ Control". • If testing a Negative Control, fill in " – Control". • If testing a client sample, fill in Test ID number (or use sticker).
Staff Initials	Fill in the initials of staff conducting the rapid test.
Temperature	Fill in the current temperature of the testing site.
Start Time	Write the exact time that the buffer was added to the test strip for Determine or other rapid test was started.
Read Time	Write the exact time that the result was read.
Internal Control Valid	• If control line is present, write "Y" for yes. • If there is no control line, write "N" for no – the test is invalid. (Explain your next steps under the comment section).
Result	• For a nonreactive result – write "neg ". • For a reactive result—write "react". • For an Ag reactive Determine result – write "Ag+". • For an Ab reactive Determine result – write "Ab+". • For an Ag/Ab reactive Determine result – write "Ag/Ab+". • For an invalid– write "inv".
Confirmatory Sample sent?	• If yes – write "Y". • If no – write "N". • If not applicable (in the case of controls) – write "NA".
Confirmatory Result?	• For a positive final result - write "pos" and indicate whether the positive result is an early (Ag only) or established (Ab positive) infection. • For a negative final result – write "neg". • If not applicable (in the case of controls) – write NA.

Comments	• If conducting either a Positive or Negative Control, indicate reason. • If test is invalid, indicate next steps. • If rapid test is reactive, indicate whether client received confirmatory test results and/or next steps.

Smith HIV Testing Agency
111 Main Street
Hereandnow, WI 53704

HIV staff contact: Jane Smith, R.N.
608-555-4516

Determine HIV Test Result

Date of Determine test: _____

Client Name or Code: _____

_____ **Nonreactive/Negative**
You do not have HIV or you have been exposed too recently to find out if HIV is present in your body. If you have had risk exposure in the last month, you should have a repeat test one month after your last exposure to be sure that you do not have HIV.

_____ **Preliminary Positive for HIV-1 and/or HIV-2 antibodies and/or HIV-1 p24 antigen**
A confirmatory test is required to determine whether you have HIV. A blood sample from you will be submitted for confirmatory testing today and results of this test will be available within one week. While you are waiting for your confirmatory result, do not engage in unprotected sex or share needles with others in case you pass HIV.

If you have any questions regarding your test result, please contact the person at the phone number listed above.

Referrals

In this section:

- Summary
- Referral Requirements
- Stages of Referral Process
- Counseling Associated with Referrals
- Referral Lists
- Referral to HIV Care
- Referral to Case Management and Linkage to Care
- Referral to Partner Services
- Referral Follow Up
- Expectations of Referral Follow-Up

Summary

Linking clients to community services is a critical component of HIV CTR services. With advancement in treatment for HIV, this is particularly true for clients who are diagnosed with HIV. The sooner clients access HIV care services, the better it is for their long-term health. Clients who achieve and maintain an undetectable viral load cannot pass HIV to a partner sexually.

Referral Requirements

The Wisconsin HIV Program requires all CTR agencies to attempt to link HIV positive clients to medical care and other key services, such as linkage to care specialists, case management, and partner services. In addition, CTR staff must follow-up with these clients, as appropriate, to determine if services were accessed. Although the HIV Program does not require agencies to follow up and document referrals for HIV-negative clients, agencies are encouraged to do so for the purpose of internally evaluating their programs.

Stages of the Referral Process

After assessing a client's needs, making a referral is a three-step process:

1. Linking the client to the referral source
2. Conducting referral follow-up

The CDC requires that HIV testing agencies conduct *follow-up* and document outcomes on all referrals for **positive clients**. The goal of referral *follow-up* is to determine if the client accessed the referral source.

Agency staff should offer to assist clients who test positive for HIV with scheduling a medical appoint, linkage to care services and/or case management, partner services, or other appropriate appointments. Agency staff also should encourage the client to return for another appointment for additional counseling, referral follow-up, and assessment of any barriers to accessing HIV care services. The HIV Prevention Evaluation Coordinator will document the outcomes of referrals to HIV care and partner services.

Counseling Associated with Referrals

Agency staff should assess the client's readiness to accept a referral, and identify their strengths and needs to link them to an appropriate agency or resource. Some clients will prefer to access referrals on their own. Other clients will want to be directly linked to the referral agency.

When discussing referral possibilities, counselors should:

- Clearly describe the extent of agency services.
- Cite realistic benefits to the referral, being realistic about what the agency can provide.
- Discuss advantages and disadvantages of accessing the referral
- Provide choices.
- Discuss and problem-solve possible barriers to accessing the referral source (e.g., transportation, child care, agency hours).
- Discuss referral follow-up and develop plan to determine outcomes—including client satisfaction.

Referral Lists

Agencies must develop and maintain referral lists—complete with telephone numbers and the names of contact persons—for persons with positive results, including: PS; medical evaluation and care; linkage to care services, where available; case management; risk reduction planning; and other HIV specialty services. Agencies must also develop and maintain referral lists for consumers of unknown status and consumers testing negative. The following summarizes expectations for referral lists:

Referrals for persons testing positive for HIV should include:

- Medical care and treatment (for insured and under- or uninsured)
- Linkage to Care and/or case management services
- Partner Services (PS)
- Prevention and/or risk reduction planning
- Reproductive health
- Legal (often overlooked—disclosure, employment, housing issues)
- Support groups and services
- Information phone lines
- Information internet sites

Referrals for persons with unknown status and persons testing negative should include:

- Hepatitis A & B vaccination
- Hepatitis c testing
- STD testing
- Syringe exchange
- Substance use disorder treatment and support
- Mental health services
- Information lines and information websites
- Crisis intervention
- Housing, food, domestic violence
- Other social service and daily living needs

Referral lists should contain the following:

- Name of provider or agency
- Range of services provided
- Contact name(s)
- Phone number(s)
- Hours of operation
- Location
- Cultural competency information (e.g. do they have bilingual staff)
- Costs and acceptable payments
- Eligibility
- Directions, transportation information

Referral lists should be provided to each staff conducting CTR and updated annually or as needed. The most effective referrals are those made to agencies that the testing staff are familiar with. Efforts should be made to establish connections with agencies before including them on any referral lists.

The CDC also recommends that linkages should be in place to refer:

- Sexually active persons with MSM risk to hepatitis A and B vaccination
- Persons with injection drug risk to hepatitis C testing and hepatitis A and B vaccination
- Sexually active females up to 25 years of age for chlamydia screening regardless of symptoms

Referral to HIV Care

Advances in medical treatment have significantly changed health outcomes for people living with HIV, impacted public health and transmission rates, and enhanced the role and responsibilities of public HIV testing sites.

All agencies must develop and maintain practices to link clients who test positive for HIV to a medical provider or infectious disease specialist. Linkages to HIV medical care should be maintained for consumers who are insured and those who may be under- or

uninsured and include sufficient options to ensure client choice. When linking clients to HIV care, agency staff should:

- Identify and discuss the benefits of accessing HIV care
- Inform clients testing anonymously that any link to HIV care will require their name and, therefore, initiate a case report
- Provide information on what happens at an initial medical visit
- Assist the client in determining what questions they may have for the medical provider

HIV linkage to care specialists and case managers can serve as a gateway to HIV medical care and other services. They often have relationships and systems in place to quickly facilitate linkage to services. Whenever possible, the counselor should consider using these options to link clients to medical services. If the client chooses to access medical care through a link to care specialist or case manager, the agency staff member should follow-up with the client or linkage to care specialist or case manager to identify whether the client went to their medical appointment.

Some clients will prefer to access medical care without going through a linkage to care specialist or case manager. Therefore, all agencies are required to maintain referral lists and referral processes that maintain this option.

Referral to Case Management and Linkage to Care Services

Linkage to care specialists and case managers assist clients in accessing HIV medical care and other services.

- Case managers are available throughout Wisconsin to assist clients with a wide range of challenges that may be negatively impacting their lives.
- Linkage to care specialists are available only in Milwaukee and Madison, and provide highly focused, time-limited, intensive support to clients to help minimize barriers to linkage and retention in HIV medical care. These clients may be transferred to a case manager for other supportive services after engagement in care is firmly established. Clients who test positive at CTR sites in Milwaukee or Madison should be referred to a linkage to care specialist first and will be transitioned to case management as appropriate.

Whenever possible—and with the client's consent—a linkage to care specialist or case manager should be contacted to meet with a client newly diagnosed with HIV at the agency after their result has been given. If the case manager or linkage to care specialist

cannot be available at the post-test visit, the agency staff member should attempt to assist the client in scheduling an appointment with the linkage to care specialist or case manager and with a medical provider, as appropriate.

Referral to Partner Services

Partner Services (PS) is provided by local health departments to offer options to clients living with HIV to inform their sex and needle-sharing partners of their possible exposure to HIV. A PS provider meets with the client living with HIV to identify partners who may have been exposed to HIV. The PS staff person discusses ways that the client can tell their partners or offers to notify the partners without revealing the client's identity. When the staff person does locate and notify the client's partners, the partners are also offered HIV testing and risk reduction counseling. For this reason, PS is a critical public health intervention that can both reduce further transmission and increase the number of individuals who know their HIV status.

PS also assists clients living with HIV in accessing resources for their own well-being and, therefore, plays an important back-up role to HIV CTR—especially if the person testing positive is not ready for referrals or is lost to follow-up at the time of receiving their test result.

PS is a voluntary and confidential service. It is offered routinely to everyone who tests confidentially and is reported to DPH. For clients who test anonymously, proof of HIV status (i.e. a copy of the anonymous test result) is required before PS staff will notify partners. For CTR agencies that also offer PS onsite, PS should be routinely offered and initiated when positive test results are given. If on-site PS is not available at the agency, sites should arrange for a PS staff person to meet with a positive client—with their consent—at the CTR agency following provision of the result.

