<table>
<thead>
<tr>
<th>Staff Person</th>
<th>Contact Information</th>
<th>Resource for…</th>
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<tr>
<td>Jacob Dougherty</td>
<td></td>
<td>Funding application process, quality assurance, contract monitoring, CTR program issues and information, HIV statutes in Wisconsin, policy issues related to HIV, PrEP</td>
</tr>
<tr>
<td>Sara DeLong</td>
<td></td>
<td>CTR program issues and information, testing procedures, interpretation of test results, rapid testing, ordering rapid tests, counseling recommendations, site policies, funding application process, reimbursements, new HIV testing technology, HIV CTR protocols, requests for rapid HIV test kits and test ID stickers</td>
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<tr>
<td>Dhana Shrestha</td>
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<td>Partner Services questions, training, and reimbursement</td>
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<tr>
<td>Rebecca LeBeau</td>
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<td>Contact person for HIV confidential case reports or to obtain HIV confidential case report forms</td>
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<tr>
<td>Yi Ou</td>
<td></td>
<td>Primary contact for EvaluationWeb database, including obtaining user IDs, passwords, and assistance with reports</td>
</tr>
<tr>
<td>Wis. State Laboratory of Hygiene – Retrovirus Lab</td>
<td>608-262-2366</td>
<td>Status of test results or interpretation of test results</td>
</tr>
<tr>
<td>Wis. State Laboratory of Hygiene- Clinical Orders</td>
<td>608-265-2966 / 1-800-862-1088</td>
<td>Blood or OraSure test kits, mailing supplies, questions related to shipping and processing.</td>
</tr>
<tr>
<td>Wis. State Laboratory of Hygiene- Customer Service</td>
<td>1-888-494-4324</td>
<td>Issues related to specimen collection, processing, or shipping</td>
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1. Introduction and Background

Common Acronyms
Ag/Ab – Antigen/Antibody
AODA – Alcohol and Other Drug Abuse
ASO – AIDS Service Organization
CBO – Community-Based Organization
CTR – Counseling, Testing, and Referral
EDTA – A type of anticoagulant in some blood tubes
EIA – Enzyme Immunoassay
DHS – Department of Health Services
DPH – Wisconsin Division of Public Health
LHD – Local Health Department
MSM – Men who have sex with men
OMT – Oral Mucosal Transudate
PCR – Polymerase Chain Reaction
PS – Partner Services
PWID – Person who injects drugs
SST – Serum Separator Tube
STD – Sexually Transmitted Disease
Wb – Western blot
WSLH – Wisconsin State Laboratory of Hygiene

Common Terms
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.

Acute HIV infection – the time between when a person is infected and the person develops an antibody response. During acute infection the volume of the virus circulating in the exposed person’s system is very high.

Window period – the period of time between when a client is infected and a test can detect that infection.

Discordant test results – Result from a screening test that is reactive or positive, followed by a confirmatory test that is non-reactive or negative.

Indeterminate – Describes when bands develop on a Western blot test, but the bands do not meet the criteria for positive result.
Invalid – a failure of a rapid test due to operator error or an issue with the device.
Intended Audience for this Protocol
This protocol is intended for agencies funded by the Wisconsin Division of Public Health – AIDS/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 the Protocol
This protocol was developed to provide an overview of the Wisconsin HIV CTR Program, identify requirements of agencies contracted to provide CTR services related to counseling, testing, referral, data collection, and record-keeping. CTR sites are required to adhere to this protocol and the terms and conditions of contractual agreements and memoranda of understanding (MOUs) with the Wisconsin Division of Public Health (DPH).

Purpose of the CTR Program
The DPH AIDS/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 client risk of acquiring or transmitting HIV; and,
- appropriate referrals for HIV medical services, case management, partner services, social and emotional support, risk reduction interventions, STD testing, hepatitis vaccination and testing, 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.
Section 1: Introduction and Background

Overview of the CTR Process

Client is contacted through outreach → Client engaged → Client comes into agency

Client completes questionnaire

Pre-Test Counseling
- Prevention counseling
- Test-decision counseling
- Assess for acute Infection
- Informed consent
- Specimen collection

Send specimen to laboratory for laboratory-based testing → Conduct rapid test
- Provide results
- For reactive results – submit specimen to laboratory

Post-Test Counseling
- Provide results
- Prevention counseling
- Provide referrals/linkage to care

Referral Follow-Up for Positive Clients
- Assess & document referrals completed
- Address additional referral needs
### Overview of HIV Counseling, Testing, and Referral Services

Prior to the session, the counselor establishes a folder for the client, which includes informed consent and EvaluationWeb forms.

#### I. Pre-Test Counseling Session:

#### Completion of Questionnaire

Client completes the *Client Questionnaire* alone while waiting to see counselor or completes it together with the counselor.

#### Client-Centered Prevention/Risk Reduction Counseling

Counselor meets with the client to:

- review information on the *Client Questionnaire* with the client and assess for other risks
- determine client’s interest in testing and knowledge of HIV
- identify client risks and self-perception of risk
- acknowledge steps taken to reduce risk
- identify barriers to risk reduction, and
- establish a mutually agreed-upon, incremental, attainable risk reduction goal.

#### Test-Decision Counseling

Counselor discusses the following topics with the client:

- feelings about being tested
- what test result will mean for changing behavior
- pros/cons of testing
- benefits of confidential testing
- client concerns about confidential testing
- option of anonymous testing if client has significant concerns
- recent risk exposure and an appropriate test based on this information
- options among types of tests available—including pros/cons of each method
- reporting of confidential positive results and Partner Services (PS)—including:
  - voluntary, client-centered nature of PS
  - objectives of PS
  - automatic contact by local health department if tested confidentially with a positive result
  - ability to access and utilize PS if tested anonymously with a positive result

#### Obtaining Informed Consent

Counselor obtains written or verbal consent and discusses the following:

- meaning of test results
- reporting of positive test results
- services available, including PS if positive
- barriers to obtaining test results and plans to overcome barriers
- plan to obtain results if appointment is missed
Specimen Collection and Processing
- A blood or oral fluid specimen is collected to be sent to the Wisconsin State Laboratory of Hygiene (WSLH) or to be used to conduct a rapid HIV test

For Conventional Testing....
- summarize session and risk reduction plan
- discuss any client questions
- confirm appointment to obtain test results
- submit specimen to the WSLH

For Rapid Testing....
- conduct rapid HIV test
- interpret results
- if negative, proceed to Post-test Counseling Session below
- if rapid reactive, obtain specimen for confirmatory test
- confirm appointment to obtain test results
- submit specimen to the WSLH

II. Post-Test Counseling Session:
Providing Test Results
Counselor meets with the client in person to
- provide test results, and gauge client understanding
- interpret results for client and address misperceptions, if appropriate

If negative, the counselor:
- encourages the client to express thoughts and feelings about receiving a negative result
- acknowledges risk reduction steps taken
- assesses need for re-testing

If positive or rapid reactive, the counselor:
- encourages the client to express thoughts and feelings about receiving result
- assesses client’s social and emotional support
- assesses client’s short-term plans and refers for crisis intervention services if indicated

Prevention Counseling
If negative, the counselor:
- reviews risks and progress toward any risk reduction goals made at pre-test
- discusses client progress toward risk reduction
- assesses and addresses barriers to goal attainment
- assesses client strengths and support, and discusses plan for future risk reduction

If positive, the counselor:
- determines client’s readiness to discuss transmission and prevention issues
  ✓ if not ready, negotiates a return date or follow-up contact
  ✓ if ready, follows steps above for prevention counseling
Providing Referrals/Linking to Services

If negative, the counselor:
- assesses possible need for future testing
- follows protocols for recommending annual testing, hepatitis vaccination and testing, STD testing
- assesses client interest and ability to access referrals directly
- offers linkage to referrals as needed, and arranges for referral follow-up
- documents referrals made and completed on Form 3: Referral Tracking

If positive, the counselor:
- assesses and prioritizes client referral needs
- assesses client interest and ability to access referrals directly
- offers referrals to medical evaluation
- offers referrals to other HIV specialty services—at minimum, case management and prevention planning
- discusses options for Partner Services and options for informing partners
- determines if client has a partner or partners that would benefit from testing and be willing to test – offer to test partners
- facilitates linkages to referrals
- arranges for referral follow-up—one week later
- assess client’s immediate plans once they leave, including disclosure issues
- offers clients materials on medical evaluation and disclosing status to others (see articles – Section 7, pages 7.17 – 7.23)
- documents referrals made and completed on Form 3: Referral Tracking

Summary and closing
The counselor summarizes the session, including:
- counselor contact information and confirming client contact information
- recommendations for re-testing
- mutually-agreed upon plans for referral follow-up, if positive
- dates and times of any referral follow-up meetings, if positive

III. Referral Follow-up for HIV Positive Clients--One Week Later

The referral follow-up session provides the counselor an opportunity to:
- further support linkages to resources, particularly if client was unable to address referrals in the post-test session
- assess and document referrals completed and referral outcomes
- assess and address barriers to referrals not completed
- assess and address additional referral needs
**Target Audience for HIV CTR Services**

The Wisconsin CTR Program is designed to serve those individuals at increased risk for HIV as a result of sexual or drug use behavior, particularly those persons without resources or a health care provider. Access to 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.

Populations at high risk comprise the majority of reported cases of HIV in Wisconsin and are the primary target audience of CTR services. 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)
- High risk heterosexuals, including:
  - Opposite sex partners of persons with HIV disease
  - Opposite sex partners of persons with history of recreational injection drug use
  - Women whose male sexual partners have had sex with men
- Persons who inject drugs for recreational purposes (PWID)

Populations at moderate risk for HIV comprise a very small percentage of HIV cases reported in Wisconsin. Populations at moderate risk for HIV infection are defined as:

- Individuals with sexually-transmitted disease (STD)
- Individuals that trade sex for money, drugs, shelter, etc.
- Individuals that use non-injection recreational drugs, particularly in association with sexual activity
- Victims of sexual assault

Populations at moderate risk for HIV are an appropriate secondary target audience for HIV CTR services. This is because this population may have other unidentified risks and because an active STD can increase the likelihood of contracting HIV if an exposure occurs. LHDs may test populations in moderate risk categories with the exception of victims of sexual assault who should be referred as indicated below.

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. Agencies should develop referral lists that include health care providers for insured, under-insured, and uninsured persons who have no or low risk for HIV infection – as available within their local service area.

**Persons Not Appropriate for HIV CTR Services**

- Individuals requiring an HIV test as 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/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.

- Victims of sexual assault may be tested but should be strongly encouraged to report the assault to authorities and receive confidential HIV testing through private providers—both as soon as possible after the assault and at three- and six-month post-assault. Reporting the assault provides the victim the opportunity of going through the legal system to have the assailant tested for HIV and other sexually transmitted diseases.

**Testing at Health Fairs and Community Events**

Agencies funded by the DPH to provide CTR should not provide testing at health fairs, school/university events, or community events intended for a general audience because these events do not identify persons at increased risk for HIV infection. 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 infection, (identified above), such as at LGBT pride festivals.

The exception to testing at health fairs and community events is limited to events designated by the U.S. Centers for Disease Control and Prevention as “National Testing or Awareness Days” for various populations. These include the following:

- National Black HIV/AIDS Awareness Day: February 7th
- National Women and Girls HIV/AIDS Awareness Day: March 10th
- National Native HIV/AIDS Awareness Day: March 20th
- National Asian & Pacific Islander HIV/AIDS Awareness Day: May 19th
- Caribbean American HIV/AIDS Awareness Day: June 8th
- National HIV Testing Day: June 27th
- National HIV/AIDS and Aging Awareness Day: September 18th
- National Gay Men’s HIV/AIDS Awareness Day: September 27th
- National Latina/o AIDS Awareness Day: October 15th
- World AIDS Day: December 1st

When agencies do offer testing on these days, they should inform the CTR Coordinator and their contract monitor 30 days before the scheduled event for
review and approval. They 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 among high risk members of the population through advertisements in LGBT publications, promotion among IDU and syringe exchange clients; and in neighborhoods with high HIV prevalence. This is particularly relevant when conducting events on National HIV Testing Day, June 27th and World AIDS Day, December 1st.

**Testing at Short-Stay Correctional Facilities**

HIV CTR sites are discouraged from offering testing in city and county jails. These venues historically have a very low incidence of identifying undiagnosed HIV infection. This is particularly the case when presentations are conducted at a jail and inmates are then offered the opportunity for private testing. This self-select process generally yields the lowest risk inmates opting for testing. The average stay in a short-stay correctional facility in Wisconsin is eleven days. This can affect post-test return rates if conventional testing is used or a rapid test is used and an inmate requires a confirmatory test.

