

Tab 5: Getting Started: Sample Policies, Procedures & Protocols



**Toolkit for Integrating HIV Services in
Native Health Settings**

- 1. Getting Started HIV Integration Checklist**
- 2. Sample Work Plan for Implementing Routine HIV Testing**
- 3. Material Needs and Inputs**
- 4. HIV Prevention Education, Counseling and Testing
Sample Protocols A**
- 5. HIV Prevention Education, Counseling and Testing
Sample Protocols B**
- 6. Sample Clinic HIV Protocol -
Denver Indian Health**
- 7. Oraquick Advance Rapid HIV-
1/2 Antibody Testing
Guidelines**

Getting Started HIV Integration Checklist

This checklist was created to help you to systematically think about all of the different issues to consider in introducing and integrating routine HIV testing into standard practice at your health center/clinic. Use this checklist as a guide to assess what you have in place and what you need to put into place. Not all issues will apply to your agency. This tool can also be used in conjunction with the *Sample Work Plan for Implementing Routine HIV Testing* when seeking to construct a solid course of action.

There are four layers of integration, each one building upon the foundation created by the previous service: 1.) Education, 2.) Counseling, 3.) Testing, and 4.) Treatment. There are a variety of activities/services that can be initiated at each layer that can complement not only other HIV/STD services, but can work with other clinical services as well. Integration is about creating a variety of services within a framework that utilizes existing resources, does not duplicate work, and creates a seamless and wrap around service delivery to the community recipients.

Agency currently provides (check all that apply):

- No HIV services
- 1.) Education
 - Basic HIV Education
 - HIV Outreach
- 2.) Counseling
 - HIV Counseling
 - HIV Referral System
- 3.) Testing
 - Conventional HIV testing
 - Rapid HIV Testing
- 4.) Treatment
 - HIV Treatment
 - HIV Support Group
 - HIV Case Management
 - Traditional Healing Services
 - Other: _____

What agency could provide (check all that apply):

- 1.) Education
 - Basic HIV Education
 - HIV Outreach
- 2.) Counseling
 - HIV Counseling
 - HIV Referral System
- 3.) Testing
 - Conventional HIV testing
 - Rapid HIV Testing
- 4.) Treatment
 - HIV Treatment
 - HIV Support Group
 - HIV Case Management
 - Traditional Healing Services
 - Other: _____

Vision

What is your vision for the future and timeline to accomplish this?

What existing programs lend themselves well to integrating (e.g., CHR, family planning, STD clinic, teen pregnancy program, fatherhood program, substance use program, OB/GYN office):

- a.) HIV education: _____
- b.) HIV counseling: _____
- c.) HIV testing: _____
- d.) HIV treatment: _____

Identify the (clinical and non-clinical) staff who can be advocates to help ensure success of an HIV Integration effort.

The following will help you to determine courses of action in order to bring any one of these new services to your clinic. Depending on what you are hoping to introduce some of these action items may not be relevant for you or your program.

Policies and Procedures

- Updated protocols and guidelines about the following available and easily accessible to staff:
 - How to provide HIV education and risk reduction counseling to interested parties
 - How to educate/counsel people about the testing available
 - How to conduct the HIV test(s) being used
 - Creating and using culturally appropriate materials (age, tribe, language, gender, sexual orientation, age, and the local interpretation of these characteristics should be considered)
 - How to allay fears about confidentiality to the person
 - How to protect the person's confidentiality
 - Procedure for acquiring consent from the person for the testing (each tribe, state, and/or federal funding source may have different requirements for informed consent)
 - Documentation of education, counseling and testing
 - Appropriate referrals, especially for those who test positive
 - Reporting requirements (knowing to whom and how what results are reported [IHS, CDC, state, tribe, etc.]) and
 - Updating all HIV-related forms
 - Quality assurance requirements (clinical supervision, training, satisfaction surveys and feedback mechanisms, data/file maintenance, etc.)
 - Staff training requirements (to conduct tests, disclose results, counsel, provide referrals, etc.)
 - Process for conducting confirmatory tests
 - Laboratory procedures and/or any agreements with referral laboratory (including CLIA waiver) (contact your Indian Health Service or the state health department's HIV/AIDS office for guidance; If conducting rapid testing, a CLIA Waiver must be obtained)
 - Other: please specify _____
- Clinic has identified process for reimbursement/funding for HIV testing.
- Laboratory has been notified of new testing changes (if applicable)

Documentation and Administration

- Procedures for specimen flow and quality assurance identified
- Current reimbursement options and procedures for HIV testing and other services are identified
- Offering of HIV counseling and/or testing and test results currently being documented in patient charts
- Identify current tribal, state, and/or federal laws addressing sharing of HIV test results. Identify how test results will be shared among staff (as needed)
- Quality assurance plan created

Cost of New Services

- Anticipate what the costs of the new services will be and how to cover the costs
- How will your agency be reimbursed for new services?
- What other sources of funding might you have or need?
- What are the costs of each type of test? How can you order more tests to lower the cost (check in with other organizations to share costs)?
- How will the staff training costs be different with new services? Will staff need less training (e.g. some clinics do little or no counseling with rapid testing) or more training.

- How will your staff be trained? Do you have access to internal training or would you need to hire trainers from the community or local Training Centers?

Community Involvement

- New and existing patients are notified of the availability of HIV testing services
- Appropriate HIV testing literature and materials are available to any interested parties
- Community Advisory Council comprised of active and interested community members who can help to guide programmatic decisions and review materials
- HIV prevention materials (condoms, personal lubricant, female condoms, dental dams, etc.) have been obtained and are available to all interested parties
- Marketing efforts have been created to notify the community of the availability of the new service

Clinic Flow

- Observe your current clinic flow and assess best times to add HIV services
- Be flexible: Start with a plan about how/ when (before exam, after, etc.) and be flexible
- Try to be realistic about how much time added services will take for staff and build into flow
- Determine how many visits will be needed for testing (e.g. rapid is one but two with confirmatory)
- Decide when HIV services will be offered, (to everyone, to certain visit types, etc.).
- Identify which staff will be involved in offering new services including offering education or testing
- Walk through the clinic and identify where and how each new piece will take place before starting.

Staff Training and Other Issues

- Identify any staff concerns or resistance to new HIV services
- Identify one clinical and one non-clinical to be the advocates of new HIV services
- Involve staff in the discussions and meetings as much as possible from the beginning
- Identify barriers or challenges for individuals and agency to making changes and discuss what will make it easier/more efficient.
- Identify any tribal, state, federal or funder requirements for staff training
- Train staff on coding/reimbursement guidelines, as needed.
- Train staff on new services (education, counseling, testing, care, treatment) as needed
- Hold a staff in-service on HIPAA and HIV/AIDS
- Determine whether cultural proficiency training is appropriate
- Pilot the new service in a given time (e.g. Friday mornings) or with a particular visit type (annuals)
- Work out the kinks in the first few weeks and assess with staff what is working/not working.
- Give staff opportunity to give feedback on the proposed new services and after a couple weeks.
- Decide whether to cross train staff (preference) or keep HIV staff separate. Some training topics may include:
 - How to conduct the education, counseling, and testing of clients.
 - Phlebotomy, finger sticks, and other specimen collection
 - How to give positive (reactive) test results.