Referral Follow-up

"Referral follow-up" refers to how agency staff plan to determine if the client accessed the referral provided. Follow-up should be discussed with the client as part of the referral process. In most cases, this involves explaining to the client that you would like to follow-up on the referral to ensure they accessed services. Agency staff will develop an individualized plan with the client regarding options for referral follow-up.

Conducting referral follow-up provides the agency staff an opportunity to assess and address barriers that may have prevented the client from keeping a referral appointment, assess their level of satisfaction with referral services, and assess additional referral needs. For example, a client testing positive may request a referral for

medical care but be hesitant or require time to think about accepting a referral to case management. During referral follow-up, the client may accept a referral to case management.

There are four options for referral follow-up, including:

1. Active referral
3. Agency referral
4. Client verification
5. None

The options are defined as follows:

- Active Referral: This option refers to when the agency staff has directly linked the client to the referral source (service provider or agency). An example of directly linking a client to a referral source would be arranging for a linkage to care specialist, HIV case manager, or PS staff person to meet with a client living with HIV at your site.
- Agency Referral: This option refers to when the agency staff contacts the referral agency to determine if the client accessed services. In this instance, the client agrees to the counselor following up with the referral source. For this to happen, the client must sign an Authorization for Release of Confidential HIV Test Results form or similar disclosure form. Aside from an active referral this is probably the most reliable method to follow-up on a referral.
  With client authorization, an agency staff member can contact the client's case manager or linkage to care specialist to find out if and when the client accessed medical care and other services. Otherwise, the agency staff member must contact the medical clinic and other referral agencies to find out when or if the client accessed these services.
- Client Verification: This option refers to when an agency staff member follows-up directly with the client. In most cases, this is accomplished by scheduling a subsequent meeting with the client. Client verified referral follow-up can also take place over the phone. However, this method is less personal and less conducive to assessing additional referral needs. In addition, arranging for the client to contact the agency staff member is the least reliable method of follow-up. Agency staff can phone clients for follow-up but would need to ensure that it is done in a manner that does not breach client privacy or confidentiality. This may involve finding out from the client a preferred time to call, how to ensure the agency staff member is talking with the client rather than a third party, how to identify oneself if someone other than the client answers the phone, whether it is appropriate to leave a message, and whether to call from a phone that blocks caller ID. If leaving a voicemail, be very careful on what you leave as a message. Never provide any information about services.

- None: This option refers to client refusal for follow-up. It is the expectation of the Wisconsin HIV CTR Program that agency staff will attempt to follow-up whether a client has accessed a referral. However, this should not be done if the follow-up jeopardizes the linkage to the referral. For example, it is more important to link a client testing positive to medical care (either directly or through HIV case management services) than it is to insist a client allow an agency staff member to conduct referral follow-up if the client is hesitant to do so.

Expectations of Referral Follow-up

HIV CTR agency staff are expected to develop follow-up plans with clients regarding referrals made on their behalf. Even the best developed plans, however, do not always work as anticipated. As previously mentioned, using a client verification method to conduct referral follow-up can pose unique challenges. If clients are lost to initial follow-up, agencies and their staff are expected to make a "good faith" effort to continue follow-up efforts within time and situational constraints for up to 60 days after the initial date of referral. It may be of particular value to make one last attempt to follow-up on clients lost to follow-up shortly before the 60 days is up.

An exception to this expectation is if the client is actively referred to a linkage to care specialist. For example, if the linkage to care specialist is there to meet the client and provide support when the client returns for their confirmatory testing results and the client accepts the assistance of a linkage to care specialist. The referral follow up then becomes the responsibility of the linkage to care specialist instead of the testing staff.

Data Collection and Reports

In this section:

- Summary
- Accessing the EvaluationWeb Website
- Accessing HIV Testing Data Collection Form
- EvaluationWeb Requirements

Summary

To evaluate the Wisconsin HIV Counseling, Testing, and Referral (CTR) Program's utilization and effectiveness, data on clients' individual testing events is entered into a Center for Disease Control (CDC), web-based data system called EvaluationWeb. It is used for collecting and evaluating HIV prevention services data in compliance with the reporting requirements of CDC.

EvaluationWeb was developed and is implemented by Luther Consulting LLC, a vendor contracted by CDC. The Wisconsin HIV Program and partner agencies can use the data system to directly enter data and easily access the CTR data for evaluation, including creating agency-specific reports.

Accessing the EvaluationWeb Website

All HIV CTR sites are registered in the EvaluationWeb System by Luther Consulting LLC and the Wisconsin HIV Program. The website address is: http://www.evaluationweb.com. Select "Wisconsin" from the drop-down menu of choices under "Please select your jurisdiction to be taken to the correct login page" heading. It will be directed to the Wisconsin EvaluationWeb login page.

Accessing HIV Testing Data Collection Form

The EvaluationWeb data collection forms were updated in January 2019. The client friendly versions of the forms include the Test Questionnaire (English) and Testing Questionnaire (Spanish).

For PrEP navigators who have been contracted to enter data about PrEP sessions into EvaluationWeb, the client-friendly form for PrEP only sessions include PrEP Questionnaire (English) and PrEP Questionnaire (Spanish).

Please refer to Appendix G for the instructions to access EvaluationWeb for entering the testing data after data collection.

EvaluationWeb Requirements

E-Authentication

To gain user access to EvaluationWeb for data entry, new users (i.e. agency testing, data entry and supervisory staff) are required to go through CDC's user identity proofing process, which is called e-authentication. Please refer to Appendix G for the e-authentication guide to complete the process.

User Names and User Passwords

The newly e-authenticated users are provided user names and create their own passwords, which can be used to access the EvaluationWeb website to enter data and view or produce reports. If you forget your password, click on the 'Forgot your password" link on the Wisconsin EvaluationWeb login page to reset the password or contact the HIV Prevention Evaluation Coordinator. Program directors or supervisors should maintain a list of user names of their current staff.

User Account Updating Agency Staff

All HIV CTR agencies should update the HIV Program regarding staff changes in a timely manner. When new staff are hired and trained in CTR, contact the HIV prevention evaluation coordinator with their contact information to initiate the e-authentication process. When staff leave the agency, notify the HIV Prevention Evaluation Coordinator to disable their EvaluationWeb user account. **Under no circumstances should new**

and current staff be allowed to use someone else's user account to access EvaluationWeb,

Test ID Stickers

EvaluationWeb data collection forms require the use of a Test ID sticker that consists of 1 alpha character, followed by 9 numeric characters. Test ID stickers are distributed by the HIV CTR Coordinator in packets with 9 stickers for each 10-digit Test ID Number. The stickers should be used in the following manner.

Place one Test ID Numbered Sticker on each of the following forms:

- Client-friendly Testing Questionnaire form
- WSLH Laboratory Requisition
- Client HIV Consent form, Appendix B
- Authorization for Release of Confidential HIV Test Results, Appendix D
- HIV test blood samples sent to the WSLH, and/or the rapid test device
- Client file folder. A Test ID sticker should be placed on the client file folder even if agencies file confidential (name-associated) tests by client name.

To order Test ID stickers please email or call the HIV Prevention Supervisor.

Data Entry Requirements

The following summarizes EvaluationWeb data entry requirements for agencies providing CTR services.

Fee-for-service (FFS) testing sites and all grantee agencies are required to enter data directly into the EvaluationWeb website.

For the grantee agencies, negative tests should be entered into EvaluationWeb as soon as possible after completing a CTR session with a client—no later than a weekly basis. As for the FFS testing sites, please follow the data entry timeline for negative tests approved in your contract with the state. But for all agencies providing CTR services, positive HIV tests are required to be entered within 72 hours after informing the client of their final test result. In addition, testing staff are required to report an HIV case to the state, within 72 hours of identification through confirmatory laboratory-based results. For case reporting, call the HIV Program surveillance team at 608-266-8658 or 608-267-6727. Please refer to Appendix G for more detailed information on data entry and reporting requirements.

The preferred method for data entry is for each individual counselor at an agency to enter data on tests and follow-up activities they conduct. This option is particularly appropriate for agencies with a relatively limited number of testing staff as it limits the number of people who handle data collection forms and client files. Agencies may choose to establish a system that allows a designated staff person to enter data on behalf of HIV test counselors. This option may work particularly well for agencies that regularly conduct a large volume of tests and have a large number of testing staff or volunteer testing staff. This type of data entry system may make program monitoring easier as a limited number of persons are responsible for entering data on a timely basis.

Regardless of how data is entered, a quality assurance system should be put in place to assure that data is being entered into the system in the required timeframes. The HIV prevention epidemiologist can provide technical assistance regarding methods for monitoring data entry and maintaining data quality.

Agencies should contact the HIV prevention epidemiologist or the HIV Prevention Program if they are unable to meet the data entry deadline due to unexpected circumstances beyond their control. The state program staff may be able to work with the agencies to arrange an alternative deadline accordingly for data entry.

Under no circumstances should data be entered directly into the EvaluationWeb website during a counseling session or in front of a client. Completing data forms or data entry in the presence of the client contradicts CDC guidelines for HIV testing sites.

See Appendix G for additional information about data entry.

Data Entry and Confidentiality

Ensuring confidentiality and security of client records is imperative for the integrity of HIV testing programs. Therefore, data should be entered at a secure and confidential location (i.e. designated staff office space at the agency). It is not permissible for testing staff to enter data from a home computer or from an agency laptop in their home.