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 voluntary testing, on-site, based on an inmate’s medical history and specific medical indicators, such as:

**Medical Conditions:**
- STI diagnosis
- Positive TB PPD test
- Hepatitis diagnosis
- Pregnancy
- Mental Illness
- Undiagnosed Symptoms Indicative of Viral Infection
- Reoccurring Vaginal Yeast Infections

**Medical History:**
- Injection drug use
- Non-injection drug use
- Males taking female hormones
- Men who have had sex with men

Certain criminal charges/offenses have also been demonstrated to be linked to possible activities at high risk for HIV infection and, therefore, should be considered for referral to voluntary testing. These include:

**Criminal Charges/Offenses:**
- Possession/drug charges
- Property offenses
- Disorderly conduct offenses
Charges associated with violence  
Prostitution  

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 AIDS/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.

Agency Reimbursement  
Agencies are either grant-funded or reimbursed on a per-client basis for services.

For grant-funded agencies to receive scheduled monthly payments, agencies must follow the criteria outlined in their grant agreement.

For per-client funded (fee-for-service) agencies to receive reimbursement, agencies must adhere to the criteria outlined in their contract. These agencies are reimbursed at $15 for every client to whom they provide services. Fee-for-service agencies that provide counseling and testing services for 1,000 or more clients per year, 50% or more of whom are representative of high risk populations, are reimbursed at $20.00 per client. Reimbursement for per-client funded agencies is generated once all data are entered into the EvaluationWeb system. Post-test counseling data must be entered into EvaluationWeb or received by the Program for data entry within 60 days of specimen collection to be eligible for reimbursement. Reimbursements for fee-for service sites will be generated once every month. It generally takes 7-14 days after reimbursements are processed for agencies to receive checks.

Agencies that are providing testing as part of PS receive reimbursement based on the criteria and methods defined by the DPH - PS Program.

NOTE: The DPH reserves the right to alter fee schedules and reimbursement systems for fee-for-service and grant-funded HIV CTR services.
2. Program Requirements

Agency Requirements
To assure quality services and to meet State and Federal Standards, agencies must agree to meet the following core requirements:

- Abide by Wisconsin AIDS/HIV Program protocol regarding HIV CTR services.
- 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.
- Provide services to clients regardless of their ability or willingness to pay for these services.
- Adhere to State statutes related to HIV infection, including those concerning confidentiality, informed consent for testing, and HIV case reporting.
- Develop a plan addressing how clients will obtain their test results
- Coordinate services with local agencies to facilitate referrals for all clients related to HIV and STD prevention, hepatitis vaccination or testing, general health, and daily living needs.
- Coordinate services with local agencies to facilitate referrals for HIV positive clients to access medical evaluation and care, Partner Services, HIV case management, risk assessment and prevention services, and other HIV specialty services to meet individual needs.
- Monitor quality of services through observation of counselors, client satisfaction surveys, or other means, within agency limits.
- Submit specimens to the Wisconsin State Laboratory of Hygiene (WSLH) for laboratory processing, as appropriate.
- Confirm rapid reactive test results by submitting a blood or oral specimen to the WSLH for laboratory testing. Assure access to conventional testing with blood to resolve inconclusive oral fluid results.
- Comply with State data collection, entry, and reporting requirements – including quarterly and annual reports as mandated.
- Participate in training sponsored by the Wisconsin AIDS/HIV Program regarding provision of HIV CTR services.
- 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.
- 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.

Additional requirements for agencies conducting rapid HIV testing are included in Section 4C – Rapid HIV Testing.
Staff Training Requirements
Testing staff are required to attend the following DPH sponsored trainings in sequential order:

- HIV: Basic Facts (online)
- HIV Counseling, Testing, Referral Services Program: New Provider Training

Additionally, staff providing rapid HIV testing services will be trained on use of the rapid test device at the HIV Counseling, Testing, and Referral Services Program: New Provider Training.

Agencies may train staff internally under the following conditions:

- Permission is granted by the HIV CTR Coordinator.
- Internal training guidelines are followed (see Appendix A: Internal Agency Training Policy; Internal Agency Checklist).
- Staff trained internally attend the next available series of DPH trainings as identified above.

Note: Typically, internal staff training is not an option for HIV rapid testing. However, exceptions may be made on a case-by-case basis.

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.
- 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 name, since the client’s name or medical record number may be used to link anonymous results to the client’s name.
- When conducting outreach- or field-based testing, testing forms and client records should be transported in portable locked file containers. All files should be returned to the agency at the end of the testing events. This should be done in a manner that addresses 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.
- Counseling at all designated agencies should be provided in a private, comfortable and non-threatening 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 counselors, supervisory oversight staff, etc.)
- Agencies must provide all testing and program support staff with copies of Wisconsin AIDS/HIV Program requirements, Wisconsin confidentiality statutes for AIDS and HIV, and agency policies pertaining to client confidentiality. In addition,
agencies must require all testing and program support staff to sign confidentiality agreements which should be maintained in their personnel files.

- Agencies should periodically review confidentiality policies and monitor agency procedures to ensure client confidentiality is maintained.

**Reporting Requirements**

Wisconsin statutes require that persons testing positive on confidential, name-associated tests must be reported to the AIDS/HIV Program within 72 hours of the result. Agency staff may contact the surveillance unit with a positive report by calling 608-266-8658. 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 (DOH 4338). This form should be completed and sent in an envelope marked “Confidential” to:

James Vergeront, M.D.
Division of Public Health
One West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659

**Record Keeping Requirements**

- *Establishing a Client File* - A file should be established for each client tested. The file should retain copies of all Wisconsin AIDS/HIV CTR Program documents and EvaluationWeb data collection forms used as part of the HIV testing process. These forms will include: client consent form, Wisconsin HIV CTR EvaluationWeb forms, release of information forms (if used) and a copy of test results received from the WSLH.

- *Record Retention* - The following documents should be retained in client files for a period of eighteen months after the calendar year in which the client tested:
  - EvaluationWeb HIV Test Template- Part One;
  - EvaluationWeb HIV Test Template- Part Two—if used.

The following documents should be retained in client files for a period of three years, or longer if agency policy dictates, after the date the client was tested:

- WI DPH F-43018 (revised 10/11) : Consent For HIV Testing—all clients; and
- WI DPH F-42016 (revised 06/10) : Authorization for Release of Confidential HIV Test Results—if used.

**Material Review Panel Requirements**

Grantee agencies receiving funding from the Wisconsin Department of Health Services (DHS) for HIV prevention services must document review and approval of AIDS/HIV-related materials by a program content review panel. Examples of AIDS/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 Center for Disease Control and Prevention (CDC). Details regarding this requirement are delineated in Appendix B.

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 accessibility of services, services and materials 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.

The following is a list of quality assurance measures required of all HIV Counseling, Testing, and Referral sites:

- Review program materials for cultural appropriateness
- Evaluation of physical space and client confidentiality of in-agency testing services
- Evaluation of physical space, client confidentiality, and client and staff safety in outreach-based testing settings/venues
- Annual review/update of referral lists
- Quarterly review of record keeping and security practices
- Quarterly monitoring accuracy of data collection and entry

Below 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.

- Supervisory observation of client CTR session
- Use of “Observational Consumers” to assess quality of counselor/client interaction
- Client satisfaction surveys for testing services and referrals
- Case conferences
- Annual review of outcomes by site if conducting outreach testing
- Comparison of 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.
3. Counseling

The Pre-test Counseling Session

Components of Pre-test Counseling
The initial meeting with the client is called the pre-test counseling session. The purpose of this session is to assist the client in obtaining an HIV test, as appropriate, and to encourage behavior change to reduce their risk for HIV infection. During the session, the following happens:

1. The client completes a questionnaire. The client can also complete the questionnaire in the waiting room prior to the session.
2. The counselor listens to the client’s concerns and engages the client in prevention or risk-reduction counseling to identify behavior changes the client can take to reduce their risk for acquiring or transmitting infection.
3. The counselor supports the client in making a decision to obtain an HIV test by offering information and assessing client’s readiness and social support.
4. If the client decides to get tested, the counselor obtains written informed consent. Verbal consent can be obtained in certain settings with approval from the CTR Coordinator (see below).
5. The counselor either obtains a blood or oral specimen to send to the Wisconsin State Laboratory of Hygiene (WSLH), or conducts a rapid HIV test. If the rapid test is reactive, the counselor obtains a blood or oral specimen and sends it to WSLH.
6. When a specimen is sent to the WSLH, the counselor schedules a return appointment to provide client test results.

The sections below describe in more detail these components of pre-test counseling.

Completing the Client Questionnaire
All clients must complete a client questionnaire regardless of whether or not a blood or oral fluid specimen is eventually obtained. The client questionnaire collects demographic and risk profile information. Data from the questionnaire is used by the AIDS/HIV Program to comply with federal reporting requirements, and to evaluate program utilization and efficiency.

The information collected on the client questionnaire is entered into the EvaluationWeb data system for the AIDS/HIV Program. Detailed information on EvaluationWeb is in Section 6 of this protocol - Data Collection and Reports. A copy of EvaluationWeb forms can be found at this web page:

Although the questionnaire can be completed during the time the client is waiting for their testing session, counselors should assess client literacy and provide assistance as appropriate. The questionnaire should also be reviewed with the client to ensure:

- the questionnaire is correctly completed
The questionnaire provides significant information on the client’s risk for HIV, but should not be considered a complete risk assessment.

**Prevention or Risk Reduction Counseling**

HIV prevention counseling provides a critical opportunity to assist the client in identifying their risk of acquiring or transmitting HIV, and to negotiate and reinforce a plan to reduce or eliminate risk. 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 Counselors should engage in prevention counseling based on the skills identified in day one of the *HIV Counseling, Testing, and Referral Program: New Provider Training* course.

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 *Client 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;
- desire/readiness to alter risk activities;
- resource and support systems;
- benefits of annual HIV screening for persons at high risk; and,
- receptiveness to available services and referrals.

Listen for and address the following information:

- sexual activity: type of sexual activity, sexual or gender-identification, sex 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 infection;
- needle-sharing history and other drug use activities;
- STD history;
- sex in exchange for drugs/money;
- history of sexual assault; and,
- use of alcohol, cocaine, etc. in connection with sex.
Based on the assessment, the counselor 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 AIDS/HIV Program provides condoms to CTR agencies to distribute to their clients, at no-cost, in order to support safer sexual behavior. (See Appendix D for the AIDS/HIV Program’s Condom Distribution Guidelines).

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

In general, HIV risk-reduction counseling should be offered to all clients, and should be based on the client questionnaire and the risk interview. In addition, prevention counseling should:

- acknowledge and provide support for positive steps the client has already taken
- clarify critical misconceptions
- negotiate one concrete, obtainable risk reduction goal for the client to attempt
- be flexible in prevention and counseling approach—avoid 1-step approach, such as “always use condoms.”
- follow-up on progress toward behavior change and offer further risk reduction planning during post-test counseling

HIV prevention counseling should not be promoted:

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

If the counselor is unable to provide prevention counseling based on the above circumstances, the counselor 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, etc.). Providing one or more of the critical aspects of prevention counseling can often take just a few minutes. Counselors should also plan to offer prevention counseling during post-test counseling session after the client receives their results.

**Test Decision Counseling**

Assisting a client to make an appropriate decision to take the HIV test based on their life circumstances will increase the client’s investment in the result, motivation to return for results, and alter activities to reduce risk. To assist the client in making the decision to test, the following topics should be discussed:

- potential benefits to being tested
- potential concerns associated with being tested
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- 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
- anticipated feelings about possible test results
- benefits and limitations of available testing methods (laboratory-based testing with blood or oral fluid, rapid testing)
- relationship between testing and behavior change plan

Deferring Testing
Counselors have authority to defer testing of any client. Deferral should be based on a determination that testing the individual is not in his/her 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; has psychiatric issues to resolve; or, has expressed intent to harm themselves or others.
Addressing Repeated Risk-Taking

Persons prone to continued high risk activity are likely to be dealing with some of these issues:

- Social isolation - they may have fewer connections to their community and fewer people in their life that they feel understand and accept them for who they are.
- Alcohol and other drug abuse
- History of sexual abuse, low self-esteem, unresolved grief, or mental health issues—particularly undiagnosed depression.
- Desire for intimacy, which makes them hesitant to initiate a discussion of safer practices.

Many times, however, persons engaging in high risk activities are simply acting within the norms and practices of their social and/or sexual networks. This may be particularly true among youth due to their desire to conform to the behavior of their peers. Asking a person to act in a manner inconsistent with their social network can be challenging since it may alienate them from their friends, leave them open to suspicion, or take away their ability to feel connected to, and safe within, a group.

MSM may not use condoms during anal sex due to a desire for greater physical stimulation and emotional connectedness, as well as the desire to move on from risk reduction practices during a long and ongoing epidemic.