HIV Testing:

- Choosing which HIV test(s) to offer: Weigh the pros and cons of each HIV test considering the following:
 - Cost of each test
 - Weight time for time results
 - Specificity/sensitivity/potential for false results

- Confidential and/or anonymous
 - Blood tests versus oral fluids
 - Stability of test (Can we move it once we run it or does it need to stay in one place?)
 - Reliability in the field (temperature, storage, running controls, etc.)
 - Shelf life of the tests
 - Rapid testing (How long does it take to run the test? How long to read the results?)
 - Laboratory considerations (Who runs the confirmatory testing? How long does it take)
- Before testing:* agency will offer nothing education counseling informed consent information
- Other: *Please explain:* _____
- Will the same staff do the education/counseling, explain and run test, and give the results?
- Discuss whether your agency will use an on-site or off site lab for testing/confirmatory testing
- For Rapid Testing: Determine the State Laboratory Approval Process for CLIA-waived tests
- Will the clinic offer incentives for completing an HIV test? If so, what incentive will be used?

Results and Referrals

- Identify procedure and staff for giving negative and positive test results.
- For conventional testing, how to give results (e.g. 2nd appointment, no news is good news, phone)
- Ensure that procedures for delivering positive results include:
- Ensure adequate time for discussion
 - Include knowledgeable personnel
 - Provide the patient with referrals to care
- Devise a system for those who do not return for results
- Create a log or system to follow up on clients testing positive
- Identify local health department contact for HIV reporting
- Identify support agencies to refer patients to (recovery, hotlines, mental health, etc.)
- Establish a relationship with an HIV specialist in the area to whom to refer clients
- Contact local referrals to confirm what services are offered, requirements, hours of operation, etc.
- Create a referral list for clients that includes all types of agencies that can provide support
- Ensure all referrals are culturally appropriate/competent
- Ensure that all referral agencies accept referrals from I/T/U clinics or appropriate insurance

Client Considerations

- How will clients find out about new HIV services, how will you advertise or market new services?
- What information and educational materials will you provide
- How will you keep HIV materials up to date?
- Identify materials that are culturally appropriate for client population
- Anticipate how the new services may attract a new client population (e.g. teens, men who have sex with men, IDU, etc.)
- If new services attract a new population, determine whether there are special considerations related to the waiting room (creating a sense of safety, confidentiality, educational materials, etc.) to consider

Implementation Ideas

- Make sure that the appropriate people are invested in new changes
- Educate staff about CDC HIV Testing recommendations and purpose of new services
- Design a pilot test or practice to begin the new services slowly before a full scale roll out

- Conduct staff meetings to check in about how the implementation is going (1 week later, 1 month later)
- Clinician advocate selected: _____
- Non-Clinician advocate selected: _____
- Vision of what agency wants is outlined and discussed

Next Steps Planned:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Sample Work Plan for Implementing Routine HIV Testing

This tool should be used in conjunction with the *Getting Started HIV Integration Checklist*, as the *Checklist* provides the needed detail to execute these action items.

Steps	Lead	Date Scheduled	Date Performed
1. Launch of project to implement routine testing			
Introduction to CDC Guidelines, rationale for routine testing			
Notify tribal leadership and/or regional IHS leadership of intention to begin offering HIV testing (or obtain permission)			
Agreement on key work plan deliverables			
Identification of project team			
Assembly of project team			
Analysis of fiscal feasibility/impact			
Creation of work plan			
Creation of evaluation plan			
Completion of baseline assessment for evaluation plan			
Decision about roll-out strategy (phases? unit? patient group?)			
Decision about which staff will offer testing/obtain consent			
2. Preparations for reimbursement			
Examine reimbursement for HIV tests conducted through funding source (IHS, state, etc.). Identify needed changes.			
Identify ICD-9,CPT, and/or HCPCS Codes accepted for HIV routine testing			
Create pocket cards for reimbursement codes			
3. Revision of policies and procedures			
Identification of type of HIV test to use (rapid v. conventional)			
Creation of patient & specimen flow template			
Assessment of laboratory procedures, identification of needed revisions			
Gain buy-in from laboratory staff			
Assessment of clinic testing procedures (including consent), identification of needed revisions			
Assessment of patient education materials, identification of needed revisions/updates			
Assessment of HIV testing documentation procedures, identification of needed revision			
Revision of laboratory procedures			
Revision of clinic testing procedures			
Revision of patient education materials			

Steps	Lead	Date Scheduled	Date Performed
4. Revision of test result delivery			
Assessment of current procedure for test result delivery, identification of needed revisions			
Assessment of referral processes, identification of needed revisions			
Revision of test result delivery process			
Revision of referral process			
5. Incorporation of staff feedback			
Provide open comment period on new policies, procedures, and materials to staff			
Revise materials as necessary and appropriate			
6. Delivery of staff training			
Meeting with staff to assess buy-in, identify possible obstacles, needed training			
Identify needed training			
Creation of scripts for offering testing, receiving consent, delivering test results, providing referrals			
Delivery of training			
7. Launch of pilot			
Implement routine testing in pilot groups			
8. Assessment/management of obstacles			
Assessment of obstacles during first week of pilot, identification of solutions			
Assessment of obstacles during first month of pilot, identification of solutions			
Identification, delivery of any further needed staff training			
9. Launch of routine testing			
Implement routine testing in entire clinic			
Assessment of obstacles during first month of roll-out identification of solutions			
Identification, delivery of any further needed staff training			
10. Evaluation of project			
Completion of project assessment			

Material Needs and Inputs

The following is a sample list of materials that may be needed in order to conduct various HIV prevention activities. The actual materials needed will vary from site to site, and upon available local resources.

HIV medical treatment services should be integrated into the general clinical practices and so there is no specific materials list for medical treatment and case management services requires no more materials than what is already covered in other areas of service provision.

HIV Education

- Culturally appropriate literature
- List of local services and testing sites
- Table
- Banners
- Baskets/jars to hold prevention materials
- Pens
- Tracking forms/Sign-in sheets (if needed)
- Waiting room educational materials
- Penis and/or vagina models
- Coupons or referral cards
- First Aid kits for emergencies for clients, volunteers, and staff
- Business cards
- Duct tape
- Clear tape
- Scissors

The below *safer sex supplies* should be in the counseling room – supplies are more likely to be accepted by clients in the privacy of the counseling room.

- Latex condoms (lubricated, flavored and non-flavored, and many sizes)
- Lubricants (flavored and non-flavored)
- Female condoms
- Dental dams
- Powder-free gloves

Bleach kits should contain the following:

- Bleach
- Lotion to keep the skin moisturized (to reduce further breakages on the skin's surface, reducing possibility for other infections)
- Distilled water
- Cooker
- Cottons
- Tie off
- Instructions for safer injection use

All messages contained in marketing materials should be clear, simple and reflect important themes, symbols, and images in the AI/AN community. Materials include:

- Brochures and/or palm cards describing HIV and/or your services
- Posters in offices
- Flyers for distribution in community and during outreach activities

HIV Counseling

- Door signs indicating counseling in session or counselor free
- Comfortable chairs or couch
- Lockable room or confidential area
- Sage, cedar, sweetgrass, or other local medicine
- Counseling protocol
- Satisfaction surveys

HIV Testing

The required forms and paperwork to keep on file will vary by site and jurisdiction. A general list includes:

- Check-in forms or list
- Client consent forms for both confidential and anonymous based on service offered
- Appointment cards
- HIV Pre-test documentation form for all clients
- HIV post-test documentation form for clients who choose to test
- HIV lab request form
- HIV lab result form
- Lab slips
- Result letters
- Window period chart
- Referral resource guide
- Referral information and tracking forms
- Test results form (for patient)
- Client satisfaction surveys
- Authorizations for release of information and referrals
- Clear policies and procedures
- Application for Registration of HIV Testing Programs
 - Memorandum of agreement with contracted entity
 - Physician statement
 - Proof of training
 - Proof of liability coverage

Organizations should contact local health departments and manufacturers for possible in-kind or monetary contributions to obtain the following lab supplies:

- Biohazardous waste and red bags
- Sharps containers
- Specimen tubes
- Sterile cotton pads

- Band-Aids
- Alcohol swabs
- Counter covers
- Lancets or butterfly syringes
- Blood delivery bags
- One small cooler for delivering specimens
- A refrigerator to store blood specimens and controls
- Control kits
- Rapid test kits
- Test stands
- Collection loops
- Timers
- Thermometers
- OraSure or OraQuick test kits
- Different sized protective gloves
- Disposable lab coats
- Protective eyewear
- Spill kits

Each organization must decide if incentives are needed and why. Some organizations do not use incentives as they may lead to unnecessary testing and believe that finding out one's HIV status, which is often free of cost, is incentive enough. Others believe that incentives can help bring in high-risk clients and that this outweighs all other disadvantages. Possible incentives include:

- Free health education supplies (e.g., safer sex supplies, hygiene kits, bleach kits)
- Local traditional gifts
- T-shirts
- Phone cards
- Grocery vouchers
- Coupons
- Food or candy
- Money

HIV Prevention Education, Counseling and Testing Sample Protocols A

Policy

Voluntary and confidential HIV prevention counseling and testing is an integral part of comprehensive medical care; therefore, all health care settings (whether they be agencies, clinics [rural, reservation or urban], or AIDS service organizations) must be equipped to provide routine, on-site confidential prevention education, counseling, and/or testing. Referral to anonymous testing services must always be available to clients who prefer anonymous instead of confidential testing (if your clinic or agency doesn't provide this service). Screening for HIV infection must be offered routinely to all patients, at least once a year. Additionally, any client who engages in sex without using a barrier method, or who presents with symptoms of an STD should be advised to have STD and HIV testing. Providers must have systems in place to ensure and monitor that clients receive both positive and negative results.

It is the policy of this agency/clinic that all services provided to the community and to individual clients be done so with the utmost respect for them as a person and member of the community. Each person in this clinic will be empowered to make informed decisions about their own care and will receive the support from the staff to make that happen.

Procedures must be in place in all clinics related to: screening guidelines, informed consent and confidentiality, prevention counseling and education, providing results, partner counseling and referral services, personnel requirements, reporting requirements, and consumer grievance. All family planning providers must adhere to all local, state, and federal regulations and policies that govern the provision of HIV services.

Rationale

Every client needs to receive education about HIV/AIDS and how it is acquired, its impact among Native peoples and communities, and information about other sexually transmitted diseases. This education should permit clients to examine their own behaviors and how those behaviors may or may not expose them to risk. Every client should have access to HIV counseling and testing services that will provide them with an understanding of their HIV status and help to reduce risks for acquiring or transmitting HIV.

The CDC revised its HIV testing recommendations in 2006 (and were adopted by the Indian Health Service) advising that, diagnostic testing and opt-out HIV screening be part of routine clinical care in all health care settings. Many HIV infected persons who access healthcare are not tested for HIV until symptomatic. Awareness of HIV infection leads to substantial reductions of high-risk behavior that will reduce the spread of HIV.

Procedure

Screening Guidelines

HIV prevention education must be provided routinely to all clients. All clients must be offered the opportunity to know their HIV status at least on an annual basis. Opportunities to do so include but are not limited to: initial visits, annual exams/physicals, STI exams and treatments, ECP visits, symptomatic consultations, and pregnancy testing visits. Although pregnancy testing and emergency contraception are episodic visits, HIV testing must be offered to those who disclose that they have engaged in unprotected intercourse or present with an STI.

Providers cannot refuse an HIV antibody test to any client who requests one during a clinic visit, except in cases where the provider deems the client mentally unstable or unable to cope with the stress of an HIV test. Providers must be able to offer HIV testing within 2 weeks for clients calling on the phone to schedule appointments, and also for those who walk into their clinics requesting testing. If the provider is unable to offer testing within 2 weeks, they must offer the client at least 2 referrals.

Providers are encouraged to incorporate opt-out screening in their HIV testing practices. Opt-out screening is performing the HIV screening after notifying the client (orally and/or in writing) that 1) the test will be performed, and 2) the patient may elect to decline or defer testing. Consent is inferred unless the patient declines testing. It is important that the client clearly understands that he/she will be receiving an HIV test in order to defer the appearance of impropriety. Screening is still voluntary and undertaken only with the patient's knowledge and understanding that HIV testing is planned.

All patients seeking treatment for STDs must be offered routine screening for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have behavior risks for HIV.

Women who are seeking pregnancy and have a positive pregnancy test must be informed about the importance of knowing their HIV status early in pregnancy in order to decrease transmission to her child. HIV/CTR services should be offered to these women in a confidential, informed and voluntary basis.

Informed Consent and Confidentiality

A separate consent, specific to HIV testing, is not required. Providers can use a general consent for medical services that also states an HIV test will be given as part of routine medical care unless the client declines the test. Supplemental information and/or counseling should be given to the client pertaining to the testing procedure, how to obtain test results, limitations and meaning of test results, and means and avoidance of HIV transmission. Clients must be informed of and offered options among available HIV antibody test technologies on-site or through referral.

The general consent form, that includes consent for HIV testing, only needs to be given and signed at the initial client visit; however, there must be chart documentation stating that patient agrees to HIV testing for each subsequent HIV test that is provided.

Clients must be informed of confidentiality issues such as reporting requirements for positive results, and/or information released to commercial insurance companies. Clients should be assured of internal measures taken by the agency to ensure confidentiality. Because of these issues, clients must be informed of the availability of and difference between anonymous and confidential testing. If anonymous testing is not available on-site, and the client requests it, a referral must be available to the client. Any disclosure of HIV results must be in accordance with tribal and/or state laws and ordinances.

Prevention Counseling and HIV/AIDS Educational Material

Appropriate counseling must be offered before an HIV test is performed. All clients must receive accurate and thorough client-centered counseling about STDs and HIV to include:

- An explanation of the test procedure
- How and when to receive test results, including method of follow up if the client does not return for their results
- How HIV is and is not contracted, taking in to account the client's current level of understanding about the disease
- The impact of HIV on Native communities
- The meaning of the test result (screening vs. confirmatory) and the prior period of time for which a HIV-positive client may still receive a negative test result
- When to return for another HIV test, if indicated
- Discussion about personal risks
- Risk reduction and infection prevention information to address all methods and manners to lower HIV risk.
- Development of an individualized and culturally responsive risk reduction plan
- Advise on retesting
- Referral services

Educational materials can be provided to client as a means of supplementing prevention education. Providers must ensure that the materials are culturally sensitive, of appropriate reading level, and in languages of the populations served at the site.

Providing HIV Test Results

The only acceptable mode of providing HIV antibody test results is in person, face to face. All posttest counseling must include pertinent information on risk reduction, accuracy and reliability of test results, and the significance of test results.