Reporting Requirements for Publicly Funded HIV CTR Sites

Agencies receiving public grant funds to provide HIV CTR services are required to submit quarterly narrative reports pertaining to their approved intervention plan by Wisconsin HIV Prevention Program staff. Quarterly reports should be submitted via email to the HIV prevention coordinator.

The narrative report should briefly address the following points:

- Answer all questions posed in the quarterly template
- Any changes or requested changes to the approved intervention plan, including changes to service delivery, testing venues, and needs assessment or program development activities, staff changes; receipt of additional private or public funds to support testing activities
- Program successes and achievements
- Barriers and challenges to reaching target audience and/or anticipate outcomes
- Technical assistance needs.
- Other agency-specific reportable items approved in the Intervention Plan.

Narrative reports should be submitted within 30 days of the end of each quarter. Due dates are as follows:

Quarter	Parameter	Report Due
Q1	Jan. 1–Mar. 31	April 30
Q2	April 1–June 30	July 31
Q3	July 1–Sept.30	Oct. 31
Q4	Oct. 1–Dec. 31	Jan. 31

Custom Data Reports

EvaluationWeb provides agencies the opportunities to query testing data entered into the system through the Reflexx report writing function. Any combination of the variables from the testing forms can be queried to produce custom reports. For example, you can create reports to monitor and evaluate services by zip code, site location, or risk group. Reports you create can either be one-time queries or saved as permanent reports you can view at any time to monitor and evaluate services. For technical assistance on developing custom reports in Reflexx or requesting data from EvaluationWeb, please contact the HIV prevention epidemiologist.

Appendix

Appendix A: Wisconsin HIV Program Policy for Agency Internal Training
Appendix B: Consent for HIV Testing
Appendix C: Testing Questionnaire
Appendix D: Authorization for Release of Confidential Test Results
Appendix E: HIV Program Policy: Revised Materials Review Panel Guidelines
Appendix F: Blood Sample Guidelines for HIV, Hepatitis C, and Syphilis Tests
Appendix G: EvaluationWeb Access

Links to Download CTR Forms

- Consent for HIV Testing (English) (Spanish)
- CTR Client-Friendly Testing Questionnaire (English) (Spanish)
- Authorization for Release of Confidential Test Results (English) (Spanish)

A: Wisconsin HIV Program Policy for Agency Internal Training

Agencies funded by the Wisconsin HIV Program to conduct HIV CTR services may train new staff in-house to provide HIV testing if the following circumstances are met:

- The agency receives prior approval to train staff internally from the HIV CTR Coordinator.
- The agency is able to demonstrate that access to testing services would be compromised if internal staff training did not occur.
- The agency must develop a training that, at minimum, addresses the following components:
  - ☐ Basic HIV information
    - Completing the Wisconsin HIV Program HIV Basic Facts Online Training meets this requirement.
  - ☐ Wisconsin statutes (§ 252) regarding HIV testing and disclosure
    - Confidentiality of test results
    - Disclosure of HIV test results
    - Civil and criminal penalties for intentional and unintentional violation of confidentiality and disclosure statues
    - Lawful access to test results
    - Informed consent
    - Testing of adolescents
  - ☐ Testing options; including benefits and limitations of each available type of test.
  - ☐ Testing algorithms, including:
    - Ag/Ab, Geenius HIV-1/2 Antibody Test, and DNA PCR testing:
      - Acute HIV algorithm
    - Rapid testing
    - Interpretation of test results and situations where additional testing may be recommended
  - ☐ Elements of pre-test counseling, including:
    - Prevention counseling
    - Test decision counseling
    - Obtaining informed consent
  - ☐ Confidential vs. anonymous testing, including
    - Benefits and limitations of both methods
    - Mandatory reporting if name-associated
    - Voluntary PS as part of mandatory reporting and as an option for people testing anonymously

- ☐ Resources and referrals
    - Prevention risk assessment and risk reduction planning
    - Local resources for all people accessing testing; i.e. substance use disorder services,
    - Mental health services, emergency shelters, domestic violence
    - Local resources for people who test positive, including:
        - HIV medical care
        - PrEP
        - PEP
        - HIV case management
        - Linkage to Care (if applicable)
        - Legal services
        - Reproductive health
        - Other supportive services
        - Resource helplines
- ☐ Forms and Data Collection
    - Consent for Anonymous or Confidential HIV Testing
    - Authorization for Release of Confidential HIV Test Results
    - Testing Questionnaire
    - WSLH Laboratory Requisition
    - Agency policy for data entry
- ☐ Observe a CTR staff member with at least two years' experience conduct pre-test counseling a minimum of three times.
- ☐ Be observed by a CTR staff member with at least two years' experience conducting pre-test counseling sessions a minimum of three times. After observation, the observer should provide the new staff member with feedback, allow the new employee to ask questions, and identify additional training needs.

- The agency must have a signed copy of a confidentiality agreement on file for the new employee.
- The agency must supply the new employee a copy of this CTR Protocol and the new employee must review it completely prior to testing.
- The employee must attend the following courses offered by the HIV Program within six months of employment:
    - ☐ HIV Basic Facts (online)
    - ☐ HIV Counseling, Testing, Referral Services Program New Provider Training (in person)

Required Agency Internal Training Checklist

Agencies are required by the Wisconsin HIV Program to complete this Internal Training Checklist with new employees, if the new employee is going to begin providing CTR services prior to completing the Wisconsin HIV Program required trainings.

Employee Name: _____

Objective	Date Provided	Trainee's Initial & Date	Trainer's Initial & Date	Comments
1. Identify basic HIV information (can be met by completing the HIV basic facts online training.)				
2. Review and supply a copy of WI statutes related to HIV testing and disclosure, including: • Confidentiality of test results • Disclosure of results or status • Civil and criminal penalties • Lawful access to test results • Informed consent • Testing adolescents				
3. Identify testing options and benefits and limitations of each.				
4. Identify testing algorithms, including possible test results and procedures in the event of an indeterminate test result.				
5. Elements of pre-test counseling, including: • Prevention counseling • Test-decision counseling • Obtaining informed consent				
6. Identify aspects of different testing methods—anonymous vs. confidential: • Benefits and limitations of each method • Mandatory reporting for confidential testing • Voluntary Partner Services support as mandatory reporting and as an option for persons testing anonymously				
7. Identify referrals and resources: • For all people accessing testing • For people who test positive for HIV				

8. Forms and data collection: • Client Testing Questionnaire • Consent Form • Lab slip • Test Results Form for the client • Release of Information • Agency policy for data entry				
9. Signed employee confidentiality agreement on file				
10. Received and reviewed copy of this CTR Protocol				
11. Observation of experienced testing staff member				
12. Observation of experienced testing staff member				
13. Observation of experienced testing staff member				
14. Observation by experienced testing staff member				Record any corrective reminders
15. Observation by experienced testing staff member				Record any corrective reminders
16. Observation by experienced testing staff member				Record any corrective reminders
17. Training and observation checklist added to personnel file				
18. Attended HIV Basic Facts online training				
19. Attended HIV Counseling, Testing, And Referral New Provider Training				

Please retain a copy of this training checklist in the employee's personal file for one year after date of employment.

DEPARTMENT OF HEALTH SERVICES
Division of Public Health
F-43018 (Rev. 01/2019)

STATE OF WISCONSIN
Wis. Statutes 252.15(2m)(a)(2) and 252.15(3m)

B: Consent for HIV Testing

I want to be tested for HIV (human immunodeficiency virus).

I understand:

- The benefit and possible risk of testing, including the benefits of confidential (name-associated) testing.
- My HIV test results will be kept confidential. Wisconsin statutes allow my test results to be released to specific persons under limited circumstances, and allow for reporting positive test results to the State for the purposes of disease monitoring and intervention. A listing of the circumstances under which my HIV test result can be disclosed is available for review, if I request it.
- The option of an anonymous test is available for persons with concerns about having their name associated with a test.
- Additional counseling and assistance with health care and other services are available if I need them.

In addition, I understand that if I choose a rapid HIV test:

- If the test result is nonreactive, the result is interpreted as negative and is available today.
- **If the test result is reactive, I am agreeing to a second (confirmatory) test that will be performed to determine whether I have HIV. This second test requires that a blood sample be collected today and be sent to an off-site laboratory. Results will be available 3-7 days after the confirmatory test.**
- Only a positive result from the confirmatory test would indicate that I have HIV.

I have read the above information. It has been explained to me. My questions have been answered. I agree to be tested for HIV. I have indicated below the type of test to which I am agreeing.

☐ **I want my test to be confidential (with my name listed on the test result).**

Name _____ Telephone Number _____

Address _____ Date of Birth _____

City _____ State _____ Zip _____

_____ _____
SIGNATURE – Person Receiving Test Date Signed

_____ _____
SIGNATURE –Person Legally Authorized to Consent on Behalf of Person Receiving Test Date Signed

_____ _____
Telephone Number of Signee Relationship to Person Receiving Test

☐ **I want my test to be anonymous (without my name being listed on the test result).**

_____ _____
CODE – Person Receiving Test Date Signed

HIV Testing: What You Need to Know

What is HIV?

HIV is the human immunodeficiency virus that can sometimes lead to AIDS.

How is HIV passed from person to person?

A person living with HIV can pass the virus to others if they are not receiving the right treatment. HIV is most commonly passed through:

- Sex
- Sharing needles for injection drug use

People who are pregnant or breastfeeding should know:

- HIV treatment can prevent a person giving birth and living with HIV from passing HIV on to their baby before or during birth.
- HIV can also be passed from a person breastfeeding to child through breast milk.