Individuals Actively Seeking a HIV Infection:
Few studies have been conducted among persons who actively seek an HIV infection. One study conducted by the CDC identified undiagnosed and untreated depression as the most common trait among the participants. Other reasons for seeking an HIV infection may include:
- wanting to access services known to be available for persons with HIV infection such as housing assistance and medical or social services.
- striving to feel part of a community,
- gaining an identity;
- gaining attention, sympathy or notoriety; or
- obtaining a relationship

A small number of persons without HIV infection seek only HIV-positive partners. The reasons for this vary and need to be assessed on an individual basis. However, it may be HIV-positive partners are seen as having fewer community connections, smaller social networks, and are, therefore, potentially more open to a long-term, committed relationship—particularly if an HIV transmission occurs.

Discordant Couples:
Continued risk taking among HIV-discordant partners, (a couple in which only one person is HIV-infected), has increasingly become an issue for both heterosexual and homosexual couples. This is because medical treatment has enabled HIV-infected
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individuals to live longer, healthier lives. Reasons for risk taking between discordant couples is highly varied and may involve the following:

- the desire to engage in a perceived "normal" relationship free from risk reduction practices,
- the desire to feel a greater sense of intimacy with a partner, and share in their HIV experience
- condom-related issues such as discomfort during use or erectile dysfunction

Wanting to increase closeness with a partner and share in their HIV experience has been an issue seen in public testing sites, but is often never discussed within the relationship. Anecdotal information from CTR counselors who have arranged for discordant couples to discuss this issue usually reveal that the HIV-positive partner does not want their partner to become infected, would not feel closer to them if they did, and would feel guilty if a transmission occurred. Counselors should reiterate that keeping the HIV-positive partner in care and virally suppressed is essential to reducing risk of HIV transmission, and should recommend that the HIV-negative partner consider pre-exposure prophylaxis (PrEP) as a tool to stay HIV-negative.

The following are guidelines and discussion points for HIV CTR counselors:

**Ongoing Risk Taking with Persons of Unknown Status:**
- Acknowledge past or current risk reduction steps taken by the client, even if these do not eliminate risk, such as: limiting sex without condoms to oral sex; practicing serial monogamy; and decreasing partners.
- Assess client’s perception of risk and chances for obtaining HIV infection.
- Assess client’s self-efficacy and the type and degree of support they receive within their community.
- Assess the community norm for practicing safer sex in the client’s social and sexual networks. Ask the client how their relationship within these networks might be affected if they change how they go about sexual activities.
- Assess the client’s desire to make risk reduction changes and any barriers they may face if they attempt to do so.
- Assess whether the client has unresolved AODA, depression or other mental health issues, or has a history of sexual abuse.
- Determine if client wants to avoid HIV infection and their perception of how their life might change if they acquired HIV.
- Offer to assist and support client in making one small risk reduction goal.

**Individuals Actively Seeking HIV acquisition:**
- Ask the client casually and directly if they are seeking to acquire HIV.
- Explore if the client is seeking a relationship and whether HIV is merely a possible consequence of obtaining a relationship.
- Determine how the client feels about him/herself and their relationships with family, friends and the community.
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- Assess whether the client has unresolved AODA, depression, or mental health issues, including childhood sexual abuse.
- Discuss how the client’s life and relationships might change if they acquired HIV infection.

Discordant Partners:
- Assess and acknowledge any risk reduction steps taken by the couple—even if these may not constitute elimination of risk.
- Determine if the uninfected partner wants to acquire a HIV infection and, if so, assess the following:
  - Identify what the client will gain by acquiring HIV as an individual and as a couple
  - Determine how the client’s HIV-positive partner feels about the possibility of transmitting HIV.
- If the client is not seeking to obtain HIV, assess their perception of risk based on partner’s adherence to medical treatment and viral load.
- Determine if the positive partner is in medical specialty care and is aware of their viral load level.
- Determine if the couple has discussed the level of risk associated with various sexual activities with the positive partner’s HIV medical specialist.
- Determine if the client or couple has discussed how positive partner’s viral load counts may affect the level of risk associated with various sexual activities.
- Assess the level of comfort the client’s partner has with asking their medical specialist questions about risk.
- Assist the client and their partner to prepare for asking sexual risk questions of their HIV medical specialist if they are uncomfortable doing so.
- Determine if the HIV-negative partner has tried to access pre-exposure prophylaxis (PrEP), and assess any barriers they have encountered.

Addressing some of these issues may be beyond the scope of HIV counselors and may involve linking the client to outside services. This emphasizes the need for agencies to maintain updated referrals lists with, among others, AODA, mental health providers, and HIV medical specialists. (See Section 5: Referral). Counselors should also be aware that in some instances, the desire, motivation, and ability to make changes can be a long, incremental process. In other instances, people will not want to or are not ready to make any changes. In these circumstances, the counselor should provide information, risk reduction counseling, and referrals to the degree and at the pace that the client is willing to accept.

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. However, if the parent indicates that 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 specimen from a child.
Adolescents and teens determined by a counselor to be of sufficient maturity (understand what the test is and the implications of testing) to provide informed consent for testing should be offered counseling and testing services.

Obtaining Written Informed Consent

Wisconsin statute requires that individuals provide verbal consent for HIV testing. 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.

Despite this change in law, the Wisconsin AIDS/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. In the case of anonymous testing, the client would initial on the consent form.

The reasons of requiring written informed consent at the majority of CTR sites are:

- The CDC recommendations are intended for health care settings and meant to increase HIV testing in such 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 acceptance cannot be documented as required in the statutes. The written consent form documents the client’s acceptance of testing, particularly in a non-medical setting.

Discussion points when obtaining consent

Prior to obtaining consent, the counselor should provide the client the following information, much of which is on the back of the consent form (see Section 7, p. 7.1):

- simple explanation of the test - benefits and limitations - and the meaning of test results,
- reporting requirements for positive HIV test results,
- procedures for obtaining test results,
- importance of, and availability of HIV specialty medical evaluation and treatment,
- availability of PS and various options for informing partners of potential exposure,
- availability of HIV specialty case management and other supportive services.

As part of the process for obtaining written informed consent, counselors 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; and,
• ensure individuals electing to be HIV tested sign or initial/write their code and date the consent form.

Exceptions to obtaining written informed consent:
Clinical CTR sites, such as STD 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 to the CTR Coordinator an updated testing protocol reflecting this change.

Clinical HIV test sites that adopt oral 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 infection, HIV test results, requirements for reporting HIV infection, and services provided to those who are infected. (The Wisconsin AIDS/HIV Program has developed a patient fact sheet to satisfy this requirement. See Section 7, pp. 7.9 and 7.10 for English and Spanish version, respectively).
3. notify the client that the client 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 the decision of the client 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 non-clinical testing site or through use of a written consent form supplied by the Wisconsin AIDS/HIV Program and maintaining all HIV testing documents separate from the patient’s confidential medical record(s).

Confidential and Anonymous Testing
Confidential testing uses the client’s name on the consent form and lab result, 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 AIDS/HIV Program expects that most tests will be conducted confidentially. Confidential testing makes it is easier to locate individuals who test positive but fail to return for their
final results, conduct follow-up on referrals to HIV specialty services, and eliminates the need for re-testing when a person is linked with medical evaluation and care.

Anonymous testing does not use the client’s name but uses the unique client code on the consent form and lab result. 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 AIDS/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.

*Expectations for Recommending Confidential Testing*
CTR and PS 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 testing anonymously with rapid reactive results 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. These benefits include:

- receiving a test result with their name. This is particularly beneficial for clients who want to identify their HIV status to their partners. The client should be aware that this result is only as good as their last risk exposure.
- streamlining access to medical evaluation for clients testing positive
- serving as a verification of status for persons testing positive to access case management and other specialty services and programs
- helping their community by allowing a better understanding of which groups are most affected in order to direct funding and develop programs to address community needs.

Counselors 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 Partner Services 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/ethnic groups may have similar concerns as well as concerns over trust of government-associated agencies. These may include concerns over immigration status. The chief concern of all clients may be others in their social circles somehow learning their status. This may be particularly true of minority groups as they often have more closely associated social networks.
Counselors should provide anonymous testing only if the client is unwilling to get tested with their name.

**Points to Discuss with Confidential Testing**
When testing someone confidentially there are three points that should be discussed. These points are related to each other:
1. reporting requirements for positive test results
2. contact with the LHD’s Partner Services staff
3. availability of HIV specialty services for persons who test positive

There are several ways counselors may explain the above three points, depending upon the client’s knowledge and literacy, level of anxiety, and risk behavior. Some clients who are anxious or are at high risk for infection 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.

**Points to Discuss with Anonymous Testing**
When testing someone anonymously, there are five points that counselors should discuss.
1. need to return in person for test result at the appointed time
2. barriers to returning for test results and methods to contact the client while maintaining their confidentiality
3. availability of Partner Services
4. if result is positive, the need to test confidentially in order to access medical evaluation and other services
5. HIV reporting of test results once HIV specialty services are accessed

There are various ways counselors 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. Counselors should be prepared to offer a detailed description of available services, particularly when testing persons at high risk for infection or partners of persons with HIV disease.

**Additional Recommendations**
CDC promotes additional recommendations for persons accessing HIV testing. Test counselors should include the following recommendations when providing prevention counseling with clients:
- **HIV testing for sexually active MSM twice a year.** Assess whether sexually active MSM are receiving bi-annual testing, identify the benefits of regular testing, and assist the client in developing a plan to be tested twice a year. (e.g. timing HIV testing with other regular screening tests, timing testing to coincide with daylight savings changes in fall and spring, supplying MSM with a list of items they should discuss with a health care provider, etc.).
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- **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 active people who inject drugs (PWID):** Assess whether active recreational drug users receive annual testing, identify the benefits of annual testing, and assist the client in developing a plan to be tested annually. Have referral systems in place for hepatitis C testing.

- **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 years of age 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.

**Scheduling a Post-Test Appointment**
Counselors 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 7-10 days after their initial visit. The counselor 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. The counselor may want to complete a “Client Locator Information” form with the client to help with this planning. (see Section 7, p. 7.13)

Some individuals may be anxious during the waiting period while they are waiting for their result. Counselors should assess each client’s ability to cope with the wait and provide, as appropriate, the telephone numbers of support/resource persons (e.g., Wisconsin HIV/STD/Hepatitis C Information & Referral Center; CTR counselor phone number) they can contact in the interim.

Information regarding the various HIV tests used in the CTR program - including specimen collection and processing - is in Section 4: “HIV Tests and Procedures.”

**The Post-test Counseling Session**

**Components of Post-Test Counseling**
The meeting when the CTR counselor provides HIV test results to the client is called the post-test counseling session. This session may happen on the same day as the pre-test
session for rapid tests, and 7 to 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
- Renegotiate or reinforce the existing plan for reducing risk, as appropriate

**Notification of HIV Test Results and Follow-Up Prevention Counseling**

Providing HIV antibody test results to a client involves:

1.properly interpreting the test result based on the client’s specific risk for HIV
2.addressing the client’s reaction to their test result.

Because the client will most often focus on the result, client-centered counseling is particularly important during the follow-up session to reassess behavioral risk that may influence the interpretations of the result. The primary purposes of this counseling session are:

- reinforcing the perception of risk for those who are unaware or under-informed;
- assisting HIV-negative persons to initiate or sustain changes that reduce risk of acquiring HIV;
- facilitating access to necessary medical, case management, and prevention services for persons with a positive test result;
- assisting people living with HIV in reducing transmission risks and remaining healthy; and
- supporting people living with HIV in notifying their partners and referring them to testing.

Prior to the counseling session, the counselor should review existing client risk assessment and any counselor notes from the pre-test appointment. In the majority of circumstances, results should be provided in person. Providing results in person provides an opportunity for the counselor to:

- ensure that the appropriate individual is receiving the result;
- ensure that the client understands the test result;
- interpret the result for the client based on their risk for HIV;
- renegotiate/reinforce the risk reduction plan developed during the initial session

And, particularly for HIV-positive results:

- determine how the client is coping with the result;
- address immediate emotional concerns;
- facilitate needed referrals for follow up medical care and other HIV specialty services.

Interpretation of HIV test results depends upon the timing of the client’s risk activities, and the type of test that was conducted. Some recently infected clients may have a negative test result if the test was conducted too soon after the risk exposure to identify infection. If this is the case, the counselor should recommend repeat testing.
Providing Test Results by Phone
In their Revised Guidelines for HIV Counseling, Testing and Referral guidelines (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm), the CDC notes that many clinicians routinely notify clients of negative test results for various diseases and conditions by telephone or through the mail. They also noted that clinicians “ask clients to return to discuss positive test results that might indicate potential life-threatening illnesses.” The guidelines stress that providing HIV test results in person is important for person with a positive result or who has a negative result but is at high risk for HIV. The guidelines acknowledge, however, 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.

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.

Failure to Return For Results
There are a variety of reasons why persons do not return for their result. The individual may have simply forgotten, the clinic hours may be inconvenient or incompatible with his/her schedule, or he/she 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, counselors should discuss at the initial, pre-test, session:
- client’s 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 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 CTR staff are unable to locate a client, local PS staff will attempt to locate them to provide the test result and offer them services. CTR staff should report the case to the AIDS/HIV surveillance program, indicating that the client did not return for their result. Surveillance staff will provide this information to the state PS coordinator, who will provide this to local PS staff.