If a client receives a negative HIV antibody test result, she/he must be counseled on the importance of being retested in 3-6 months. If the client with a negative test result is pregnant, she must be counseled on the benefits of being retested before the end of her 3rd trimester of pregnancy.

The HIV prevention counselor must assure that clients who test positive receive HIV primary clinical care, along with case management services – even if those services are not provided at the agency/clinic. Clients with positive antibody test results must also receive counseling and information regarding:

- The availability of early intervention primary care services, including providing referrals for those services. Provider agencies **must** have a formal mechanism for referring clients to primary medical care. See “Partner Counseling and Referral Services” section of this policy for further instructions.
- The availability of therapies to treat HIV infection
- The availability of the mental health support needed by the newly diagnosed HIV positive client (family, peers, or mental health providers).
- The availability of traditional services to clients
- The benefits of disclosing the names of partners that may have been exposed.
- The importance of continuing to receive family planning/reproductive health care either at the family planning clinic or through a primary care provider.

A client who receives an initial indeterminate HIV antibody Western Blot result must be re-tested at least (30) days after the initial test result. A person receiving two (2) indeterminate HIV antibody Western Blot results must be referred for further medical assessment.

Contacting Patients About Results

All testing sites must have a system in place to ensure that all clients testing for HIV receive their results, both positive and negative.

Contact Requirements:

- A minimum of two (2) documented attempts should be made to contact the patient with at least one being a letter.
- The first attempt to contact the patient should be initiated within 2 weeks of receipt of the test result(s).
- For positive test results: if 2 contact attempts were unsuccessful, a final letter with a return receipt requested is to be sent. The letter should communicate that this will be the last effort made at contacting the client. If the client should fail to return for the test result within (60) days of the date of his/her test, the provider should forward their case to the county health department for further follow up.
- Appointments for the evaluation of these abnormal results must be available within one (1) week of a successful contact with the client.

Chart Documentation

All prevention counseling, pretest counseling, and posttest counseling must be part of the patient’s medical record. Regardless of the test result, there must be documentation that results were given to the patient, or that follow up attempts were made according to the policy.

Lab reports or written verification of test results must be part of the patient’s family planning medical record. If patient self reports that he/she has had and HIV test and states the results, this information should be documented in the patient chart.

Partner Counseling and Referral Services

All clients who receive an HIV antibody test must be informed of partner counseling, partner notification, and referral services, should they receive a reactive test result.

While giving results to seropositive clients, the significance of partner counseling, partner notification, and referral services for both sex and needle sharing partners must be emphasized. The chosen option must be documented in the client's medical record. The following options must be available to and discussed with seropositive clients:

- Provider Referral: Partner contact information is recorded and given to a Disease Intervention Specialist (DIS) for follow-up.
- Dual Referral: In compliance with provider protocol, joint notification of partners by the counselor and the seropositive client can take place.
- Agreement Referral: In compliance with provider protocol, agreements can be made between the seropositive client and the counselor in which the client will notify partner(s) if possible, within a given time frame, and if this does not occur, provider shall utilize DIS for PCRS.
- Client Referral: Counselor will assist client in developing a plan to notify partners.

Individuals who test positive for HIV must be linked to early and appropriate medical and ancillary services. Providers must develop a collaborative relationship with at least one HIV care provider, if the agency/clinic doesn't provide infectious disease or chronic disease care for HIV positive individuals. In addition each provider must maintain up to date referrals for HIV services.

Referrals to prenatal service providers that specialize in treating HIV infected women must be made available to any pregnant woman who is found to be HIV (+) and seeks referrals for prenatal care.

Personnel Requirements

Staff that provides HIV prevention counseling and testing must demonstrate experience and training specific to confidential HIV prevention counseling, testing and referral services. Such training may include, but is not limited to, fundamentals of HIV testing, prevention risk reduction counseling, making appropriate referrals and cultural competency (including local cultural practices).

Posttest counseling, for clients, should be provided by staff that received training to ensure clients receive pertinent information on risk reduction, accuracy and reliability of test results, and the significance of test results.

When obtaining serum or oral swab specimens, agency/clinic staff must adhere to the Occupational Safety & Health Administration (OSHA) Universal Precautions guidelines.

Reporting Requirements

HIV is a reportable disease. All HIV reactive antibody test results must be reported (agencies/clinics should research specific reporting requirements and procedures for their tribe, reservation, and/or state). The standard for documenting the results must be confidential.

HIV Prevention Education, Counseling and Testing Sample Protocols A

Introduction

(Agency) offers HIV testing, risk reduction counseling and education about how to prevent HIV transmission to all clients. HIV testing and counseling, as detailed below may, also be offered off-site in controlled environments. Appropriate referrals are provided for any needed services not readily available at the (Agency). Healthcare may be available for clients with HIV or AIDS or linkages to care will be provided, as appropriate. Advocates are available to assist clients to navigate the testing process and the clinical structure.

Staff Training

HIV screening and counseling may be provided by clinicians and support staff who are trained to provide these services.

- A. HIV counseling staff and medical staff must be knowledgeable about:
 - Available counseling, testing and services within (Agency).
 - The process for people who test positive
 - Available services for people who test positive
 - All considerations regarding confidentiality.
 - Tribal, local, state and federal regulations that govern HIV services.
 - Providing care that is appropriate to the client's culture, language, sex, gender orientation, age and developmental level.
 - Community resources and appropriate referral agencies.

- B. All center staff will receive training on:
 - Progression, transmission and prevention of HIV
 - Assessment of risk for HIV infection.
 - Signs and symptoms associated with HIV infection
 - Pros & cons of testing
 - Fundamental of risk reduction counseling
 - Types of tests offered by the agency/clinic.
 - Differences between anonymous and confidential testing.
 - Meaning of indeterminate test results.
 - Developing risk reduction plans.
 - Infection control practices in the center to ensure the control of the spread of infection.
 - Appropriate chart documentation
 - Cultural competency and responsiveness
 - The integration of traditional and Western approaches to HIV treatment

- C. Supervision and evaluation of staff that are approved to provide positive HIV results must include:
 - Staff self assessments and agency assessments to determine training and development needs
 - Observation by a qualified trainer in counseling and testing sessions

- Observation of counseling skills
- Repeat observations and feedback as needed should be conducted at least annually
- Chart audits

Client Selection

A. When to test

HIV antibodies can usually be detected by HIV tests as early as 21 days after infection. It is generally agreed that at least 95% of patients will have detectable HIV antibodies within 3 months of infection. The latest research indicates that it can take 3-6 weeks, and in a few cases up to 6 months before HIV antibodies show up.

B. Initial and Repeat Screening

The Indian Health Service has adopted the Centers for Disease Control and Prevention *Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* adopted in 2006 and revised in 2009. Based upon these recommendations, HIV screening is recommended for all patients (between the ages of 13 and 64) in health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening). This is true even if the client's risk behavior or risk co-factor is not known or readily ascertainable. Persons known to be at high risk for HIV infection should be screened for HIV at least annually.

Providers should encourage clients and prospective sex partners to be tested before initiating a new sexual relationship.

Education, Counseling and Informed Consent

A. Consent

HIV testing must be voluntary and conducted only with the client's knowledge and understanding. The decision whether or not to have HIV testing rests with the client unless the staff person providing the counseling and testing feels that it is dangerous to test the client or that the client is unable to provide informed consent.

Clients may need to receive education on the testing process, especially if they propose questions, in advance of proceeding with the test.