Why is HIV testing important?

About one out of five persons living with HIV do not know they have HIV. This means they are missing out on drug treatment that could help them live a long, healthy life. The right treatment plan can also mean never passing HIV on to a partner.

An HIV test is the only way to know whether you have HIV. It's important to get tested regularly if you are at risk for HIV.

How can I prevent HIV?

Today, there are more ways to prevent HIV than ever before. If someone living with HIV is on the right treatment plan, it can mean never passing HIV on to partners sexually. Here are a few other ways to prevent HIV:

- Wear condoms
- Use PrEP (one pill, once a day that prevents HIV)
- Avoid sharing needles when injecting drugs

Do I have a choice?

Yes, it's your choice -- you can decide if you want an HIV test. Other health care services and treatment cannot be denied if you decide not to be tested.

Who will be told if I have HIV?

State law permits only a very limited number of people to know if someone is living with HIV. Positive HIV test results are reported to public health officials. Strict state laws safeguard confidential information on HIV.

Who can assist people if they test positive?

There are many medical and social services available for people living with HIV at no or low cost to the person. Your health care provider is one person who can help connect you to these services, or you can get assistance from the local health department.

There are community-based organizations that can help people living with HIV find services that include:

- Specialized HIV medical care
- Drug payment assistance for HIV medication
- HIV case management
- Mental health services
- Housing assistance
- Food pantry
- Legal assistance

For more information on resources in Wisconsin, visit the Wisconsin HIV Program website at www.dhs.wisconsin.gov/aids-hiv.

There are three possible HIV test results:

- A **negative screening test result** means that a person probably doesn't have HIV. However, if a person has been recently exposed to HIV, it may be too soon to find out if the person has HIV. Re-testing may be necessary.
- A **positive screening test result** means that the test detected HIV in a person's blood. If this is the first time someone tested positive for HIV, it is highly recommended that another test be done to confirm the result.
- An **invalid screening test result** is neither negative nor positive. The person should be tested again as soon as possible.

No test is 100% accurate. Additional testing may be needed or recommended.

C: Test Questionnaire

Test ID A# Sticker Here

Today's Date: / /

Date of Birth: / /	**State Where You Live**	**County Where You Live**	**Your Zip Code**

Ethnicity

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Don't know
- ☐ Decline to answer

Race (Check all that apply)

- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Not specified
- ☐ Decline to answer
- ☐ Don't know

Sex at Birth

- ☐ Male
- ☐ Female
- ☐ Decline to answer

Current Gender Identity

- ☐ Male
- ☐ Female
- ☐ Transgender Male to Female (MTF)
- ☐ Transgender Female to Male (FTM)
- ☐ Transgender - Unspecified
- ☐ Another Gender
- ☐ Decline to answer

Have you ever been tested for HIV previously?

☐ Yes ☐ No ☐ Don't know

If you have been tested for HIV before, what was the result?

☐ Negative ☐ Positive ☐ Don't know

To the best of your knowledge, in the past 5 years have you:

(Check the box for yes)

- ☐ **Had vaginal or anal sex with a male?**
- ☐ Had vaginal or anal sex with a male **without using a condom**?
- ☐ Had vaginal or anal sex with a male **who injects drugs**?
- ☐ Had vaginal or anal sex with a male **who is HIV+?**
- ☐ **Had vaginal or anal sex with a female?**
- ☐ Had vaginal or anal sex with a female **without using a condom**?
- ☐ Had vaginal or anal sex with a female **who injects drugs**?
- ☐ Had vaginal or anal sex with a female **who is HIV+?**
- ☐ **Had vaginal or anal sex with a transgender person?**
- ☐ Had vaginal or anal sex with a transgender person **without using a condom**?
- ☐ Had vaginal or anal sex with a transgender person **who injects drugs**?
- ☐ Had vaginal or anal sex with a transgender person **who is HIV+?**

To the best of your knowledge, in the past 5 years have you:

(Check the box for yes)

☐ Injected drugs? ☐ Shared injection drug use equipment?

For syphilis testing only

☐ In the past 12 months, have you given or received oral sex?

For women only

☐ In the past 5 years, have you had sex with a man who has sex with men?

Check the box for yes: (Check all that apply)

☐ Have you ever heard of PrEP (Pre-Exposure Prophylaxis)?

☐ Are you currently taking daily PrEP medication?

For Testing Staff Only

HIV Test Election
☐ Anonymous ☐ Confidential ☐ Test Not Done

Worker Name (Enter in Local Use Field 1): _____

Test Type:

(When entering into Evaluation Web select only the **final** test type. If an HIV lab-based test was performed, select lab-based test. If **only** a rapid test was performed, select rapid test in EvaluationWeb.)

☐ CLIA-waived Rapid Test(s)
↓ Sample Date: _____

- ☐ Preliminary Positive
- ☐ Negative
- ☐ Invalid

☐ Laboratory-based Test
↓ Sample Date: _____

- ☐ HIV-1 Positive
- ☐ HIV-1 Positive, possible acute
- ☐ HIV-2 Positive
- ☐ HIV Negative
- ☐ Inconclusive, further testing needed

Result provided to the client?
☐ No ☐ Yes ☐ Yes, client obtained the result from another agency

For HIV Negative Results Only:

Is the client at risk for HIV infection?

☒ Risk Not Assessed

Was the client screened for PrEP eligibility?
☐ No ☐ Yes

Is the client eligible for PrEP referral?
☐ No ☐ Yes, by CDC criteria

Was the client given a referral to a PrEP provider?
☐ No ☐ Yes

Was the client provided services to assist with linkage to a PrEP provider?
☐ No ☐ Yes

Co-Infections: (Check if applicable)

Was the client tested for Syphilis?
☐ No ☐ Yes ----------▶ **Syphilis Test Result:** ☐ Newly identified infection ☐ Not infected ☐ Not known

Was the client tested for Gonorrhea?
☐ No ☐ Yes ----------▶ **Gonorrhea Test Result:** ☐ Positive ☐ Negative ☐ Not known

Was the client tested for Chlamydia?
☐ No ☐ Yes ----------▶ **Chlamydial Test Result:** ☐ Positive ☐ Negative ☐ Not known

Was the client tested for Hepatitis C?
☐ No ☐ Yes ----------▶ **Hepatitis C Test Result:** ☐ Positive ☐ Negative ☐ Not known

Essential Health Benefits: (Check box for yes, check all that apply)

	Screened for Need	Need Determined	Provided or Referred
Health benefits navigation and enrollment	☐	☐	☐
Evidence-based risk reduction intervention	☐	☐	☐
Behavioral health services	☐	☐	☐
Social services	☐	☐	☐
(HIV+ Only) Navigation services for linkage to HIV care *(Referred to a Linkage to Care Specialist)*	☐	☐	☐
(HIV+ Only) Linkage services to HIV medical care *(Referred to a Provider)*	☐	☐	☐

(HIV+ Only) Medication adherence support	☐	☐	☐

DEPARTMENT OF HEALTH SERVICES
Division of Public Health
F-42016 (Rev. 02/19)

STATE OF WISCONSIN
s. 252.15 (3m)

D: Authorization for Release of Confidential HIV Test Results

1. Name of person whose HIV test results will be released: _____

2. Name and address of organization that I am authorizing to release HIV test results:

a. Name of Organization: _____

b. Address of Organization: _____

3. Person(s) or organization(s) that I am authorizing to receive these HIV test results:

a. _____

b. _____

c. _____

4. This authorization will expire on the following date OR when the following event takes place:

a. Date of Expiration: _____

b. Event: _____

5. Reason for signing release of confidential HIV test results form: _____

I understand that, unless otherwise stated below, I am not required to sign this form and signing the form is not a condition of receiving treatment, payment, enrollment, or eligibility for benefits.

6. Purpose for need of discloser (if applicable): _____

I can change my mind at any time and revoke this authorization in writing. The written revocation must be given to the person(s) that I authorized to release the test results. I understand that if I do revoke this authorization, it will not affect the uses and disclosures of test results that have already occurred based on my authorization.

I understand that information used or disclosed based on this authorization may possibly be re-disclosed by the recipient and/or no longer be protected by Federal privacy standards.

My questions about this two-sided form have been answered to my satisfaction. I also understand that if I sign this authorization, I will be provided a copy of this authorization.

7. ☐ **I authorize the person(s) and organization(s) that I have designated above to receive my HIV test results (or the test results of the person named above).**

_____ _____

SIGNATURE of Test Subject | Date Signed

SIGNATURE of Person Legally Authorized to Sign on Behalf of Test Subject | Date Signed

Print Name of Person Legally Authorized to Sign on Behalf of Test Subject

Relationship of Person Legally Authorized to Sign on Behalf of Test Subject

Disclosure:

Wisconsin law requires that HIV test results can only be given to people who are authorized to have access to these results or in the limited circumstances specified in statute 252.15(3m).

The following are persons who may receive name-associated HIV test results under certain circumstances specified by Wisconsin statute 252.15(3m).