Agencies should develop policies and procedures identifying how they will develop plans 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 clients testing anonymously.
Repeat Testing for HIV Positive Clients
In some circumstances, a repeat test for a person with a confirmed positive result is warranted:
- to confirm a first-time positive result—however, this confirmation can be done at the client’s first medical visit and does not need to be done at the CTR agency;
- when the positive result is inconsistent with the client’s risk history, or
- the client is unable to accept their positive result and a repeat test might ease their adjustment to their HIV positive status and the need to access medical care.

Referrals and Referral Follow-up for HIV Positive Clients
Prior to closing a post-test counseling session with clients testing positive, the counselor should arrange for referrals for the client and develop a follow-up plan. Details regarding referrals and follow-up are in Section 5.

The time and method of a follow-up appointment should be mutually agreed-upon between the counselor and client. Ideally, follow-up regarding the referrals made should be done in-person. If this is not a practical option for the client, arrangements for telephone follow-up can be made. If telephone contact is arranged, the counselor:
- provides a contact number and sets a specific date and time the client can call the counselor; or
- arranges to call the client at a specific phone number on a specific date and time

The counselor should also review the following points with the client when arranging telephone follow-up:
- whether to block caller ID
- whether to leave a voicemail or answering machine message
- whether to identify self or agency if leaving a message
- whether to identify self or agency if another person answers the phone.
- method to determine counselor is speaking with the right person.
All of these points are identified on the Client Locator Information Form in Section 7.

The referral follow-up session provides a variety of opportunities:
- to serve as the primary referral session if the client needs time to consider referral options, was not prepared to discuss referral at the initial post-test session, was under time constraints, or otherwise did not feel comfortable addressing referrals during the initial post-test counseling session.
- to assess and document referrals completed and referral outcomes.
- to assess and address barriers to referrals not completed.
- to assess and address additional referral needs.

Details regarding referrals and follow-up are in the Section 5 of this protocol.
4. HIV Tests and Procedures

Types of HIV Tests
There are several types of HIV tests:
- Laboratory-based antibody or antibody/antigen tests that require a specimen to be sent to a laboratory for processing.
- Rapid antigen/antibody tests that allow an initial test to be run at a testing site ("point-of-care"), and require further laboratory testing only if the initial test result is reactive.
- Laboratory-based tests that detect viral genetic material, not antibody, and are effective at detecting HIV in the very early stages of infection.

In addition to the different types and methods of testing, tests may use different specimen types such as whole blood, oral fluid, plasma, or serum.

The AIDS/HIV Program uses tests within all of these categories:

- **Antigen/Antibody Testing (Ag/Ab):** this refers to a test that identifies both HIV antigen and HIV antibodies in a blood specimen. Antibodies are proteins produced by the body to fight specific viruses. Antigens are proteins produced by the HIV virus that are detected early in infection. At Wisconsin CTR sites, a blood specimen is sent to the Wisconsin State Laboratory of Hygiene (WSLH) to test the specimen for HIV antigen and antibody. If the test is positive, the laboratory tests the specimen with another antibody test - the Geenius HIV 1 and 2. If this test is positive, the client is considered infected. If this test is negative, the laboratory will test the same specimen with a DNA PCR test to identify whether the client is in acute or early infection.

- ** Antibody testing for oral specimens:** An oral fluid specimen is collected and sent to a laboratory to identify HIV antibodies. The specimen is first tested with an enzyme immunoassay (EIA). If this test is reactive, the specimen is then tested with a Western blot antibody test. If this test is positive, the client is confirmed to be infected with HIV. If the Western blot is negative, the client is considered uninfected unless the client has had a recent risk exposure.

The period between the time of infection and when a test is capable of identifying infection is called the "window period". For the antibody test, the window period can be as much as 3 months after exposure, although some individuals will test positive earlier. Clients who have risk within the 3 months previous to a negative result should be re-tested.

- **Fourth Generation Rapid antigen/antibody testing:** this refers to antigen/antibody tests that can be run easily, quickly, and on-site, without the equipment or expertise of a dedicated laboratory. Rapid antigen/antibody tests are considered as screening tests. If the rapid result is negative and the client has not had risk exposure in the past 1 month, the client is not infected with HIV. If the test is reactive, this result must be confirmed by collecting another specimen to be sent to the WSLH for further testing. There are rapid tests available that use either whole blood or oral fluid specimens.
Section 4: HIV Tests and Procedures

- **DNA PCR testing:** this refers to tests that identify the HIV viral nucleic acid rather than antibody. It is in a classification known as nucleic acid amplification tests (NAAT). The AIDS/HIV program uses the DNA PCR to identify acute infection very soon after exposure and before antibody tests are effective.

The following sections go through basic testing information related to the WSLH and protocols for the various types of HIV tests. Each test section will cover information regarding specimen collection and processing, and provide additional information related to counseling messages and referrals specific to that HIV test.

**Testing and the WSLH Services**

All CTR sites, except for Milwaukee Health Department’s Keenan Central Health Clinic, must send their testing specimens to the WSLH for testing. This testing is supported financially by the State and is not charged to individual agencies providing CTR.

**Registering Agency Contacts for WSLH**

Each testing site is required to register two staff persons with the CTR Coordinator as primary contacts who are authorized to order HIV testing of specimens sent to WLSH. Only these contacts can order HIV tests, receive test results, order testing supplies from WSLH, and request test results. If contact persons change at a site, the HIV CTR Coordinator must be notified either in writing or through an e-mail message. The CTR Coordinator will update the WSLH of the change. This procedure must be followed to maintain confidentiality since the WSLH staff cannot distinguish over the telephone whether a CTR provider or client is requesting information on a test result. Agencies should not establish or update agency contact names directly with the WSLH.

**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 specimens 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 AIDS/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 relating to shipping and processing specimens may be directed to the WSLH Retrovirus Laboratory at 1-888-494-4324 or 608-262-2366. All calls or questions related to interpretation of tests results and missing test results should be directed to the CTR Coordinator at 608-261-9429. If the CTR Coordinator is unavailable and you need a laboratory result, a staff member at your agency authorized to receive test results may contact the laboratory directly at 608-262-2366.
4A. Antigen/Antibody Testing with Blood Specimens

The Abbott Diagnostics HIV Ag/Ab Combo test is the first FDA-cleared test that detects both HIV-1 p24 antigen and HIV-1 and HIV-2 antibody simultaneously in the same test. HIV-1 p24 antigen 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 infection. Because of this, the Ag/Ab test can identify a client who is in acute HIV infection - the initial stage of infection prior to antibody response (see p. 4D.1 “What is Acute HIV Infection?). 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 infection. To test a client, the counselor draws a tube of blood from the client and sends it to the WSLH.

Specimen Collection and Submission to the WSLH
To send a specimen to the WSLH, sites can use WSLH Kit #22P. This kit contains an EDTA tube (lavender top), Styrofoam mailer, cool pack, specimen bag, absorbent, and shipping labels. For sites that conduct a high volume of tests, all of the components of the test can be ordered in bulk from the WSLH. Supplies are available from the WSLH at no charge and can be ordered by calling the WSLH at 608/265-2966 or 800/862-1088.

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.
- 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 “Blood HIV Screen – Ag/Ab (SS00099).” This is necessary to properly bill the test.
- The specimen tube should be labeled with a Test ID sticker and the Unique Client Code, 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. The WSLH has a label for the Retrovirus Laboratory or the mailer can be addressed to:

  Attention: Retrovirus Laboratory  
  Immunology Section  
  State Laboratory of Hygiene  
  2601 Agriculture Drive  
  Madison, WI 53718

Results are generally reported back to sites within 7-10 days depending on the agency location and the length of time it takes for specimens to reach the WSLH. Post-test
Section 4A: Antigen/Antibody Testing with Blood Specimens

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 site.

HIV Testing Algorithm
Specimens that are negative on the HIV Ag/Ab combo test are reported by the WSLH as “Non-reactive -HIV p24 Ag and HIV-1/HIV-2 Ab not detected.”

Blood that is initially reactive in the HIV Ag/Ab combo test will be tested again by repeating the Ag/Ab combo test in duplicate.

- If at least 2 of the 3 Ag/Ab tests are reactive, the Geenius HIV 1 and 2 antibody test will be performed.
- If the Geenius test is reactive, the result will indicate whether the result is positive for HIV-1 or HIV-2.
- If the Geenius test is negative, a DNA PCR will be conducted to determine if the client is in acute or early infection.

Meaning of HIV Test Results

Negative Result: - Specimens are considered negative if the Ag/Ab combo test is non-reactive. If the client engaged in risk behavior less than 1 month from the date of the test, the client should test again 1 month after their last exposure to be certain that he/she is not infected.

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 Ag/Ab result is repeatedly reactive,
- the Geenius HIV1/2 is non-reactive or indeterminate, and
- the DNA PCR is reactive.

This set of results indicates that the client has been recently infected (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.
Section 4A: Antigen/Antibody Testing with Blood Specimens

Laboratory HIV Testing with Blood

START

Ag/Ab

Positive

Negative

STOP

Positive for HIV-1 or HIV-2

Geenius Ab HIV 1 and 2

Negative

Positive

Acute Infection

DNA PCR

Negative

STOP

STOP

STOP

STOP
4B. Rapid HIV Testing

All rapid HIV tests are screening tests. A reactive result on a rapid test must be confirmed by supplemental tests. A non-reactive result is interpreted as negative and means that the client is either not infected with HIV or it is too early to find out if infection has occurred. If the client has had a risk exposure within the last month, the rapid HIV antibody test should be repeated one month after exposure.

The Wisconsin AIDS/HIV Program is currently using one rapid test: Alere Determine HIV-1/2 Ag/Ab Combo. The following protocol has a section that addresses how to use this test.

Program Requirements
In order to provide rapid HIV testing, sites must meet the following requirements (a listing of core requirements is at the end of this section):

1. **Compliance with all government and regulatory requirements including the Clinical Amendments Improvement Act of 1988 (CLIA) and Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standards.**

**CLIA Requirements**
The rapid tests used by the Wisconsin AIDS/HIV Program are classified as “waived” by the FDA when used with whole blood or oral fluid specimens. 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 and Medicaid Services website at www.cms.gov/clia/. Staff in the Clinical Laboratory Section of the Wisconsin Division of Quality Assurance (see below) are also available to answer questions.

The CLIA application should be mailed to:
Clinical Laboratory Section  
Division of Health Services  
1 W. Wilson  
PO Box 2969  
Madison, WI 53701-2969  
Phone: (608) 261-0653

When submitting the application, please add the e-mail 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.
Section 4B: Rapid HIV Testing

OSHA Requirements
All sites must also adhere to the Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens standard. (See: 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:

- Determination of employee exposure.
- Methods of compliance addressing exposure control (including standard precautions, engineering and work practice controls, personal protective clothing and equipment.)
- Vaccination and antibody testing for hepatitis B.
- Post-exposure evaluation and follow-up.
- Communication of hazards to employees.
- Utilizing biohazard signs, labels, and waste disposal methods.
- Keeping of records, including a sharps injury log.
- 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/communicable/InfectionControl/

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: 608-266-3358 (telephone), docsales@doa.state.wi.us (E-mail), http://www.doa.state.wi.us/dsas/docserv/docsales (Internet web site).

For additional technical support and resources, agency staff may contact the HIV CTR Coordinator at 608-261-9429 or at the e-mail address provided in the contact list. These resources include:

- Policies and procedures related to bloodborne pathogen exposure control.
- A sample sharps injury log.

2. Establishment of policies and procedures describing all steps in the performance of the test, including description of site flow and activities in the various settings where the test is performed.
This protocol may serve as an agency’s basic policies and procedures related to rapid HIV antibody 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 where agency staff conduct testing.

The following policies and procedures must be in place:

- Provision of pre-test counseling information related to providing client information regarding 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 testing steps and activities in both in-house and outreach settings.
- Collecting a specimen
- Performing steps in the test procedure and reading results
- Performing quality control testing and identifying what to do when controls fail
- Participating in external quality assessment (proficiency testing) as required
- Reporting results
- Specimen collection and submission for confirmatory testing
- Documenting client and control test results
- Post-test counseling and provision of referrals
- Record review, storage, and disposal
- Troubleshooting activities – what to do when things go wrong
- Staff training, competency assessment, and documentation of training

3. **Utilization of personnel who are trained and competent in all components of rapid testing. Staff must participate in all training required by the Division of Public Health and have thorough knowledge of the package insert instructions for the rapid test prior to testing.**

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.

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

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

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 core courses or rapid testing 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.

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.

4. Compliance with all quality assurance (QA) activities detailed in the package insert and additional activities delineated by the Wisconsin AIDS/HIV Program.