Separate written consent for HIV testing is no longer required; general consent for medical care should be considered sufficient to encompass consent for HIV testing. Although there may be times when it is appropriate to have a client sign the consent form in order to convey a sense of propriety and ownership over the testing process.

Verbal consent must be obtained from all clients prior to testing. Verbal consent is implied by a client being aware that he or she will be screened for HIV and has had the opportunity to ask questions and to decline testing.

If the counselor/clinician feels that it would be dangerous to test the client at this time (i.e. suicidal), explain this and make appropriate interventions/ referrals. Encourage the client to return in the future when he or she may be more able to deal with the possible results.

B. Counseling & Education

Prevention counseling does not need to be linked to HIV testing. However, some clients might be more likely to think about HIV and consider their risks when undergoing an HIV test.

Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings. Although prevention counseling is the best method that we have to promote risk reduction among those individuals who receive HIV testing, and so at least minimal counseling is recommended and sample protocols are contained within this document. In addition, HIV prevention counseling is recommended for all clients at increased behavioral or clinical HIV risk.

HIV education is the simple provision of information, and may or may not be included as part of behavior change prevention counseling. Clients who do not want to receive an HIV test can still receive HIV prevention counseling and/or counseling.

a. Confidential vs. anonymous testing

- When **confidential** testing is chosen, the client's name will appear on all laboratory slips that are sent to a commercial testing laboratory. When a confidential testing specimen is sent to the laboratory, the client's name or chart number can be used as client identification.
- For confidential testing, chart documentation is in the client's medical record. Medical records with HIV information may only be released/transferred after the client gives written consent to release the HIV information as within HIPAA guidelines. Positive confidential results are reported to (*designated reporting agency*).
- When **anonymous** testing is chosen, only an identification number will be used on laboratory specimens, forms and chart. Anonymous tests cannot be sent to the commercial laboratory. Anonymous test results cannot be transferred or released to another provider. Positive anonymous results are not reported to (*designated reporting agency*).

b. The two laboratory test options:

Clients must be offered information on the test being used including explanation of false positive rate. Brochures, handouts, or a copy of the package labeling is acceptable, but verbal descriptions are more common and also acceptable.

- i. Rapid test: Single-use, qualitative immunoassay to detect antibodies to HIV done by whole blood (finger stick or venipuncture) or oral fluid sample. This is not an ELISA test. The test is done on site. Rapid tests test for HIV-1 and HIV-2. There are several rapid tests available produced by pharmaceutical companies.

The client must be made aware that if the test result is reactive, a blood test must be done either at (*Agency*) or another HIV testing facility and sent to the lab for a confirmatory Western blot or other confirmatory test (such as HIV RNA or IFA) before the client can be said to be HIV positive.

Staff must be trained and approved to provide the rapid test before performing the test independently.

- ii. Serum (blood) ELISA test sent to either a tribal, local, country, state, or commercial lab. The Western Blot is an ELISA test; and the Western Blot is generally used as a confirmatory test after a reactive rapid test. A positive or indeterminate ELISA test is rerun by the lab. If the second ELISA is still indeterminate or positive, the result is followed with a Western Blot. An HIV test is only considered positive when both the ELISA and the confirmatory tests are positive.

C. Minors

- Minors (under 18 years) may consent for HIV screening and treatment. Minors must be encouraged to tell their parents and get them involved.
- Testing of a minor may be refused by the counselor/provider if it is felt that the minor is in crisis (e.g. suicidal) or unable to give informed consent (e.g. psychotic). Appropriate interventions/referrals must be made.
- Minors may be tested anonymously or confidentially.

a. Reporting Requirements

Only positive Western Blot or other confirmatory results should be reported. Preliminary positive rapid test results that are not confirmed should not be reported.

i. Under age 13 years:

(research tribal or state laws regarding minors HIV test results)

Following the receipt of a report, a state HIV epidemiologist will contact the reporting clinician for more information and to ensure that the clinician is aware of available services and resources for the client.

Clients who are less than 13 years of age and present for screening must be informed of these reporting requirements so that the client can decide if they wish to be tested confidentially or anonymously. Some of these clients may prefer confidential testing so that their entry into the healthcare system will be facilitated by the reporting and follow-up procedure.

i. Positive results

In anyone **13 or older** who tested confidentially must be reported by name. Coinfection with tuberculosis is also reportable. Anonymous testing may not be reportable.

Results

A. Notification of results when positive

Clients who have rapid testing receive the results when the test is completed, if the client consents to receiving the results, and the providers deems the client prepared for the results.

For confidentially tested clients whose test is sent off site to a remote lab, attempts must be made to notify the client when the results are received, whether they be reactive or non-reactive.

Provisions must be made to provide the test results to clients who test anonymously.

B. Client Notification and Confirmation of Care

1. For all positive HIV results – three attempts, two of which **must** be in writing, **must** be made to notify client within two weeks of receiving results.
 - Call client within 72 hours of receiving results.
 - If no response to telephone attempt, first letter **must** be sent within seven days of receiving results.
 - If no response to first letter, second letter **must** be sent within 14 days of receiving results.
2. Confirmation-of-care follow-up is required as per the seriousness of the referral. See below for positive result counseling recommendations.

Testing Procedures & Coordinating Counseling Strategies

A. Scheduling

- Clients may make an appointment for anonymous screening or confidential screening as a stand-alone visit or may have screening as part of a visit for other services.
- A client having HIV screening as part of a service requiring a clinician should be scheduled with the clinician.
- Clients wishing rapid testing must be scheduled when there is a staffperson available to do the test who is trained in doing the rapid test and when there is a staffperson available who is trained to provide post test counseling for a positive result.
- HIV testing should be done on a walk-in basis when possible.
- HIV testing may be done at venues outside of the health center. Off-premises certificate of insurance must be obtained
- The testing environment must meet requirements for safe and confidential testing.

B. Client centered HIV prevention counseling should be offered as appropriate to the client's need:

- The primary goal of client-centered counseling is risk reduction through personal goal setting. This starts with a risk assessment. The risk assessment helps the client identify, understand and acknowledge at-risk behaviors and situations.
- The following information may be covered as appropriate to client concerns
 1. HIV prevention - general and particular to client's current lifestyle or high risk factor(s)
 2. Resources for crisis services, including identification of support system during the waiting period, and other resources to obtain further information or services if needed

C. Repeat Testing Documentation

Repeat testing may be documented on an interim note. Ask/explain and document as

appropriate to client need:

- New risks if any
- client resources to manage results
- partner notification
- Confirm client's understanding of
 - Reporting requirements
 - Type of HIV test being done
- Discuss how the client will receive the results of the test
- The patient education brochure may be offered each time.

D. Testing for reference lab

1. Ensure that the client is aware that s/he is being screened and has had the opportunity to ask questions and has had the opportunity to decline testing (informed consent).
2. Collect the specimen and label with the client name and or I.D. number. Place the name and/or I.D. number on the lab slip and also enter the HIV test in the lab log.
3. An HIV test that is done as a part of another service cannot be an anonymous test. To protect client privacy, an HIV laboratory specimen can be sent to the laboratory without a client's name. In this case the client's chart number is used as the identifier. The client's name must be on the pre/post test check-off form and the test documentation is part of the client's chart.
4. Advise client of the expected date when results will be available.