1. The person tested; and if the person is incapacitated, the person designated as the agent in the health care power of attorney;

2. The person's health care provider, including a health care provider who provides emergency care to the person tested;

3. An agent or employee of the tested person's health care provider who provides patient care or handles specimens of body fluids or tissues or prepares or stores patient health care records;

4. A blood bank, blood center or plasma center that subjects a person to a test;

5. A health care provider who procures, processes, distributes or uses a human body part for the purpose of ensuring medical acceptability of the donated body part;

6. The State Epidemiologist or their designee or to a local health officer or their designee for the purpose of communicable disease investigation or control or epidemiological surveillance;

7. A funeral director or to other persons who prepare a corpse for burial or other disposition; or to a person who performs or assists in an autopsy;

8. Health care facility staff committees or accreditation or health care services review organizations for conducting program monitoring, evaluations and reviews;

9. Under a court order;

10. A person who conducts research, if the researcher:

    a. Is affiliated with the tested person's health care provider, and

    b. Has obtained permission to perform the research from an institutional review board, and

    c. Provides written assurance that the information will not be released and will not identify the person tested without informed consent;

11. A person rendering emergency care to a victim if significantly exposed;

12. A coroner or medical examiner or assistant if:

    a. the HIV status is relevant to the determination of cause of death, or

    b. during direct investigation the coroner, medical examiner or appointed assistant is significantly exposed to the subject;

13. A sheriff; jailer; keeper of a prison, jail or house of correction; for the purpose of assigning private cells;

14. If the test results were positive and the tested patient is now deceased, persons known by the deceased patient's physician to have had sexual contact or shared intravenous drug equipment with that patient;

15. A person who consents for testing an individual who is under 14 years of age, or declared incompetent by a court, or is unable to communicate because of a medical condition;

16. An alleged victim or victim of sexual assault, the victim or alleged victim's parent or guardian and the victim or alleged victim's healthcare provider;

17. To a person who is significantly exposed, as defined by state statute, through certain occupations;

18. To a foster parent or treatment foster parent or the operator of a group home, child caring institution or correctional facility in which a child is placed.

19. If the person is a prisoner, the prisoner's health care provider and medical and intake staff of the prison or jail

E: HIV Program Policy: Revised Materials Review Process

Whenever your agency produces or purchases materials with HIV prevention grant funds, or produces, purchases or obtains materials to promote HIV prevention grant activities, you must conduct a committee review process. Materials that must be reviewed include, but are not limited to:

- Pamphlets
- Posters
- Flyers
- Wallet cards
- Print advertisements
- Radio PSAs
- Website advertisements
- Banner advertisements

Review of materials produced by U.S. government agencies (CDC, HRSA, HHS, etc.) or State of Wisconsin agencies (DHS, etc.) is not required, but should be considered to ensure that materials are appropriate for the local target population.

Step one: Assemble review committee and document membership

In order to determine the cultural appropriateness and effectiveness of materials, the committee reviewing the materials should include:

- At least one individual representative of the population(s) to whom the materials are targeted, and
- At least one individual with background in health education, HIV prevention, social marketing and/or similar expertise.

You need to *document* who is on the committee for each material as it is reviewed. This can simply be a list of persons on the committee, including contact information and short description of each person's expertise and/or role:

Chris Jones	*555.123.4567*	*Health Educator*
Pat Smith	*555.456.7891*	*Substance Abuse Counselor*

Committees can be any size, with a recommendation of no fewer than three members.

Step two: Review material(s) and document committee approval

Committees may review materials by gathering in person, via phone or web conference, or other process. The committee should consider who the material is targeting, and what the key messages are of the material and how they relate to the agency objectives.

At the end of the process, documentation should include a statement(s) signed by committee members listing the following:

- Name of the material that was reviewed

- How the review was done (in person, via phone conference, via mailing sample materials, etc.)
- Statement that the material was approved for use by the agency
- Statement that the target audience the material is approved for ("everyone," "general population," "gay men," etc.)
- Notation of additional comments from the committee, if any ("needed also in Spanish," "not to be used with persons under 18 years of age," etc.)

Keep this statement on file with the list of committee members and a copy of the approved material.

Step three: BEFORE purchasing or producing approved materials:

Forward one copy of the reviewed material (or appropriate alternative, such as web address of draft advertisement, etc.) to your HIV Program contract monitor, along with copies of your committee list and the statement approving the material. Your contract monitor will respond to you promptly, providing feedback about the review process or confirming that everything is in order.

F: Blood Sample Guidelines for HIV, Hepatitis C, and Syphilis Tests

Wisconsin State Lab of Hygiene (WSLH)

Last Updated: January 2019

Note: The Wisconsin State Lab of Hygiene allows hepatitis c and syphilis blood samples to be collected in the same tube. It is not required to send two separate tubes of blood to run these tests. However, a full tube or minimum 3mL serum is required.

	HIV Ag/Ab (and PCR if needed)	Hepatitis C Antibody and PCR Tests	Syphilis Test
Tube Type	Lavender Top	Tiger Top (also called Marble Top)/Red Top	Tiger Top (also called Marble Top)/Red Top
Amount of blood required for State Lab to process the test.	• Ideally: Full tube • Minimum: 5mL blood	• Ideally: Full tube • Minimum: 3mL serum	• Ideally: Full tube • Minimum: 2mL serum
Rejection Criteria—Any unique factors that would cause WSLH to reject the sample? *(Standard collection protocols for submission still apply)*	Must receive sample within 72 hours of collection	Must receive sample within 72 hours of collection	Must be tested within 7 days of collection if maintained at refrigerator temp*
Special Processing Requirements	Do not spin	• Wait to allow blood to clot (15-30 min) in an upright rack • Spin in centrifuge within 24 hours of collection	• Wait to allow blood to clot (15-30 min) in an upright rack • Spin in centrifuge within 24 hours of collection
Storage Requirements	Keep cold (Refrigerator temp)	Keep cold	Keep cold

G: EvaluationWeb Access

Why Use EvaluationWeb?

To evaluate the Wisconsin HIV Counseling, Testing, and Referral (CTR) Program's utilization and effectiveness, data on clients' individual testing events is entered into a Center for Disease Control (CDC), web-based data system called EvaluationWeb. It is used for collecting and evaluating HIV prevention services data in compliance with the reporting requirements of CDC.

EvaluationWeb was developed and is implemented by Luther Consulting LLC, a vendor contracted by CDC. The Wisconsin HIV Program and partner agencies can use the data system to directly enter data and easily access the CTR data for evaluation, including creating agency-specific reports.

To gain user access to EvaluationWeb for data entry, you are required to go through CDC's user identity proofing process which is called e-authentication. Please refer to the e-authentication guide on pages 112 to complete CDC's user identity proofing process.

FAQ for Data Entry and Reporting Requirements

How do I access the data entry form in EvaluationWeb?

Please refer to the guide on page 117.

When do I enter negative tests in EvaluationWeb?

It is recommended negative tests are entered on a regular basis (no later than weekly). As soon as you complete a client visit, fill out all required fields on the Testing Questionnaire and enter it into EvaluationWeb. This helps prevent a backlog on data entry.

If you are collecting **only PrEP related data** along with client demographic and risk information, enter the Testing Questionnaire in EvaluationWeb as soon as you complete a client visit (no later than weekly).

When do I enter positive HIV tests in EvaluationWeb?

Each positive HIV test is required to be entered within 72 hours after informing the client of their final confirmatory test result. If the confirmatory test is not performed after the rapid test, enter the test session within 72 hours after delivering the rapid test result to the client. If unable to reach the client after making three attempts to inform them of the final test result, go ahead and enter the test session within 72 hours.

Note that a positive HIV test with the rapid test (finger prick) result that is listed as the final test result is considered preliminary positive. Meanwhile a positive test with the

confirmatory laboratory-based test (blood draw) result that is listed as a final test result is considered confirmed positive.

What if the test session involves an HIV test and additional tests for STI and/or HCV?

Wait to enter the test session into EvaluationWeb until all of the test results from the laboratory are provided to the client. If the HIV test result is positive, please follow the 72-hour data entry requirement described above. If unable to reach the client after making three attempts, enter the test session within 72 hours.

After the HIV positive test result is entered into EvaluationWeb, notify Yi Ou (608-266-3073; yi.ou@dhs.wisconsin.gov) of the HIV-positive test. You may send a copy of the completed test form to Yi, but **do not include a client's personally identifiable information (e.g. the client consent forms) in emails or voice messages.**

Is it required to report HIV cases in Wisconsin?

Yes, you are **required** to report confirmed positive HIV test results to the Wisconsin HIV Program surveillance team, within 72 hours after identification of a case through confirmatory laboratory-based results. **Please call 608-266-8658 or 608-267-6727 to report an HIV case.** You will be asked questions regarding the case, including personally identifying information.

What if I have made an error(s) in a previously submitted test entry in EvaluationWeb?

Please log into EvaluationWeb and search the test entry by the assigned A# on the sticker provided by the Wisconsin HIV Program. You can update the data fields with the errors and re-submit the form to save the changes in the data system.

If you cannot find a submitted test entry in EvaluationWeb or if you think the A# was entered incorrectly, contact Yi Ou immediately at yi.ou@dhs.wisconsin.gov . Once Yi verifies that the original submission contains an incorrect A#, you can re-enter the test with the correct A#. Yi will delete the original submission.