All sites must ensure quality testing by:
1) Assigning a lead staff person responsible for overseeing rapid testing and all QA activities on-site.
2) Ensuring that staff participate in state-sponsored trainings and successfully complete a competency assessment.
3) Following all testing requirements detailed in the most current package insert.
4) Using external controls as required in the protocol.
5) Documenting testing process and results.
6) Recording the storage temperature of test devices and external controls.
7) Participating in a state-sponsored proficiency testing program as outlined in this protocol.
8) Communicating testing problems to the on-site lead staff person (#1 above), the WSLH, or the Wisconsin AIDS/HIV Program, as appropriate and taking action to ensure that the test is providing valid and reliable results.

Quality assurance requirements are detailed in this protocol on p.4C.13.

5. Adherence to all program record-keeping and data collection requirements.

Agency staff must document all testing processes, including receipt of inventory; storage temperature of tests and controls; and details related to conducting clinical tests and external controls.

Data related to rapid testing must be completed on EvaluationWeb Form 2: Testing Information.
## Core Requirements for Rapid HIV Testing

The requirements for rapid HIV testing described in the previous section (#1-5 under Program Requirements) are listed with more detail below under the following categories.

### Laboratory and Bloodborne Pathogen Requirements
- Valid CLIA certification for conducting waived tests
- Refrigeration to store controls, and provision for monitoring refrigerator temperatures (Per bloodborne pathogen standards – the refrigerator must not store food or beverages)
- Compliance with blood borne 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 standard precautions
  - 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 & follow-up - to be kept for duration of employment + 30 years
  - Training records to be kept for 3 years from the date of training
  - 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
- Procedures describing activities and flow in various settings where testing is performed
- 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 or oral fluid) to confirm reactive rapid tests.
- Participation in the State’s QA activities and compliance with its QA plan
- Referral systems for reactive rapid results
Section 4B: Rapid HIV Testing

Staff Training and Quality Assurance Requirements
- Prior attendance at Wisconsin AIDS/HIV Program core courses, including the HIV Counseling, Testing and Referral training
- Attendance at Wisconsin AIDS/HIV Program training regarding rapid HIV testing and counseling
- Competence in conducting fingerstick blood draws
- Thorough knowledge of and adherence to package insert instructions for the rapid test
- Successful completion of a competency assessment by testing samples and accurately reading the results prior to testing clients
- Successful test administration and interpretation of test results for both positive and negative controls prior to testing clients
- Agency participation in the state proficiency program to assure staff competency in testing.

Record-Keeping Requirements
- Maintenance of testing logs for a minimum of three years. Logs with personal identifiers on them must be shredded.
- Maintenance of temperature and inventory logs should be stored for two years
- Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up to be kept for duration of employment, plus 3 years
- Training records to be kept for 3 years from the date of training
- Sharps Injury Log
Agency Flow of Services
Rapid HIV testing may not feel “rapid” to the client being tested. Since the pre-test counseling, specimen 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 AIDS/HIV Program does not encourage adopting this practice, except in special circumstances.

Rapid testing typically requires more personnel for conducting the same quantity of tests since agency staff must now do the testing 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 non-reactive (negative) results.

Rapid Testing in Non-Traditional or Outreach Settings
The Wisconsin AIDS/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 Testing Site Log (a sample of this form is at the back of the Determine section of this protocol). Test kits should be stored during transport and prior to testing 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
Section 4B: Rapid HIV Testing

the area where testing is performed. Staff should set up their workspace as recommended under “Testing Steps” in the Determine section of this protocol.

The psychosocial conditions associated with rapid testing in non-traditional settings are as important as the above technical conditions. Agency staff must maintain the following conditions to assure that clients who are being tested are able to receive their result in a confidential and emotionally supportive setting.

- **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, prevention, 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 non-reactive 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 possible HIV infection. 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.

Pre-test Counseling with Rapid Tests
Additional information that should be discussed during pre-test counseling when offering a rapid HIV test is:

- The differences between laboratory-based testing and rapid testing.
- Procedures related to each of the testing options – how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat testing.
- Relevant information regarding the “window period” i.e. the time between possible exposure to the HIV virus and when the test is likely to identify HIV infection. Some clients mistakenly believe that the term “rapid test” refers to identifying infection rapidly – that the test can accurately determine whether a risk exposure last night resulted in infection today. Staff must be clear that rapid HIV testing only refers to obtaining results rapidly, and should explain that the Determine rapid HIV test can detect infection that may have occurred prior to one month ago. If a client believes a possible infection occurred more recently than one month ago, the counselor should suggest re-testing in one month.
- The difference between acute (or early) infection and established infection. Since the Determine Ag/Ab rapid test and the conventional laboratory test can both detect a potential acute infection, the client should understand what it would mean if they are in the early stages of HIV infection, and the importance of being linked into care as quickly as possible.

If the client decides to be tested with a rapid test staff should:

- Provide the client with the “Subject Information” pamphlet supplied by the manufacturer.
- Ensure that the client understands the meaning of test results, including that a reactive result requires that confirmatory testing be performed immediately.
- Assess client’s potential reaction to receiving a reactive rapid test. Staff might ask “How would you feel if this test comes back reactive today? What would you do?” This discussion will help staff understand and plan for the client’s support needs if their test result is reactive.
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 non-reactive.

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 to cope 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 are infected with HIV, regardless of how the staff person describes this 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 reacted. 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 indicate HIV infection – 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 infection.
Staff should provide the client with written documentation of their result (see p. 4C.33 and 4C.34).

2. **Explain confirmatory testing**: A specimen for supplemental laboratory testing should be obtained immediately. If possible, a blood specimen should be drawn.

   Supplemental test results should be available from the WSLH within one week.

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 provision of 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.

4. **Discuss what client intends to do during waiting time, including disclosure issues**: 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 he/she is truly HIV infected.

5. **Encourage 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 transmitting the virus to others. This includes examining the client’s possible risk behavior during the waiting period 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 be a support to the client by phone or in
Section 4B: Rapid HIV Testing

person. In addition, the client may need referrals to a mental health counselor, risk reduction specialist, or crisis line. Staff should assess the need for referrals based on the steps defined in the *HIV Counseling Skills* and the *HIV Counseling, Testing, and Referral* training courses and in this protocol.

Staff should also mention the services that are available to them if their confirmatory test is positive. A brief description of Partner Services, as well as access to medical evaluation and care, case management, risk reduction counseling, legal services, and the drug reimbursement or health insurance programs should be provided.

**Non-reactive results:**
The following information should be covered when counseling someone with a non-reactive result:

1. Interpret the result and discuss possible need for re-testing.
2. Assess need for referrals.

1. **Interpret the result and discuss possible need for re-testing:** A non-reactive 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 a re-test one month after their last exposure.

2. **Assess need for referrals:** Staff should assess for additional services needed by the client, such as AODA treatment, economic assistance, domestic violence services, housing, STD testing and treatment, and hepatitis vaccination and testing in accordance with CDC guidelines.

**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;
- devices and controls are used prior to expiration;
- the agency has sufficient test devices and controls to provide efficient services to clients; and
- 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 at 608-261-9429 or the HIV Testing Technology and Policy Specialist at 608-267-3583. Either of these contacts 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 AIDS/HIV Program through the Wisconsin HIV/AIDS Training System:

- HIV Basic Facts
- HIV Counseling, Testing, and Referral New Provider Training

The lead QA staff person should assure that staff is competent in rapid testing procedures by observing them in the various steps required for conducting a rapid test, (see Training Checklist at the end of the Determine section).

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 fingerstick collection of whole blood specimens. The Wisconsin AIDS/HIV Program will provide opportunities for training on bloodborne pathogen control and fingerstick specimen collection, as needed. It is the responsibility of the agency to assure that staff are proficient and are using standard precautions. To comply with OSHA standards, the agency should document training of staff in bloodborne pathogen control and fingerstick specimen collection. All relevant training and results of competency assessment should be documented in the personnel file.

**Competency Assessment**

At the completion of Wisconsin AIDS/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 AIDS/HIV Program recommends that the lead QA person at each agency complete the training checklist (see Training Checklist at the end of the Determine section) to assure that staff accurately conduct rapid HIV testing. Lead QA staff should observe the newly trained staff when initially conducting rapid testing with clients.
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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 AIDS/HIV Program enrolls sites in the WSLH PT Program, and pays for its cost. Staff at the agency test the specimens 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 staff person who tested and interpreted each specimen. 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 AIDS/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 an important tool to maintaining quality testing. Please refer to the details of how to use each test’s controls in the specific Determine section of this protocol.

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

1) Testing Log – documentation of key information related to each specimen 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. 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:
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- Date of test
- Test ID number and client 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 non-reactive
- 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 specimens 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 p. 4C-40 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. Staff must try to answer the question “What went wrong?” 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 specimen 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 e-mail 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.
The Test Was Invalid...Now What?

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 the test device properly seated?
   ___Was the buffer solution added to the test device?

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. If a client specimen was used and the second test is also invalid - run a set of external quality controls.

5. If the control tests come back invalid, discontinue testing. Report the problem to the test manufacturer, (Alere – 1-800-257-9525) and to the HIV CTR Coordinator (608-261-9429).

6. When the invalid result is not due to human error, the agency should contact the manufacturer’s technical services department to report the invalid result.

On the next page is a process for evaluating when external controls fail.
The External Quality Controls Failed…Now What?

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 the controls brought to room temperature prior to use?
   ___ Was the test 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 devices labeled correctly? (i.e. positive on a positive control and negative on a negative control)?
   ___ Was the buffer added to the test device?

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. If the problem resolves with the second set of controls, dispose of the first set of controls.

5. If the problem remains with the second set of controls, contact the test manufacturer, (Alere – 1-800-257-9525) and the HIV CTR Coordinator (608-261-9429).
Record Review
The lead QA staff person 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 AIDS/HIV staff will review testing documentation (testing logs, temperature logs, etc.) of grantee agencies at annual site visits.

Record Storage and Disposal
Testing logs should be stored in a three ring binder or folder. The logs should be stored in chronological order. Logs should be stored for three years, and then disposed. If the logs have patient identifiers on them, the logs must be stored in a locked file cabinet in a locked room.

Completed informed consent forms should be stored for three years. Name-associated forms should be stored in a locked file cabinet in a locked room.

Temperature and inventory logs should be stored for two years, and then disposed.

For disposal, records with patient identifiers should be shredded. Otherwise, records may be disposed of in trash or recycling containers.

Obtaining Devices and Controls
Agencies should contact the HIV CTR Coordinator at 608-261-9429, or through e-mail 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.

Staff should maintain an Inventory Log documenting the following (see “Documentation” section on p. 4C-16):
- shipments receipt dates of test kits and controls
- lot numbers
- expiration dates
- when devices from the box were first used

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.
Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test

Introduction
Testing with the Determine HIV-1/2 Ag/Ab Combo test consists collecting a small amount of fingerstick 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 - 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 fingerstick 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 fingerstick whole blood samples. This means that the test correctly identified 99.9% of the people in the trial who were HIV infected, and 99.8% of those who were not infected with HIV-1. Determine is unique compared to other rapid tests because it is capable of identifying 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 is in acute HIV infection.

Some individuals who are not infected with HIV will have reactive results on 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 infected with HIV and taking highly active antiretroviral therapy (HAART) 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 AIDS/HIV Program:
- Aluminum ziplock package containing Alere Determine™ HIV-1/2 Ag/Ab Combo 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
- Chase Buffer: 1 in the 25 test box; 2 in the 100 test box.
- Disposable capillary pipettes: one pipette for each test in a box.
- Disposable workstations: one workstation for each test in a box.
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- Quick reference card
- Package insert
- Subject information notices: one notice per each test in a box.
- Customer letter

The AIDS/HIV Program also provides Alere 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 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 fingerstick 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 which 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°C and 86°Fahrenheit.
- Operating temperature (temperature during testing) 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 AIDS/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 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 ziplock package. Tear four tests off of the right side of the card. Return the rest of the tests to the ziplock package and close.
2. Remove the protective foil cover from each test and place it 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 in the pipette provided with the controls.
5. Hold the pipette vertical above the sample pad, approximately one-half inch above the pad. Squeeze one drop of buffer 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 “Troubleshooting” p. 4C.17).
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External controls shall be run under the following circumstances:
- When a staff person has been newly trained to use Determine, prior to testing client specimens.
- When opening a new test kit lot.
- 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°F.
- 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 *Determine Testing Log*. If more than one box of tests are being used simultaneously in an agency, staff must run controls on each box. External controls do not need to be run in different outreach locations provided the testing temperature conditions have been met.

Controls expire two years after production.
- 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 “Troubleshooting” on p.4C.17).
- 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 at 608-261-9429 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 is marked on the outside of the box and on the test packages. External quality controls expire two years after production.

**Ensuring Proper Temperatures for Tests and Controls**
Tests must be stored between 36°-86°F 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°-46°F 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 “Determine HIV Testing Log” at the end of this section).
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.