E. Providing Test Results and Referrals

1. Off site laboratory test results must be given to the client only after the final written results are returned to the center or after the rapid test is completed.
2. The client must provide identification as agreed at the time of pre-test counseling.
3. The client must be advised that all positive screening tests must be confirmed by the performance of a Western Blot or other confirmatory test.
4. If test results are to be provided by phone or by mail, this must be documented on the client's record.
5. If a client desires a written copy of the test result, it may be provided only within the context of confidential testing.
6. If client tests positive for both the ELISA and confirmatory tests and wishes to have blood drawn again and sent for re-testing, schedule or refer accordingly.
7. Offer client the option of further counseling or referrals as indicated.
8. Document test results and post-test counseling, partner notification plans and referral information.

F. Counseling for POSITIVE serum, POSITIVE rapid test

1. Staff providing positive test results should ensure that the client understands the test results and **must** ensure that all client questions related to the test and result are answered.
2. Clients **must** be advised —
 - Of the opportunity for further post-test counseling either at **THE AGENCY** or via referral. The purpose of this visit is to assess whether the client was able to obtain medical care, minimize transmission risk to partners and access other

needed services.

- About specific strategies to prevent transmission of HIV and other sexually transmitted or bloodborne infections. Supply or refer for safer sex equipment, condoms, contraception and emergency contraception if needed.
 - Of the importance of treatment and obtaining healthcare.
 - About medical and social support resources available.
 - To refrain from donating blood, plasma, or organs.
3. Indeterminate Western blot: The most likely reason for this is that the client is in the process of seroconverting to positive. There are also certain conditions that can cause an indeterminate Western Blot. These include:
- Prior blood transfusion, even with non-HIV-1 infected blood
 - Prior or current infection with syphilis
 - Prior or current infection with malaria parasites
 - Autoimmune disease (i.e. diabetes, Grave's disease, Lyme disease,
 - Association with "large animals.: (veterinarians and large animal trainers)
 - Second or subsequent pregnancies in women
 - Infection with other human retroviruses (e.g., HIV -2 HTLV I/II).
 - A client with an indeterminate Western blot should have the test repeated in a month. If the test continues to be indeterminate, the client should be referred for evaluation and other testing.
4. Rapid test preliminary positive results:
- That positive rapid screening tests **must** be confirmed by an FDA approved confirmatory test such as the Western Blot.
 - Have all referral information ready before talking to the client
 - Explain the result as a preliminary positive for HIV antibodies. Urge the client to have a confirmatory OraSure or serum Western blot drawn.
 - If the client agrees to the confirmatory Western blot, collect and label as required. Send the specimen to the state lab only. Indicate on the lab slip that a Western blot is needed due to positive rapid test. Schedule an appointment for the client to come in for the result. If the Western Blot is negative, if the client has known connections to western Africa, refer the client to an infectious disease specialist as appropriate or request that the lab send the specimen on to the CDC to be tested for HIV-2 (the lab may not be able to do this). If there are no known connections to Africa, ask the client to return in one month for a repeat rapid test and if positive, send serum for a Western blot with instructions to the lab to send the specimen on to the CDC for HIV-2 testing if the HIV-1 Western blot is negative.
5. Positive Rapid Test or Reference Lab EIA with Negative Western Blot
- Current recommendation is to repeat the test in one month because it may be too soon for the Western Blot to be positive if the client is in the process of seroconverting. If EIA is positive, an on-site rapid test may be offered due to its increased sensitivity over EIA. If the rapid test is also positive, the client should be recommended to have another confirmatory test in one month or to be screened for HIV 2. For EIA repeated with rapid testing, a negative rapid test result should be followed up with repeat testing as per the client's window period.

6. False positive Rapid Test

- This is unusual but possible. For clients who are not in the process of seroconverting or who are not infected with HIV 2, this can be caused by Hepatitis A or B, Epstein Barr virus, or other conditions. Note: Western Blot is not able to confirm HIV 2.

G. Counseling for Negative Test Results

- Counseling should be tailored to client interest. For some clients, providing the result may be sufficient at that time. For others, counsel as below depending on client interest.
- Negative test results should be given in the context of the risk assessment, the window period, and risk reduction plan.
- Risk reduction counseling and frequent testing interval should be suggested to individuals with an increased risk of infection
- Counseling of the above at-risk individuals should include —
 - prevention counseling as needed, if not already provided during pre-test counseling
 - interval(s) for follow up HIV test(s)
 - information about and referral to services to support prevention behaviors
 - medical services, as appropriate
- For individuals not at high risk as defined above —
 - Test results may be provided without post-test counseling.
 - All the clients questions related to the test and result must be answered.
 - Additional post-test counseling **must** be available if requested by the client.
- See Referral and Resources Section for additional information.

H. Counseling for EIA (serum) positive – Western Blot negative

1. Run Rapid Test:

- i. If Rapid Test Positive: counsel for HIV preliminary positive result, give referrals and follow up accordingly. Refer for HIV assessment with infectious disease MD who can order HIV RNA testing or provide viral load testing. WB can be negative because:

- a rapid test can identify a positive result more quickly than a WB
- WB tests can not pick up HIV 2 infection,

2. If client wants repeat testing with the affiliate because of negative WB:

Counsel for HIV preliminary positive and repeat Rapid test with WB in 1 month. By that time the WB may be able to confirm the Rapid result. If repeat test shows Rapid test positive and continued WB negative, referral for follow up care as necessary.

I. Counseling for EIA (serum) Positive - Western Blot not yet known

1. It is always best to wait for the Western Blot (WB) result before informing the patient of any result. In rare cases you may want/need to follow up before the WB is received
 - i. Run a Rapid test.

1. Rapid test negative: a false positive EIA result could be suspected. EIA may not be as accurate as Rapid test. Wait for WB result.
 - If WB is negative, the patient is not infected with HIV
 - Follow up per protocol
 2. Retest as appropriate for patient risk
 3. You can also repeat Rapid test in 1 month to confirm continued negative result.
- ii. If the WB is indeterminate,
 1. The patient may be in the process of becoming positive and the WB has identified some but not all the parts of a positive test.
 2. Follow up per protocol and retest as appropriate for patient risk or Repeat Rapid test in 1 month.
 - iii. Rapid test positive
 - Counsel for HIV preliminary positive result, give referrals and follow up accordingly
 - iv. If WB result is positive
 - Rapid test result is confirmed. The patient is HIV infected. Refer accordingly
 - v. If WB is negative
 - Follow up with referral to infectious disease clinic for HIV RNA or other HIV direct virus test
 - WB can be negative because:
 - a rapid test can identify a positive result more quickly than a WB
 - WB tests can not pick up HIV 2 infection
 - Window period for identifying an HIV infection is 3 months from last risk behavior

FYI – Acute Retroviral Syndrome (Acute HIV Infection)

This refers to the first weeks of infection after exposure to the HIV virus, sometimes before anti-HIV antibodies can be detected. This early state of HIV disease is characterized by very high viral loads and is generally a period in which the infected person continues to engage in high risk behaviors. Recent studies indicate that up to one half of HIV transmission may occur during acute infection.

Signs and Symptoms:

About half of the people with acute HIV infection don't notice anything. About half have symptoms, generally within 2 to 4 weeks. The most common symptoms are fever, fatigue, and rash. Others include headache, swollen lymph glands, sore throat, feeling achy, nausea, vomiting, diarrhea, and night sweats. The symptoms, if they occur, generally last a few days or weeks.