Electronic Authentication (E-Authentication) Steps for EvaluationWeb Access Setup

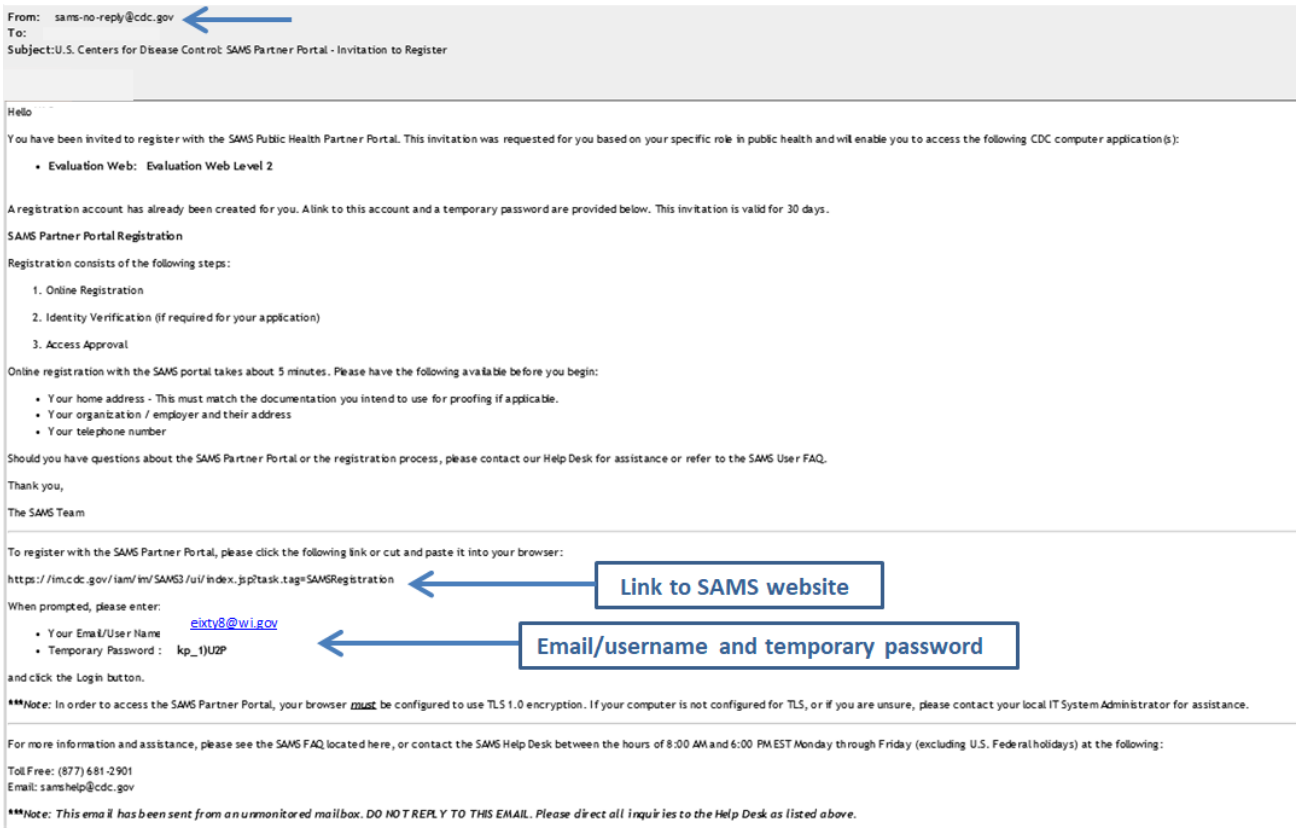
All persons requesting access to EvaluationWeb must be identity proofed via the Secure Access Management Services (SAMS) system (sams-no-reply@cdc.gov; 1-877-681-2901). Once identity proofing is complete, Luther Consulting will provide instructions for set up a user account in EvaluationWeb. Below are the steps to become identity proofed or e-authenticated.

Step 1:

Contact Yi Ou, yi.ou@dhs.wisconsin.gov to request access and provide your name, email, agency, and start date to do data entry. If approved, CDC will begin your e-authentication process.

Step 2:

You will receive an email invitation from sams-no-reply@cdc.gov. This email includes a link to the SAMS portal. SAMS is CDC's secure website where public health partners can access sensitive information and applications, such as EvaluationWeb, that are not available to the public. The email also has your SAMS user ID and a temporary password.



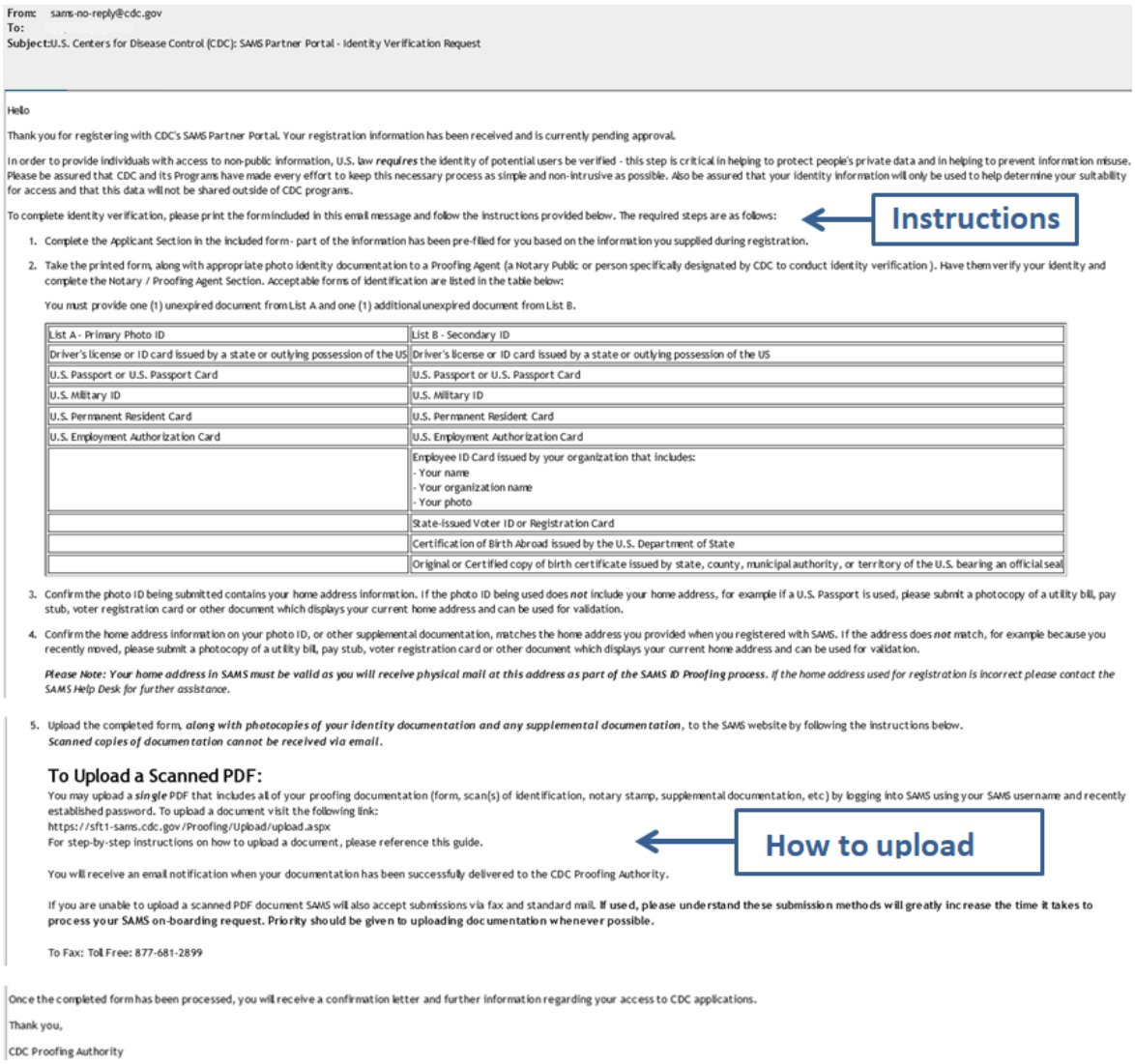
Step 3:

The invite from SAMS is valid for only 30 days. Log into SAMS using the website link (please use Internet Explorer), user ID, and temporary password included in the email and complete the registration promptly. The password you set during the registration process is for accessing your SAMS account in the future.

After registration, you will receive another email from sams-no-reply@cdc.gov to complete identity verification. Print this email which includes the identity verification request form. Read through the instructions in the email, complete the applicant portion of the form and then present the form with two ID cards to get notarized by a Proofing Agent (i.e., notary public, Designated Proofing Authority (DPA) or a badged CDC employee).

- **Acceptable identity documents include government-issued photo ID cards that have an ID number (i.e., state-issued driver's license as primary ID and employee ID with a photo as secondary ID).**

- The Proofing Agent will verify your identity document and complete their portion of the printed email. Specific instructions on verifying the identity document and completing the form are in the email.



From: sams-no-reply@cdc.gov
To:
Subject: U.S. Centers for Disease Control (CDC): SAMS Partner Portal - Identity Verification Request

Hello

Thank you for registering with CDC's SAMS Partner Portal. Your registration information has been received and is currently pending approval.

In order to provide individuals with access to non-public information, U.S. law ***requires*** the identity of potential users be verified - this step is critical in helping to protect people's private data and in helping to prevent information misuse. Please be assured that CDC and its Programs have made every effort to keep this necessary process as simple and non-intrusive as possible. Also be assured that your identity information will only be used to help determine your suitability for access and that this data will not be shared outside of CDC programs.

To complete identity verification, please print the form included in this email message and follow the instructions provided below. The required steps are as follows:

Instructions

1. Complete the Applicant Section in the included form - part of the information has been pre-filled for you based on the information you supplied during registration.
2. Take the printed form, along with appropriate photo identity documentation to a Proofing Agent (a Notary Public or person specifically designated by CDC to conduct identity verification). Have them verify your identity and complete the Notary / Proofing Agent Section. Acceptable forms of identification are listed in the table below:

   You must provide one (1) unexpired document from List A and one (1) additional unexpired document from List B.