Remember...
- Run a set of external controls if the storage temperature falls outside of the proper range for the tests.
- Run controls on tests that have been kept at the proper temperature if storage temperature falls outside of the proper range for the controls.
- Dispose of the tests or controls in question if the expected results are not obtained.

Testing Steps for Conducting the Determine Rapid Test
Below is a summary of the required steps for conducting a Determine test with a fingerstick whole blood specimen. The package insert provides detailed instructions. The “Alere 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 or ziplock package and revision date of the package insert on the Determine Testing Log.
3. Check expiration date on the box or ziplock package. 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 ziplock package. Tear the test off of the right side of the card. Return the rest of the tests to the ziplock package and close.

NOTE: Store the unused cards and test units only in the aluminum ziplock package containing the desiccant. Carefully close the ziplock, so that the cards are not exposed to ambient humidity during storage.

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 workstation is optional.
8. Write the client’s unique client code on a Test ID sticker. Label the workstation or back of the test with the Test ID sticker.
9. The test should be initiated within 2 hours after removing the protective foil cover.
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10. Do NOT touch the Sample Pad with your fingers. Dispose of the test if the pad is touched.

**Fingerstick Blood Collection:**
1. Use the disposable capillary pipettes included in the test box to collect the specimen.
2. To increase blood flow, encourage the client to rub their hands downward 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 at the last joint 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 to the last joint (not to the end of 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 mark 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. Doing so may cause air-bubbles to develop, preventing the complete transfer of the sample.
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 20-30 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 specimen. 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 is in acute HIV-1 infection. In this case the acute HIV-1 infection is distinguished from an established HIV-1 infection in which antibodies to HIV-1 are present. Please contact the HIV CTR Coordinator at (608) 261-9429 to report an Antigen 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 Alere 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 lines 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 non-reactive – 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 determine that the test was conducted properly (see “Troubleshooting” p.4C.17). 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 at 608-261-9429. If the invalid result is not due to human error, contact the manufacturer, Alere, 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 and Unique Client Code/initials on the test. Be certain that it matches with the person to whom you are about to give results.
2. Complete documentation on the Determine 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" (see pp. 4C.31, 4C.32) 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.

4. Place a checkmark next to the appropriate paragraph indicating whether the result was non-reactive or reactive.

5. 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 HIV infection.

CTR staff should draw one EDTA tube (lavender top) of blood to send to the WSLH. The tube should be mixed by inverting at least 8-10 times and should not be centrifuged.

The specimen should be sent to the WSLH with the Laboratory Requisition form. The date and time of specimen collection should be recorded on the form, and the specimen type should be identified as "EDTA whole blood." Under the section labeled "Rapid Test Confirmation" check the box labeled, "Blood HIV Screen- Ag/Ab (SS00099)." Also, check whether the Determine test was reactive for antibody, antigen, or both.

The blood specimen will be confirmed with the standard laboratory algorithm, testing the specimen with the laboratory Ag/Ab test, and if needed, the Multispot and DNA PCR. Specimens that have a positive final result on confirmatory testing indicate that the client is infected with HIV, and is either in acute or established infection depending on the results. Specimens that have a negative result indicate that the client is not infected, and instead had a false positive result on the Determine test.
Section 4B: Rapid HIV Testing

Rapid HIV Testing Algorithm

START

Determine Rapid Ag/Ab Test

Negative ⇒ STOP

Reactive

Obtain one EDTA tube of blood

Laboratory Ag/Ab

Negative ⇒ STOP

Positive ⇒

Geenius Ab HIV 1 and 2

Negative ⇒ DNA PCR

Positive for HIV-1 or HIV-2

Established Infection

STOP

Positive for HIV-1

Acute Infection

STOP

DNA PCR

Negative ⇒ STOP

STOP
Section 4B: Rapid HIV Testing

Smith HIV Testing Agency
111 Main Street
Hereandnow, WI 53704

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

Determine Rapid HIV Test Result

Date of Determine test: _____________________________
Client Name or Code: ______________________________

_____ Non-Reactive/Negative.
You do not have HIV infection or you have been exposed too recently to find out if infection has occurred. 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 are not infected.

_____ 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 infection. A blood specimen 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 are infected.

If you have any questions regarding your test result, please contact the person at the phone number listed above.
Section 4B: Rapid HIV Testing

Sixteenth Street Community Health Center
HIV Outreach Center
437 East Lincoln Avenue
Milwaukee, WI 53207

Para más información llame a
Maria Garcia
414-810-9541

Resultado de la prueba “Determine Rapid” para el VIH

Fecha de la prueba: ____________________________

Cliente/a - Nombre o código: ____________________________

No-Reactivos/Negativos. 
Usted no tiene la infección de VIH o se ha expuesto recientemente y todavía no se puede saber si se ha producido la infección. Si ha tenido el riesgo de exponerse al virus en los últimos 30 días, usted debe repetir la prueba en un mes después de su última exposición para asegurarse de que no tiene la infección.

Positivos Preliminares para los anticuerpos VIH-1 y/o VIH-2 y/o antígeno p24 de VIH-1.
Se requiere una prueba de confirmación para determinar si usted tiene la infección del VIH. Una muestra de sangre se enviará hoy para la prueba de confirmación y los resultados de esta prueba estarán disponibles en una semana. Mientras espera los resultados confirmatorios, no tenga relaciones sexuales sin protección ni comparta agujas con otras personas en caso de que usted tenga la infección de VIH.

Si tiene alguna pregunta acerca del resultado de la prueba, por favor llame a la persona de contacto que aparece arriba.
**Section 4B: Rapid HIV Testing**

**Determine HIV Testing Log**

Agency: __________________________  Location: __________________________  Box ID: _______________  Date Opened: _______________

Device Lot Number (on box): ________________  Device Expiration Date: _______________  Package Insert Revision Date: _______________

Control Lot No. (on box): ________________  Control Exp. Date: ________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Testing I.D. sticker or +/- Control</th>
<th>Staff Initials</th>
<th>Temperature</th>
<th>Start Time</th>
<th>Read Time</th>
<th>Internal control valid?</th>
<th>Result*</th>
<th>Pos/Neg/Inv (if Pos: Ag+, Ab+, or Ag/Ab+)</th>
<th>Confirmatory Result*</th>
<th>pos/neg</th>
<th>Comments</th>
</tr>
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</table>

*Indicate whether positive result is Ag+, Ab+, or Ag/Ab+

**Indicate whether confirmatory positive result is Acute/Early Infection or Established Infection
## Instructions for Determine Testing Log

<table>
<thead>
<tr>
<th><strong>Agency</strong></th>
<th>Fill in name of Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td>Fill in location of testing: e.g. Smith Clinic or outreach</td>
</tr>
<tr>
<td><strong>Device Lot # and Expiration Date</strong></td>
<td>Fill in Lot Number (on pouch) and Expiration Date for the shipment of devices in use.</td>
</tr>
<tr>
<td><strong>Package Insert Revision Date</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Control Lot No. and Expiration Date:</strong></td>
<td>Fill in Lot Number (on box) and Expiration Date of most recent control performed.</td>
</tr>
<tr>
<td><strong>Date Opened and Toss Date</strong></td>
<td>At <em>Date Opened</em> fill in the date that the controls were opened. At <em>Toss Date</em> fill in the date the controls are to be disposed. (Controls expire 56 days after opening)</td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td>Fill in date of rapid test</td>
</tr>
<tr>
<td><strong>Test I.D Sticker or +/- Control</strong></td>
<td></td>
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</tbody>
</table>
- If testing a Positive Control, fill in “+ Control”  
- If testing a Negative Control, fill in “– Control”  
- If testing a client specimen, fill in Test ID number (or use sticker) and the client code or initials. |
| **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 device was placed in the developing solution. |
| **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 non-reactive Determine result – write “neg”  
- 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 Determine result – write “inv” |
| **Confirmatory Specimen 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. |
Determine Inventory Log – Test and Controls

Log each box of tests or external controls received.

<table>
<thead>
<tr>
<th>Item Received (Tests or Controls)</th>
<th>Date Received</th>
<th>Lot No #</th>
<th>Exp. Date</th>
<th>Date when item first used</th>
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</tbody>
</table>
Determine Temperature Log

Thermometer location ________________________________
Acceptable temperature range* _________________________
Month/Year ___________________

<table>
<thead>
<tr>
<th>Day</th>
<th>Initials</th>
<th>High Temp</th>
<th>Low Temp</th>
<th>Corrective action taken when temperature is out of range</th>
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</table>

* 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.

Reviewed by _____________________________________________________

Date reviewed ________________________

4B.35
### Example 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 he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

<table>
<thead>
<tr>
<th>Objective/Procedural Step</th>
<th>Date Observed by Trainee</th>
<th>Date Performed by Trainee</th>
<th>Trainee’s initial and date</th>
<th>Trainer’s initial and date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read Determine package insert and protocol.</td>
<td>N/A</td>
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<tr>
<td>Read Biohazard Exposure Control Plan.</td>
<td>N/A</td>
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<tr>
<td>Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space).</td>
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<tr>
<td>Practice test with external controls.</td>
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<tr>
<td>Give person getting tested the “Subject Information” brochure.</td>
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<tr>
<td>Label test device and appropriate paperwork</td>
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<tr>
<td>Obtain fingerstick specimen and apply specimen into test strip. Time for 1 minute.</td>
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<tr>
<td>Apply one drop of buffer on the test strip, time test, read result.</td>
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<tr>
<td>Dispose of lancet and other biohazardous waste appropriately.</td>
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<td>Record results on report form and testing log sheet.</td>
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<tr>
<td>Record internal and external quality control (QC) results on Determine testing log.</td>
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<tr>
<td>Report test result to the person being tested (one negative and one preliminary positive).</td>
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<tr>
<td>Collect specimen for confirmatory testing.</td>
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<tr>
<td>Send confirmatory test specimen to laboratory and document submission.</td>
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<tr>
<td>Receive laboratory results and record results.</td>
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<tr>
<td>Explain what to do if results of external controls show a problem.</td>
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</table>
5. Referral
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 testing HIV positive. Clients linked to HIV medical services are better able to maintain steps to reduce transmission to others and can serve as advocates for others to seek services. In addition, clients who achieve and maintain an undetectable viral load eliminate their ability to transmit HIV to a partner sexually. And, high risk persons testing negative can reduce risks of acquiring HIV if linked to supportive agency or community services.

Referral Requirements
The Wisconsin AIDS/HIV Program requires all CTR agencies to attempt to link HIV positive clients to medical evaluation and other key services, such as to 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 and to document the outcome. Although the AIDS/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; and, 3.) documenting referral outcomes. The CDC requires that HIV testing agencies conduct follow-up and document outcomes on all referrals to positive clients. Referral follow-up refers to how the counselor plans to determine if the client accessed the referral source. (see p. 5.4) Documentation of outcome refers to documenting on EvaluationWeb Form Part 2 whether the client actually accessed the referral source.

Counselors should offer to assist clients who test HIV positive in scheduling medical evaluation, linkage to care services/ case management, partner services, or other appropriate appointments. Counselors also should encourage the client to return for another appointment for additional counseling, referral follow-up, and assessment of any barriers to accessing HIV specialty services

Counseling associated with Referrals
Counselors should assess the client’s readiness to accept a referral, and identify their strengths, needs and beliefs 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 benefits to the referral without implying miracles,
  - discuss advantages and disadvantages of accessing the referral,
  - provide choices,
Section 5: Referral

- 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 should include…
- Medical evaluation, care, treatment (for both insured and under- or uninsured)
- Linkage to Care / Case Management Services
- Partner Services (PS)
- Prevention/ Risk Reduction Planning
- Reproductive Health
- Legal (often overlooked—disclosure, employment, housing issues)
- Support Groups/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
- AODA and Mental Health
- 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/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/acceptable payments
- Eligibility
• Directions, transportation information

Referral lists should be...
• provided to each staff conducting CTR
• updated annually or as needed

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 A and B vaccination and hepatitis C testing
• sexually active females up to 25 years of age for chlamydia screening regardless of symptoms

Referral to HIV Medical Evaluation and Care
Advances in medical treatment have significantly changed health outcomes for persons with HIV infection, 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 consumers testing positive to medical evaluation with a HIV 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 medical care, the counselor should...
• identify and discuss the benefits of accessing medical evaluation and care;
• inform clients testing anonymously that any link to HIV medical care will require their name and, therefore, initiate a case report;
• provide information on what happens at an initial medical visit, and;
• assist the client in determining what questions they may have of the medical provider.

HIV linkage to care specialists (LTCS) and case managers can serve as a gateway to 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 evaluation through a LTCS or case manager, the CTR counselor should follow-up with the client or LTCS /case manager to identify whether the client went to their medical appointment (see Referral Follow-up on p. 5.4).

Some clients will prefer to access medical evaluation without going through a LTCS 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
Case managers and Linkage to Care Specialists assist clients in accessing HIV medical care and other services.