Referral/Testing:

Suspicion of acute retroviral syndrome should prompt nucleic acid testing (RNA) to detect the presence of HIV. Clients suspected of having Acute HIV infection should be referred immediately to an HIV clinical care provider for testing and medical care.

Referral

Depending on the client's needs, referrals should be offered for the following services:

- Prevention case management

- Medical evaluation, care and treatment
- Partner counseling and referral services
- Drug or alcohol prevention and treatment
- Mental health services
- Legal services
- Screening and treatment for hepatitis
- Other services (assistance with housing, food, employment, etc.)
- Traditional services
- Family counseling

Clients must be referred for care outside of (*Agency*) if the client's needs progress beyond management capability.

Testing documentation

Confidential HIV testing records are included with the existing medical chart. HIV testing documentation is not kept separate within the client's chart unless the client requests that it be kept separate. If the client presents for STD testing which includes HIV testing, documentation will be on the STD testing form.

Release of records

Medical record documentation containing information pertaining to HIV testing and counseling or HIV status may only be released if the client gives permission to release the HIV related information. Otherwise, HIV relating information may not be released. Exceptions are listed in the AGENCY's Notice of Client Privacy (as required by law, public health risks, etc.).

HIV Prevention Education, Counseling and Testing Sample Protocols B

Introduction

(Agency) offers HIV testing, risk reduction counseling and education about how to prevent HIV transmission to all clients. HIV testing and counseling, as detailed below may, also be offered off-site in controlled environments. Appropriate referrals are provided for any needed services not readily available at the (Agency). Healthcare may be available for clients with HIV or AIDS or linkages to care will be provided, as appropriate. Advocates are available to assist clients to navigate the testing process and the clinical structure.

Staff Training

HIV screening and counseling may be provided by clinicians and support staff who are trained to provide these services.

- A. HIV counseling staff and medical staff must be knowledgeable about:
 - Available counseling, testing and services within (Agency).
 - The process for people who test positive
 - Available services for people who test positive
 - All considerations regarding confidentiality.
 - Tribal, local, state and federal regulations that govern HIV services.
 - Providing care that is appropriate to the client's culture, language, sex, gender orientation, age and developmental level.
 - Community resources and appropriate referral agencies.

- B. All center staff will receive training on:
 - Progression, transmission and prevention of HIV
 - Assessment of risk for HIV infection.
 - Signs and symptoms associated with HIV infection
 - Pros & cons of testing
 - Fundamental of risk reduction counseling
 - Types of tests offered by the agency/clinic.
 - Differences between anonymous and confidential testing.
 - Meaning of indeterminate test results.
 - Developing risk reduction plans.
 - Infection control practices in the center to ensure the control of the spread of infection.
 - Appropriate chart documentation
 - Cultural competency and responsiveness
 - The integration of traditional and Western approaches to HIV treatment

- C. Supervision and evaluation of staff that are approved to provide positive HIV results must include:
 - Staff self assessments and agency assessments to determine training and development needs
 - Observation by a qualified trainer in counseling and testing sessions

- Observation of counseling skills
- Repeat observations and feedback as needed should be conducted at least annually
- Chart audits

Client Selection

A. When to test

HIV antibodies can usually be detected by HIV tests as early as 21 days after infection. It is generally agreed that at least 95% of patients will have detectable HIV antibodies within 3 months of infection. The latest research indicates that it can take 3-6 weeks, and in a few cases up to 6 months before HIV antibodies show up.

B. Initial and Repeat Screening

The Indian Health Service has adopted the Centers for Disease Control and Prevention *Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* adopted in 2006 and revised in 2009. Based upon these recommendations, HIV screening is recommended for all patients (between the ages of 13 and 64) in health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening). This is true even if the client's risk behavior or risk co-factor is not known or readily ascertainable. Persons known to be at high risk for HIV infection should be screened for HIV at least annually.

Providers should encourage clients and prospective sex partners to be tested before initiating a new sexual relationship.

Education, Counseling and Informed Consent

A. Consent

HIV testing must be voluntary and conducted only with the client's knowledge and understanding. The decision whether or not to have HIV testing rests with the client unless the staff person providing the counseling and testing feels that it is dangerous to test the client or that the client is unable to provide informed consent.

Clients may need to receive education on the testing process, especially if they propose questions, in advance of proceeding with the test.

Separate written consent for HIV testing is no longer required; general consent for medical care should be considered sufficient to encompass consent for HIV testing. Although there may be times when it is appropriate to have a client sign the consent form in order to convey a sense of propriety and ownership over the testing process.

Verbal consent must be obtained from all clients prior to testing. Verbal consent is implied by a client being aware that he or she will be screened for HIV and has had the opportunity to ask questions and to decline testing.

If the counselor/clinician feels that it would be dangerous to test the client at this time (i.e. suicidal), explain this and make appropriate interventions/ referrals. Encourage the client to return in the future when he or she may be more able to deal with the possible results.

B. Counseling & Education

Prevention counseling does not need to be linked to HIV testing. However, some clients might be more likely to think about HIV and consider their risks when undergoing an HIV test.

Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings. Although prevention counseling is the best method that we have to promote risk reduction among those individuals who receive HIV testing, and so at least minimal counseling is recommended and sample protocols are contained within this document. In addition, HIV prevention counseling is recommended for all clients at increased behavioral or clinical HIV risk.

HIV education is the simple provision of information, and may or may not be included as part of behavior change prevention counseling. Clients who do not want to receive an HIV test can still receive HIV prevention counseling and/or counseling.

a. Confidential vs. anonymous testing

- When **confidential** testing is chosen, the client's name will appear on all laboratory slips that are sent to a commercial testing laboratory. When a confidential testing specimen is sent to the laboratory, the client's name **or** chart number can be used as client identification.
- For confidential testing, chart documentation is in the client's medical record. Medical records with HIV information may only be released/transferred after the client gives written consent to release the HIV information as within HIPAA guidelines. Positive confidential results are reported to (*designated reporting agency*).
- When **anonymous** testing is chosen, only an identification number will be used on laboratory specimens, forms and chart. Anonymous tests cannot be sent to the commercial laboratory. Anonymous test results cannot be transferred or released to another provider. Positive anonymous results are not reported to (*designated reporting agency*).

b. The two laboratory test options:

Clients must be offered information on the test being used including explanation of false positive rate. Brochures, handouts, or a copy of the package labeling is acceptable, but verbal descriptions are more common and also acceptable.

- i. Rapid test: Single-use, qualitative immunoassay to detect antibodies to HIV done by whole blood (finger stick or venipuncture) or oral fluid sample. This is not an ELISA test. The test is done on site. Rapid tests test for HIV-1 and HIV-2. There are several rapid tests available produced by pharmaceutical companies.

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Staff must be trained and approved to provide the rapid test before performing the test independently.

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C. Minors

- Minors (under 18 years) may consent for HIV screening and treatment. Minors must be encouraged to tell their parents and get them involved.
- Testing of a minor may be refused by the counselor/provider if it is felt that the minor is in crisis (e.g. suicidal) or unable to give informed consent (e.g. psychotic). Appropriate interventions/referrals must be made.
- Minors may be tested anonymously or confidentially.

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Only positive Western Blot or other confirmatory results should be reported. Preliminary positive rapid test results that are not confirmed should not be reported.

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(research tribal or state laws regarding minors HIV test results)

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In anyone **13 or older** who tested confidentially must be reported by name. Coinfection with tuberculosis is also reportable. Anonymous testing may not be reportable.