List A - Primary Photo ID	List B - Secondary ID
Driver's license or ID card issued by a state or outlying possession of the US	Driver's license or ID card issued by a state or outlying possession of the US
U.S. Passport or U.S. Passport Card	U.S. Passport or U.S. Passport Card
U.S. Military ID	U.S. Military ID
U.S. Permanent Resident Card	U.S. Permanent Resident Card
U.S. Employment Authorization Card	U.S. Employment Authorization Card
	Employee ID Card issued by your organization that includes: - Your name - Your organization name - Your photo
	State-issued Voter ID or Registration Card
	Certification of Birth Abroad issued by the U.S. Department of State
	Original or Certified copy of birth certificate issued by state, county, municipal authority, or territory of the U.S. bearing an official seal

3. Confirm the photo ID being submitted contains your home address information. If the photo ID being used does *not* include your home address, for example if a U.S. Passport is used, please submit a photocopy of a utility bill, pay stub, voter registration card or other document which displays your current home address and can be used for validation.
4. Confirm the home address information on your photo ID, or other supplemental documentation, matches the home address you provided when you registered with SAMS. If the address does *not* match, for example because you recently moved, please submit a photocopy of a utility bill, pay stub, voter registration card or other document which displays your current home address and can be used for validation.

   Please Note: Your home address in SAMS must be valid as you will receive physical mail at this address as part of the SAMS ID Proofing process. *If the home address used for registration is incorrect please contact the SAMS Help Desk for further assistance.*

5. Upload the completed form, ***along with photocopies of your identity documentation and any supplemental documentation***, to the SAMS website by following the instructions below.
   Scanned copies of documentation cannot be received via email.

To Upload a Scanned PDF:

You may upload a ***single*** PDF that includes all of your proofing documentation (form, scan(s) of identification, notary stamp, supplemental documentation, etc) by logging into SAMS using your SAMS username and recently established password. To upload a document visit the following link:
https://sft1-sams.cdc.gov/Proofing/Upload/upload.aspx
For step-by-step instructions on how to upload a document, please reference this guide.

How to upload

You will receive an email notification when your documentation has been successfully delivered to the CDC Proofing Authority.

If you are unable to upload a scanned PDF document SAMS will also accept submissions via fax and standard mail. **If used, please understand these submission methods will greatly increase the time it takes to process your SAMS on-boarding request. Priority should be given to uploading documentation whenever possible.**

To Fax: Toll Free: 877-681-2899

Once the completed form has been processed, you will receive a confirmation letter and further information regarding your access to CDC applications.

Thank you,

CDC Proofing Authority

CDC User Identity Verification Request Form
Version 2.0

Identity Verification Request Form

****

Please upload the completed form, along with photocopies of your identity documentation, to:

To Upload a Scanned PDF:

You may upload a ***single*** PDF that includes all of your proofing documentation (form, scan(s) of identification, notary stamp, supplemental documentation, etc) by logging into SAMS using your SAMS username and recently established password. To upload a document visit the following link:
https://sft1-sams.cdc.gov/Proofing/Upload/upload.aspx
For step-by-step instructions on how to upload a document, please reference this guide.

****

Applicant

Name:

Preferred Name:

Primary Phone:
Alternate Phone:
Email:

Verification Initiated On:

Applicant to complete:

Printed Name: _____

Date of Birth: _____

Signature: _____

Today's Date: _____

Applicant Section

****

Proofing Agent / Notary

Proofing Agent/Notary Instructions:
The individual presenting this form is requesting access to potentially sensitive Public Health information and/or information systems operated by the U.S. Centers for Disease Control and Prevention. Federal law requires each requestor's identity be verified prior to receiving authorization for access. You are being asked to assist in this important verification process.

- **Step 1** - Please examine the Primary Photo Identification types listed below as presented by the requestor. If the ID is unexpired and, in your opinion, appears legitimate, please compare the photo to the individual in front of you. If, in your opinion, the photo matches the person, please check the identity document type and record the document number.
- **Step 2** - Please examine the Secondary Identification document types listed below as presented by the requestor. If the document is unexpired and, in your opinion, supports the Primary Photo Identification and appears legitimate, please check the identity document type and record the document number (if any).
- **Step 3** - If you are a Notary Public, please also include your stamp/seal.

If you are a designated CDC Proofing Agent, please provide your CDC email address or SAMS ID.

For more information and assistance, please see the SAMS FAQ located here, or contact the SAMS Help Desk between the hours of 8:00 AM and 6:00 PM EST Monday through Friday (excluding U.S. Federal holidays) at the following:

Toll Free: (877) 681-2901
Email: samshelp@cdc.gov

Proofing Agent / Notary to complete:

Applicant's Primary Photo Identity Document from List A (please choose only one):

- State Issued Driver's License / ID Card Number:_____
- Passport / Passport Card Number:_____
- U.S. Military ID Card Number:_____
- U.S. Permanent Resident Card Number:_____
- U.S. Employment Authorization Card Number:_____

Applicant's Secondary Identity Document from List B - ***must be different than the Primary Photo ID above*** (please choose only one):

- State Issued Driver's License / ID Card Number:_____
- Passport / Passport Card Number:_____
- U.S. Military ID Card Number:_____
- U.S. Employment Authorization Card Number:_____
- Employee ID Card Number:_____
- Voter ID or Registration Card Number:_____
- Certificate of Birth Abroad Number:_____
- Certified U.S. Birth Certificate Number:_____

Proofing Agent/ Notary Section

****

Proofing Agent/Notary Printed Name: _____

Proofing Agent/Notary Signature: _____

CDC Email Address or SAMS ID (if applicable): _____

Today's Date: _____

****

For Notaries Only:

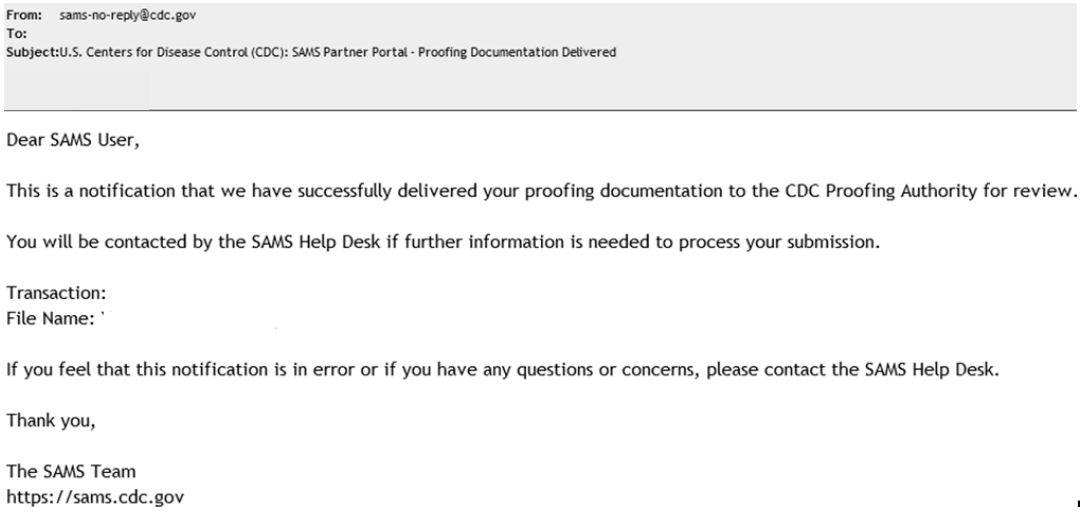
Notary Commission Expiration Date: _____

Notary Stamp/ Seal:

Step 4:

Follow the instructions to scan and upload the notarized identify verification request form, along with required identity documents by logging into SAMS with your SAMS username and recently established password. If unable to access SAMS to upload, fax the form and the required identity documents to the **toll-free fax number:** 877-681-2899.

You will receive a notification from sams-no-reply@cdc.gov about the documentation delivery to CDC.



From: sams-no-reply@cdc.gov
To:
Subject:U.S. Centers for Disease Control (CDC): SAMS Partner Portal - Proofing Documentation Delivered

Dear SAMS User,

This is a notification that we have successfully delivered your proofing documentation to the CDC Proofing Authority for review.

You will be contacted by the SAMS Help Desk if further information is needed to process your submission.

Transaction:
File Name:

If you feel that this notification is in error or if you have any questions or concerns, please contact the SAMS Help Desk.

Thank you,

The SAMS Team
https://sams.cdc.gov

Step 5:

After the final approval, you will receive two welcome emails from sam-no-reply@cdc.gov.

- Check the Spam/ Junk Mail folders if the emails have not been received within 72 hours.
- **Ignore** the following statements from the welcome email, **"You can reach the activity home directly by clicking www.EvaluationWeb.com. You may also access this activity through the SAMS Partner Portal pages by clicking here."** You cannot access EvaluationWeb through SAMS right away.

CDC will mail you a grid card within 10 days after you're e-authenticated. Keep this grid card and log into SAMS (https://sams.cdc.gov) at least once a year to maintain an active account in order to stay in compliance with CDC's recent security updates on EvaluationWeb access.

- If your SAMS account expires, contact Yi Ou at yi.ou@dhs.wisconsin.gov.

Step 6:

Notify Yi Ou (608-266-3073; yi.ou@dhs.wisconsin.gov) of your e-authentication approval so that Luther Consulting can provide you with login information for EvaluationWeb.