- Case Managers are available throughout Wisconsin to assist clients with a wide range of issues that may be negatively impacting their lives.
- Linkage to Care Specialists (LTCS) are available only in Milwaukee and Madison, and provide highly focused, time-limited, intensive support to high risk clients to diminish barriers to linkage to 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 an LTCS first, and will be transitioned to case management as appropriate.

Whenever possible – and with the client’s consent - a LTCS or case manager should be contacted to meet with an HIV positive client at the agency after their result has been given. If the case manager or LTCS cannot be available at the post-test visit, the CTR counselor should attempt to assist the client in scheduling an appointment.

Referral to Partner Services
Partner Services (PS) is provided by local health departments to offer options to HIV positive clients to inform their sex and needle-sharing partners of their possible exposure to HIV. A PS provider meets with the HIV-infected client 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 HIV-positive clients in accessing resources for their own health and welfare and, therefore, plays an important back-up role to HIV CTR--especially if persons testing positive are not ready for referrals or lost to follow-up at the time of receiving their test result.

PS is a voluntary and confidential service. It is offered routinely to all persons who are test confidentially and are reported to the 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 the how the counselor plans to determine if the client accessed the referral source. 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. The counselor will develop an individualized plan with the client regarding options for referral follow-up.

Conducting referral follow-up provides the counselor 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 evaluation, but be hesitant or require time to think about accepting a referral to case management. At referral follow-up, the client may accept a referral to case management.

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

- **Active Referral**
- **Agency Referral**
- **Client Verification**
- **None**

The options are defined as follows:

- **Active Referral**: This option refers to when the counselor 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 an HIV case manager or PS staff person to meet with a positive client at your site.

- **Agency Referral**: This option refers to when the CTR counselor 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 (DPH F-42016 - revised 06/10) 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, a CTR counselor can contact the client’s case manager or LTCS to find out if and when the client accessed medical care and other services. Otherwise, the CTR counselor must contact the medical clinic and other referral agencies to find out when or if the client accessed these services. This data is necessary to document referral outcomes on EvaluationWeb HIV Test Template Part 2.

- **Client Verification**: This option refers to when the CTR counselor 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 counselor is the least reliable method of follow-up. Counselors 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 counselor 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. (see Client Locator Information Form in Section 7: p. 7.13)

- **None**: This option refers to client refusal for follow-up. It is the expectation of the CTR Program that all counselors 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 evaluation (either directly or through HIV case management services) than it is to insist a client allow a counselor to conduct referral follow-up if the client is hesitant to do so

**Expectations Regarding Referral Follow-up**
CTR counselors 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, counselors and agencies are expected to make a “good faith” effort to continue to 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.
6. Data Collection and Reports

In order to evaluate the Wisconsin CTR Program’s utilization and effectiveness, data on individual clients is entered into an online database called EvaluationWeb. EvaluationWeb is a web-based system for collecting and evaluating HIV prevention services data in compliance with requirements of the CDC.

EvaluationWeb allows for the Wisconsin AIDS/HIV program and contracted agencies to easily access data for process and outcome evaluation. Contracted agencies are able to create agency-specific reports that can show them their HIV CTR outcomes.

EvaluationWeb was developed and is implemented by Luther Consulting LLC.

Accessing the EvaluationWeb Website

All HIV CTR and PS sites are registered in the EvaluationWeb System by Luther Consulting LLC and the Wisconsin AIDS/HIV Program. This allows all sites, regardless of whether they submit forms to the AIDS/HIV Program for data entry or are required to enter data directly into the system, to access the website and download the data collection forms from the website home page. The website address is: http://www.evaluationweb.com. Select 'Wisconsin' from the drop down menu of choices under the 'Please select your jurisdiction to be taken to the correct login page' heading.

Accessing HIV Testing Data Collection Form

To access HIV testing data collection forms, click on the blue question mark in the upper right corner of the login page at http://www.evaluationweb.com. This will take you to Luther Consulting's Help page, where you can access quick references and user guides, as well as data collection forms. Click on the ‘Templates’ icon in the main menu of the Help page, and then locate the 'EvaluationWeb HIV Test Template' under the 'Common Templates' header to access the HIV testing data collection form.

EvaluationWeb Requirements

E-Authentication

In order to create a user record in EvaluationWeb, each individual who will be doing data entry will need to complete the E-Authentication process with the CDC. To initiate the E-Authentication process, email the HIV CTR Coordinator or the HIV Evaluation Coordinator with your name, email address, and agency, explaining that you need to be E-Authenticated in order to do data entry in EvaluationWeb. They will contact the Secure Access Management System (SAMS) coordinator at the CDC.

The SAMS coordinator at CDC will email the new user requesting access to EvaluationWeb within a few days after the initial request was made. The user can expect an email from the email address sams-no-reply@cdc.gov – do not delete this email. You may need to look in your spam or junk mail folders if you do not receive it within a week of making the initial request.
The initial email from SAMS will ask the new user to create a user account in the CDC’s SAMS portal. Once the account is created, the user will receive a second email from sams-no-reply@cdc.gov with instructions on submitting identity verification documentation, which is required for all users to access a federal database with secure information.

Counselor ID Codes
All agency testing, data entry and CTR supervisory staff are assigned a four-digit Counselor ID Code. The Counselor ID code is used on testing data collection instruments and is a required field for agencies entering data directly into the website. The counselor ID code is used when completing the pre-test and post-test portion of data collection forms and referral tracking forms.

Program supervisors should maintain a list of counselor ID codes assigned to each HIV testing staff at their agency. Please see the Registering and Updating Agency Staff section of this document for information on obtaining Counselor ID Codes.

User Names and User Passwords
All agency testing, data entry and CTR supervisory staff are also 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. Staff of sites testing fewer than 100 persons per year who mail testing forms to the AIDS/HIV Program for data entry will only be assigned a Counselor ID code, not a user name or password. Program directors should maintain a list of User Names of their staff.

Registering and Updating Agency Staff
All HIV CTR agencies should update the AIDS/HIV Program regarding staff changes. When new staff are hired, they will be assigned Counselor ID Codes and will begin the E-Authentication process. When staff leave the agency, these codes will be disabled. Under no circumstances should new staff be allowed to use someone else’s Counselor ID Code, User Name or User Password. Counselor ID codes are never reassigned to a new staff person at an agency or reassigned to a staff person leaving one agency and beginning work at another.

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 Program 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 EvaluationWeb HIV testing forms used, including:

- EvaluationWeb HIV Test Template Part 1
- EvaluationWeb HIV Test Template Part 2
- WSLH Laboratory Requisition.
Place one Test ID sticker on each of the following:
- Client consent form: Consent For HIV Testing (DPH F-43018 - revised 11/14).
- Client release of information form (if appropriate): Authorization For Release of Confidential HIV Test Results (DPH F-42016 - revised 06/10)
- HIV test specimens (blood or oral fluid) 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 e-mail or call the HIV CTR Coordinator.

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

*Fee for Service Agencies Serving Fewer Than 50 Clients per Year*
Fee-for-Service agencies testing an average of 50 or fewer persons per year are not required to enter data directly into the EvaluationWeb website, although they may do so. These sites should send the following information to the AIDS/HIV CTR Program for data entry on a monthly basis:
- All copies of EvaluationWeb HIV Test Template Part 1
- All copies of EvaluationWeb HIV Test Template Part 2 after referral follow-up has been completed and referral outcomes have been noted.

Agencies should only send copies of their data collection forms. Agencies must retain the original forms in a file established for each individual client. Copies of the various forms may be submitted each month in the same envelope. Mail forms the first week of the month to:

Wisconsin CTR Program  
Division of Public Health  
P.O. Box 2659  
Madison, WI 53701-2659

Supervisors should develop methods to ensure data collection forms are completed accurately and submitted to the AIDS/HIV program on a monthly basis as described.

Agencies may use the EvaluationWeb database to enter client information rather than sending hard copies of the forms to the Program, if they prefer to do so.

*Agencies Serving 50 or More Clients per Year and Grantee Agencies*
Fee-for-service testing sites that test an average of 50 or more persons per year and all grantee agencies are required to enter data directly into the EvaluationWeb website.

- 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. Data should
be entered into the EvaluationWeb website as soon as possible after testing, post-
test counseling, or referral follow-up occurs – and no later than 72 business hours
after such events.

- 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. Ideally, data entry would be completed within 72
  business hours of testing, post-test counseling, or follow-up activity. Minimally, data
  must be entered weekly.

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 CTR
Coordinator can provide technical assistance regarding methods for monitoring data
entry.

Agencies should contact their contract monitor if they are unable to meet the data entry
deadline. Contract monitors may be able to negotiate an alternative deadline 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.

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. It is not permissible for counselors to enter data from a home computer or from
an agency laptop in their home.

Reporting Requirements for Grant-Funded HIV CTR Sites
Agencies receiving grant funds to provide HIV CTR services are required to submit
quarterly narrative reports pertaining to their approved Intervention Plan. Quarterly
reports should be submitted via email to the agency's contract monitor.

The narrative report should briefly address the following points:
- 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; and/or 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; and,
• technical assistance needs.

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

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Parameter</th>
<th>Report Due</th>
<th>Quarter</th>
<th>Parameter</th>
<th>Report Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Jan. 1st - Mar. 31st</td>
<td>April 30</td>
<td>Q2</td>
<td>April 1st – June 30th</td>
<td>July 31</td>
</tr>
</tbody>
</table>

Accessing Data Reports – Agency Process and Outcome Reports

EvaluationWeb contains certain standard reports that can be accessed by any agency whose staff has a User ID and User Password. Standard reports are specific to individual agencies and do not contain information or data from other HIV testing sites.

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, please consult the HIV Evaluation Coordinator, CTR Coordinator or contact Luther Consulting LLC directly.
Wisconsin Department of Health Services AIDS/HIV Program
Policy for Agency Internal Training

In order to maintain consistent services, and access to testing for persons at high risk for HIV infection, agencies funded by the Wisconsin AIDS/HIV Program to conduct HIV CTR services may train new staff in-house to provide conventional HIV testing provided the following circumstances are met:

• The agency receives prior approval to train staff internally from the HIV CTR Coordinator or the contract monitor for their HIV CTR services.

• 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/AIDS transmission information (if the employee does not have an HIV background); the American Red Cross “HIV Starter Facts Book” is a good source and can be purchased through any Red Cross Chapter for $10-$15—depending on location.

  ✓ Wisconsin statutes 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
    --blood collection

  ✓ Testing Algorithms, including
    --Ag/Ab, Multispot, and DNA PCR testing
    --need for repeat testing, particularly for negative results

  ✓ Elements of Pre-test Counseling, including:
    --prevention counseling
    --test decision counseling
    --obtaining informed consent
Appendix A

✓ 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 persons testing anonymously
   -- need for HIV verification to access HIV specialty programs and services (mandatory reporting once specialty care is accessed)

✓ Resources and referrals
   -- local resources for all persons accessing testing; i.e. AODA services, mental health services, emergency shelters, domestic violence
   -- local resources for persons testing positive; including, at minimum, medical evaluation and care, HIV case management, legal services, reproductive health, support service, information lines, PCRS, and prevention risk assessment and risk reduction planning

✓ Forms and Data Collection
   -- Consent for Anonymous or Confidential HIV Testing Form
   -- Authorization for Release of Confidential HIV Test Results
   -- EvaluationWeb HIV Test Template Part 1
   -- EvaluationWeb HIV Test Template Part 2
   -- WSLH Laboratory Requisition
   -- Agency policy for data entry

✓ Observing a CTR Counselor with at least 2 years experience conduct pre-test counseling a minimum of three times
   -- utilize the enclosed observation checklist

✓ Observed by a CTR Counselor with at least 2 years experience conducting pre-test counseling sessions a minimum of three times, with
   -- feedback to the new counselor
   -- opportunity for new counselor 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 their HIV CTR policy and procedure manual
- The agency must retain a documentation of training in the new employee’s personnel record for one year after start of employment; including training and observation check lists (see next page).
- The employee must attend the following state-sponsored courses within six months of employment:
  ✓ HIV: Basic Facts (online)
  ✓ HIV Counseling, Testing, Referral Services Program: New Provider Training
Appendix A

Required Agency Internal Training Checklist
This checklist is required by the Wisconsin Department of Health Services, AIDS/HIV Program when an employee is trained in CTR internally, prior to completing the required program trainings.