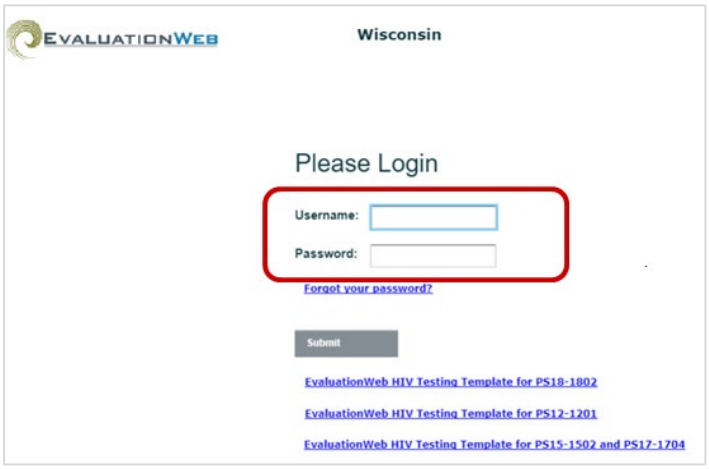
Technical Assistance: For all questions related to e-authentication and EvaluationWeb, contact Yi Ou at 608-266-3073 oryi.ou@dhs.wisconsin.gov.

Accessing the Data Entry Form in EvaluationWeb

Perform the following steps to access the data entry form to enter tests.

1. **Log into EvaluationWeb**

   (https://cdc2-ew.lutherconsulting.com/evaluationWebV6/index.cfm?jurisdiction=WisconsinCDC)

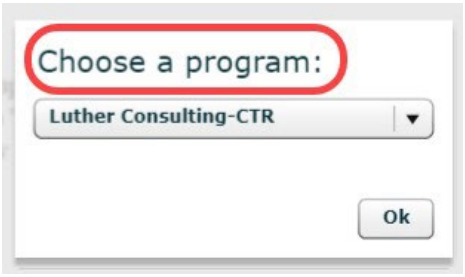


Do not use the EvaluationWeb HIV Testing Templates developed by Luther Consulting that are on the login page. The Wisconsin HIV Program will provide you with customized form you will use for data collection and reporting. The variables correspond to the ones on the online form in the database.

Result: The "Select the code you previously registered" window opens.

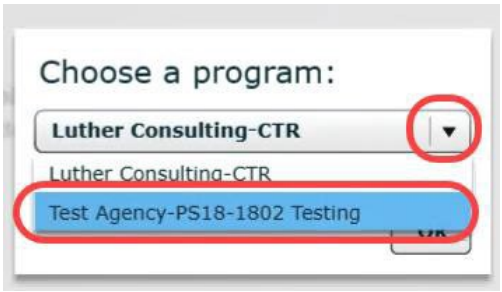
2. **Select your four digit code and click Submit.**

Result: The "Choose a program" box opens.



You may not see the "Choose a program" box, depending on how your account and agency are set up. If you do not see it, skip to Step 4.

3. **Click the dropdown arrow to see a list of programs, and then select the one you want to enter data for.**

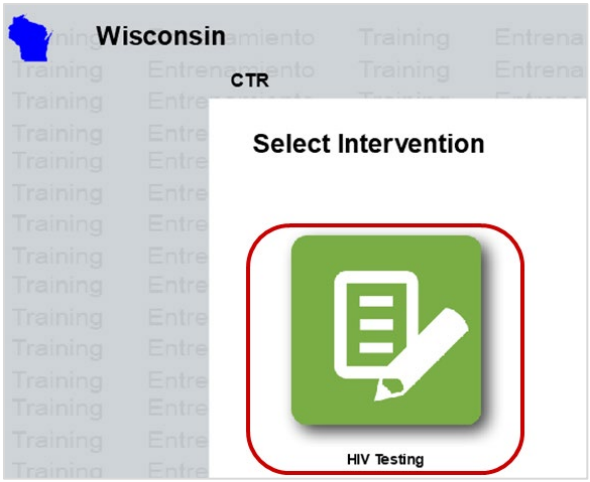


Be sure to select a program that is set up for collecting PS18-1802 data. This will ensure you are taken to the correct data entry screens.

4. **Click OK.**

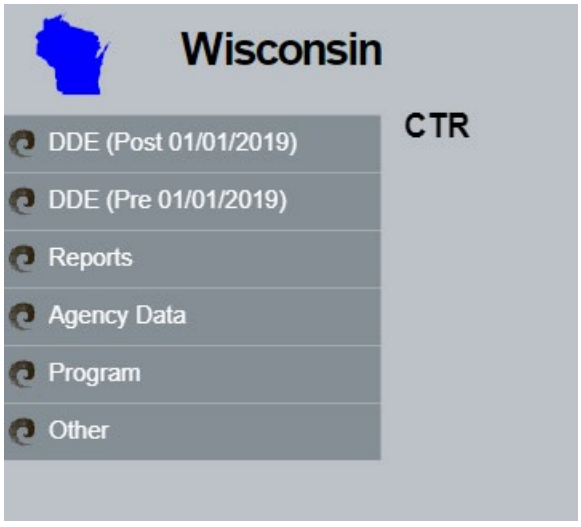
Result: The Select Intervention window opens

5. Click the HIV Testing icon in the Select Intervention window.



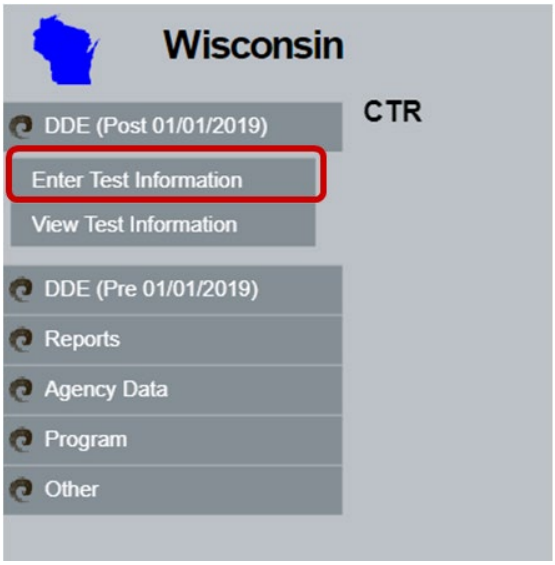
You may not see the "Select Intervention" window, depending on how your account and agency are set up. If you do not, skip to Step 6.

Result: The EvaluationWeb home page opens.

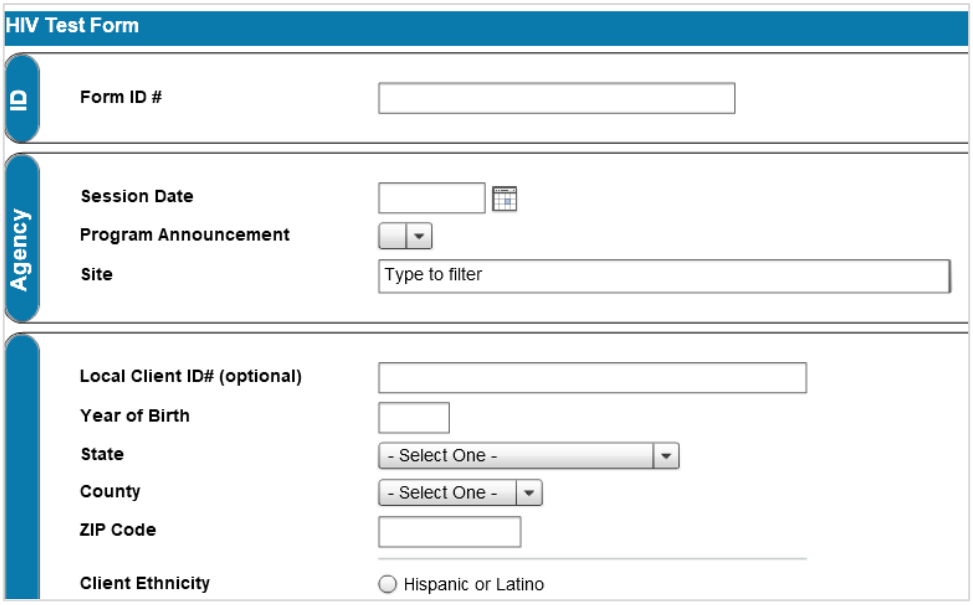


6. **Click the DDE (Post 01/01/2019) on the left side of the window.**

7. **Click the Enter Test Information button.**



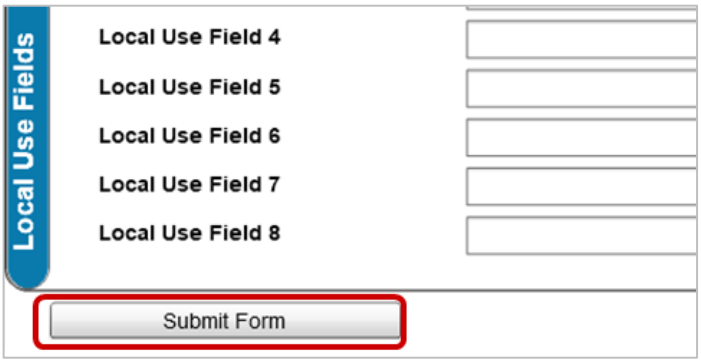
Result: The HIV Testing data form displays.



8. **Upon completion, review again and ensure the A# is correctly captured in the "Form ID #" field, consisting of a capitalized A and three zeroes followed by six additional digits (A000######).**

Note: Unlike the other fields on the form, a typo in the A# cannot be fixed within the form. Contact Yi Ou, yi.ou@dhs.wisconsin.gov immediately about the error. Once it is verified, you can go ahead and re-enter the test with the correct A#. Yi will delete the original submission.

9. **Click the Submit Form button**



Result: The Data Submitted window opens.

10. Click OK to finalize the data submission