Employee_______________________

<table>
<thead>
<tr>
<th>Objective</th>
<th>Date Provided</th>
<th>Trainee’s Initial &amp; Date</th>
<th>Trainer’s Initial &amp; Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify basic HIV/AIDS information</td>
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<td>Name source</td>
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<tr>
<td>Review and supply a copy of WI statutes related to HIV testing and disclosure, including:</td>
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<tr>
<td>✓ Confidentiality of test results</td>
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<tr>
<td>✓ Disclosure of results or status</td>
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<tr>
<td>✓ Civil and criminal penalties</td>
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<tr>
<td>✓ Lawful access to test results</td>
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<tr>
<td>✓ Informed consent</td>
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<tr>
<td>✓ Testing adolescents</td>
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<tr>
<td>Identify testing options &amp; benefits and limitations of each:</td>
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<tr>
<td>✓ Serum collection</td>
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<tr>
<td>Identify testing algorithms, including possible test results and procedures in the event of an indeterminate test result.</td>
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<tr>
<td>Identify elements of pre-test counseling, including:</td>
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<tr>
<td>✓ Prevention counseling</td>
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<tr>
<td>✓ Test-decision counseling</td>
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<tr>
<td>✓ Obtaining informed consent</td>
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<tr>
<td>Identify aspects of different testing methods - anonymous vs. confidential</td>
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<td></td>
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</tr>
<tr>
<td>✓ Benefits and limitations of each method</td>
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<td></td>
</tr>
<tr>
<td>✓ Mandatory reporting for confidential testing</td>
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<tr>
<td>✓ Voluntary PCRS services as mandatory reporting and as an option for persons testing anonymously</td>
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<tr>
<td>✓ Need for HIV verification to access HIV specialty services (mandatory reporting once specialty care is accessed)</td>
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<tr>
<td>Identify resources</td>
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<tr>
<td>✓ For all persons accessing testing</td>
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<tr>
<td>✓ For persons testing positive</td>
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</tbody>
</table>
### Appendix A

<table>
<thead>
<tr>
<th>Forms and data collection</th>
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</thead>
<tbody>
<tr>
<td>✔ Client questionnaire</td>
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<tr>
<td>✔ Consent form</td>
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<tr>
<td>✔ Testing Information form</td>
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<tr>
<td>✔ Lab slip</td>
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<tr>
<td>✔ Referral tracking form</td>
<td></td>
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<tr>
<td>✔ Release of information</td>
<td></td>
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<tr>
<td>✔ Agency policy for data entry</td>
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</table>

<table>
<thead>
<tr>
<th>Signed confidentiality agreement on File</th>
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</thead>
<tbody>
<tr>
<td>Received and reviewed copy of CTR policy and procedures</td>
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</table>

<table>
<thead>
<tr>
<th>Observation of experienced counselor</th>
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<tbody>
<tr>
<td>Observation of experienced counselor</td>
<td></td>
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<tr>
<td>Observation of experienced counselor</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Observation by experienced counselor</th>
<th>Record any corrective reminders</th>
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<tbody>
<tr>
<td>Observation by experienced counselor</td>
<td>Record any corrective reminders</td>
</tr>
<tr>
<td>Observation by experienced counselor</td>
<td>Record any corrective reminders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training and observation checklist added to personnel file</th>
<th></th>
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</table>

<table>
<thead>
<tr>
<th>Attended HIV: Basic Facts web-based training</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Attended HIV Counseling, Testing, And Referral New Provider Training</td>
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</tbody>
</table>

Please retain a copy of this training checklist in the employee’s personal file for one year after date of employment.
Wisconsin Department of Health Services, AIDS/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 US 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 the review committee & 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 the material(s) & 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.
Appendix C

Clearing Your Browser’s Cache

Often referred to as the cache, the Temporary Internet Files folder contains a kind of travel record of the items you have seen, heard, or downloaded from the Web, including images, sounds, Web pages, even cookies. Typically these items are stored in the Temporary Internet Files folder.

To clear your cache in Microsoft Internet Explorer:

1. On the Internet Explorer 6 Tools menu, click Internet Options. The Internet Options box should open to the General tab.

2. On the General tab, in the Temporary Internet Files section, click the Delete Files button. This will delete all the files that are currently stored in your cache.

3. This brings up a separate Delete Files window. Click OK, and then click OK again.
Wisconsin Department of Health Services, AIDS/HIV Program
Condom Distribution Guidelines

Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV and reducing the risk of other sexually transmitted infections (STIs). The purpose of condom distribution is to decrease morbidity associated with HIV infection and other STIs by encouraging at-risk individuals to use condoms consistently and correctly.

Wisconsin AIDS/HIV Program Condom Distribution Guidelines
The Wisconsin AIDS/HIV Program limits the distribution of condoms to agencies providing HIV counseling & testing and prevention services through contractual agreements or memoranda of understanding with the Division of Public Health:

- Condoms are provided based on the projected number of persons to which a site will provide HIV prevention or testing services.

- Condoms are also distributed as part of CDC-recommended HIV and STI control initiatives. According to public health research, structural-level condom distribution interventions or programs are efficacious in increasing condom use, increasing condom acquisition or condom carrying, promoting delayed sexual initiation or abstinence among youth, and reducing incident STIs.

The AIDS/HIV Program selects condoms based on several criteria, including cost, quality, product effectiveness, and consumer preference. The AIDS/HIV Program supplies a variety of condoms to local agencies to address client needs and preferences, as well as to promote the client’s familiarity with various condoms. The variety will include flavored condoms to prevent oral transmission of sexually transmitted diseases.

Agency Requirements
1. Condoms may be distributed to clients as tools to reduce risk of HIV and other STIs, and to support the client in meeting their agreed-upon risk reduction goals.

2. Agencies are prohibited from distributing condoms provided by the AIDS/HIV Program outside of the targeted populations for whom the Program has given approval. This includes general distribution to the community and distribution to minors outside the context of HIV testing sessions, STI testing or treatment sessions or similar individual HIV prevention services.

3. Client condom education should be supplemented with printed instructions on correct condom use. Instructions should be tailored to address the linguistic, cultural, developmental, and educational level of clients.

To obtain condoms for distribution during HIV counseling & testing and other HIV prevention services, please contact the AIDS/HIV Program Assistant at 608-266-6966. For questions related to these condom distribution guidelines, please call the AIDS/HIV Program at 608-267-5287.
## SAMPLE TOOL TO ASSESS QUALITY OF STAFF COUNSELING

### CTR OBSERVATIONAL EVALUATION FORM

<table>
<thead>
<tr>
<th>Date:</th>
<th>Agency:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Name:</td>
<td>Supervisor:</td>
</tr>
</tbody>
</table>

### Content of Counseling: Client-Centered Prevention Counseling

| Observed | Needs Improvement | Not Observed | NA |
|----------|-------------------|--------------|

1. Client is encouraged to discuss interest in considering testing and any concerns he/she may have about HIV or HIV testing.

2. Client is asked to share his/her knowledge of HIV and any steps already taken to reduce risk.

3. Counselor identifies and acknowledges client strengths and reinforces efforts and accomplishments client has made to adopt safer behavior.

4. Based on what the client knows, education is tailored to the client’s concerns and information the client already possesses. Any misperceptions are addressed.

5. The client is asked to assess his/her risk. If appropriate, the counselor discusses any misperceptions related to personal risk.

6. Risk reduction options related to sexual and/or substance use are discussed with client.

7. Throughout the session, counselor demonstrates prevention counseling skills: attending, reflecting feelings, asking open-ended questions, offering options rather than directives, giving information simply, and paraphrasing.

**For clients representative of high risk or disproportionately affected populations:**

1. Counselor identifies with client the most recent risk exposure.

2. Counselor and client identify one attainable risk reduction or safer sex goal.

3. Counselor assists client in identifying and addressing barriers to change.

4. Counselor offers prevention services, as needed – e.g. syringe exchange, etc.

5. Written materials appropriate to the client’s culture and personal risk that discuss HIV transmission, prevention, and care are available and offered to the client.

6. Counselor summarizes and closes session – including major points discussed, a concise statement of the client’s issues and decisions, and ensures summary is accurate.

### Contents of Counseling: Test Decision Counseling

| Observed | Needs Improvement | Not Observed | NA |
|----------|-------------------|--------------|

1. Advantages, limitations, and procedures of laboratory or rapid test are explained.

2. Information on “window period” for accurate testing is explained.

3. Confidential testing is recommended, including explanation of benefits. Anonymous testing is offered to those with significant confidentiality concerns. In all cases, client concerns are addressed.
### Observed Needs Improvement Not Observed NA

4. Reporting of confidential test result to State AIDS/HIV Program is explained.

5. For Rapid Testing: Meaning of test results is discussed.

6. Client’s readiness to test is assessed and possible emotional consequences of testing and receiving test result are reviewed, including:
   - Client is asked how they might feel if the test result indicates infection.
   - Common anxiety associated with receiving preliminary reactive results and waiting for confirmatory test results are discussed.
   - Possible support systems are assessed and discussed.
   - History of depression mental illness or suicidal ideation is assessed.

7. For Rapid Testing: “Subject Information Pamphlet” is provided to client prior to testing.

8. If client is under 18 years of age, support systems and possible parental notification and disclosure issues are discussed.

9. Client testing code is established and written consent is obtained.

### Provision of Test Results and Referrals – Rapid Testing

---

#### Negative Results

1. The test result is provided after assessing the client’s readiness to receive the result.

2. The meaning of the test result is explained.

3. The client is given time to react to the test result and is encouraged to express feelings and concerns.

4. The client’s immediate concerns and feelings are addressed.

5. The window period and possible need for repeat testing are discussed with the client, if appropriate.

6. Services and referrals needed by the client are discussed and provided.

7. Anticipated barriers to accessing referrals are discussed.

8. Prevention services are discussed with high risk clients, and linkage to these services is offered.

#### Reactive Results

1. The test result is provided after assessing the client’s readiness to receive their result.
### Appendix E

#### Reactive Results – continued

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Needs Improvement</th>
<th>Not Observed</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>The meaning of the reactive result is explained.</td>
<td></td>
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<tr>
<td>3.</td>
<td>The client is given time to react to the test result and is encouraged to express feelings and concerns.</td>
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<td></td>
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<tr>
<td>4.</td>
<td>The client’s immediate concerns are addressed.</td>
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<tr>
<td>5.</td>
<td>Emotional supports are identified.</td>
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<tr>
<td>6.</td>
<td>The need for confirmatory testing is explained and confidential testing is encouraged.</td>
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<tr>
<td>7.</td>
<td>Confirmatory specimen is obtained.</td>
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<tr>
<td>8.</td>
<td>Client advised to practice risk reduction while waiting for confirmatory test result.</td>
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<tr>
<td>9.</td>
<td>Importance of early medical evaluation and care is discussed, and linkage to services is explained in the event confirmatory test is positive.</td>
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<td>10.</td>
<td>“Locator Information” form is completed.</td>
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</table>

#### Provision of Test Results and Referrals – Conventional/Confirmatory Testing

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Needs Improvement</th>
<th>Not Observed</th>
<th>NA</th>
</tr>
</thead>
</table>

**Negative Results**

1. Client readiness to receive result is assessed.
2. Results are provided to client and interpretation of results are discussed.
3. The client is given time to react to the test result and is encouraged to express feelings and concerns.
4. The client’s immediate concerns and feelings are addressed.
5. The window period and possible need for repeat testing are discussed with the client, if appropriate.
6. The risk reduction strategies/target behaviors that were discussed with the client are reviewed.

**Positive Results**

1. Client readiness to receive result is assessed.
2. The test result is provided to the client.
3. Client’s understanding of the test result is assessed.
4. The client is given time to react to the test result and is encouraged to express feelings and concerns. Client’s immediate concerns and feelings are addressed.
5. Client immediate needs are assessed and addressed—including support system and possible crisis intervention.
6. Client’s immediate plans are determined (for example – the next 24 hours).
7. Counselor discusses disclosure issues with client.
8. Client linkage to medical care is recommended and facilitated.
### Appendix E

(Provision Conventional/Confirmatory Results and Referrals – continued)

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Needs Improvement</th>
<th>Not Observed</th>
<th>NA</th>
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<tbody>
<tr>
<td>9.</td>
<td>Client linkage to case management is recommended and facilitated.</td>
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<tr>
<td>10.</td>
<td>Client linkage to Partner Services is recommended and facilitated.</td>
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<tr>
<td>11.</td>
<td>Anticipated barriers to keeping referral appointments are discussed and addressed.</td>
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<tr>
<td>12.</td>
<td>Arrangements for referral follow-up are made.</td>
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<tr>
<td>13.</td>
<td>Client immediate needs are assessed and addressed—including support system and possible crisis intervention.</td>
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<tr>
<td>14.</td>
<td>Client risk reduction is reviewed.</td>
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<tr>
<td>15.</td>
<td>Support systems identified during rapid testing are reviewed, immediate plans assessed, and disclosure issues are discussed.</td>
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</table>

**Indeterminate Results**

1. Client readiness to receive result is assessed.

2. The test result is provided to the client.

3. Test result is interpreted for the client, including:
   - Possibility of non-specific reactions, cross-reactivity of another retrovirus, virus or hepatitis vaccinations
   - Possibility of early infection – this possibility is emphasized with persons at high risk with possible recent exposures

4. Recommendations for repeat testing are discussed.

5. If test was oral fluid sample (OraSure), immediate blood draw for repeat confirmatory test is obtained.

6. Recommendations for risk reduction precautions until repeat testing is complete are discussed.

7. Support needs are assessed and addressed.