Results

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Repeat testing may be documented on an interim note. Ask/explain and document as

appropriate to client need:

- New risks if any
- client resources to manage results
- partner notification
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 - Type of HIV test being done
- Discuss how the client will receive the results of the test
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3. An HIV test that is done as a part of another service cannot be an anonymous test. To protect client privacy, an HIV laboratory specimen can be sent to the laboratory without a client's name. In this case the client's chart number is used as the identifier. The client's name must be on the pre/post test check-off form and the test documentation is part of the client's chart.
4. Advise client of the expected date when results will be available.

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5. If a client desires a written copy of the test result, it may be provided only within the context of confidential testing.
6. If client tests positive for both the ELISA and confirmatory tests and wishes to have blood drawn again and sent for re-testing, schedule or refer accordingly.
7. Offer client the option of further counseling or referrals as indicated.
8. Document test results and post-test counseling, partner notification plans and referral information.

F. Counseling for POSITIVE serum, POSITIVE rapid test

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2. Clients **must** be advised —
 - Of the opportunity for further post-test counseling either at **THE AGENCY** or via referral. The purpose of this visit is to assess whether the client was able to obtain medical care, minimize transmission risk to partners and access other

needed services.

- About specific strategies to prevent transmission of HIV and other sexually transmitted or bloodborne infections. Supply or refer for safer sex equipment, condoms, contraception and emergency contraception if needed.
 - Of the importance of treatment and obtaining healthcare.
 - About medical and social support resources available.
 - To refrain from donating blood, plasma, or organs.
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 - Autoimmune disease (i.e. diabetes, Grave's disease, Lyme disease,
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 - Have all referral information ready before talking to the client
 - Explain the result as a preliminary positive for HIV antibodies. Urge the client to have a confirmatory OraSure or serum Western blot drawn.
 - If the client agrees to the confirmatory Western blot, collect and label as required. Send the specimen to the state lab only. Indicate on the lab slip that a Western blot is needed due to positive rapid test. Schedule an appointment for the client to come in for the result. If the Western Blot is negative, if the client has known connections to western Africa, refer the client to an infectious disease specialist as appropriate or request that the lab send the specimen on to the CDC to be tested for HIV-2 (the lab may not be able to do this). If there are no known connections to Africa, ask the client to return in one month for a repeat rapid test and if positive, send serum for a Western blot with instructions to the lab to send the specimen on to the CDC for HIV-2 testing if the HIV-1 Western blot is negative.
5. Positive Rapid Test or Reference Lab EIA with Negative Western Blot
- Current recommendation is to repeat the test in one month because it may be too soon for the Western Blot to be positive if the client is in the process of seroconverting. If EIA is positive, an on-site rapid test may be offered due to its increased sensitivity over EIA. If the rapid test is also positive, the client should be recommended to have another confirmatory test in one month or to be screened for HIV 2. For EIA repeated with rapid testing, a negative rapid test result should be followed up with repeat testing as per the client's window period.

6. False positive Rapid Test

- This is unusual but possible. For clients who are not in the process of seroconverting or who are not infected with HIV 2, this can be caused by Hepatitis A or B, Epstein Barr virus, or other conditions. Note: Western Blot is not able to confirm HIV 2.

G. Counseling for Negative Test Results

- Counseling should be tailored to client interest. For some clients, providing the result may be sufficient at that time. For others, counsel as below depending on client interest.
- Negative test results should be given in the context of the risk assessment, the window period, and risk reduction plan.
- Risk reduction counseling and frequent testing interval should be suggested to individuals with an increased risk of infection
- Counseling of the above at-risk individuals should include —
 - prevention counseling as needed, if not already provided during pre-test counseling
 - interval(s) for follow up HIV test(s)
 - information about and referral to services to support prevention behaviors
 - medical services, as appropriate
- For individuals not at high risk as defined above —
 - Test results may be provided without post-test counseling.
 - All the clients questions related to the test and result must be answered.
 - Additional post-test counseling **must** be available if requested by the client.
- See Referral and Resources Section for additional information.

H. Counseling for EIA (serum) positive – Western Blot negative

1. Run Rapid Test:

- i. If Rapid Test Positive: counsel for HIV preliminary positive result, give referrals and follow up accordingly. Refer for HIV assessment with infectious disease MD who can order HIV RNA testing or provide viral load testing. WB can be negative because:

- a rapid test can identify a positive result more quickly than a WB
- WB tests can not pick up HIV 2 infection,

2. If client wants repeat testing with the affiliate because of negative WB:

Counsel for HIV preliminary positive and repeat Rapid test with WB in 1 month. By that time the WB may be able to confirm the Rapid result. If repeat test shows Rapid test positive and continued WB negative, referral for follow up care as necessary.

I. Counseling for EIA (serum) Positive - Western Blot not yet known

1. It is always best to wait for the Western Blot (WB) result before informing the patient of any result. In rare cases you may want/need to follow up before the WB is received
 - i. Run a Rapid test.

1. Rapid test negative: a false positive EIA result could be suspected. EIA may not be as accurate as Rapid test. Wait for WB result.
 - If WB is negative, the patient is not infected with HIV
 - Follow up per protocol
 2. Retest as appropriate for patient risk
 3. You can also repeat Rapid test in 1 month to confirm continued negative result.
- ii. If the WB is indeterminate,
 1. The patient may be in the process of becoming positive and the WB has identified some but not all the parts of a positive test.
 2. Follow up per protocol and retest as appropriate for patient risk or Repeat Rapid test in 1 month.
 - iii. Rapid test positive
 - Counsel for HIV preliminary positive result, give referrals and follow up accordingly
 - iv. If WB result is positive
 - Rapid test result is confirmed. The patient is HIV infected. Refer accordingly
 - v. If WB is negative
 - Follow up with referral to infectious disease clinic for HIV RNA or other HIV direct virus test
 - WB can be negative because:
 - a rapid test can identify a positive result more quickly than a WB
 - WB tests can not pick up HIV 2 infection
 - Window period for identifying an HIV infection is 3 months from last risk behavior

FYI – Acute Retroviral Syndrome (Acute HIV Infection)

This refers to the first weeks of infection after exposure to the HIV virus, sometimes before anti-HIV antibodies can be detected. This early state of HIV disease is characterized by very high viral loads and is generally a period in which the infected person continues to engage in high risk behaviors. Recent studies indicate that up to one half of HIV transmission may occur during acute infection.

Signs and Symptoms:

About half of the people with acute HIV infection don't notice anything. About half have symptoms, generally within 2 to 4 weeks. The most common symptoms are fever, fatigue, and rash. Others include headache, swollen lymph glands, sore throat, feeling achy, nausea, vomiting, diarrhea, and night sweats. The symptoms, if they occur, generally last a few days or weeks.

Referral/Testing:

Suspicion of acute retroviral syndrome should prompt nucleic acid testing (RNA) to detect the presence of HIV. Clients suspected of having Acute HIV infection should be referred immediately to an HIV clinical care provider for testing and medical care.

Referral

Depending on the client's needs, referrals should be offered for the following services:

- Prevention case management

- Medical evaluation, care and treatment
- Partner counseling and referral services
- Drug or alcohol prevention and treatment
- Mental health services
- Legal services
- Screening and treatment for hepatitis
- Other services (assistance with housing, food, employment, etc.)
- Traditional services
- Family counseling

Clients must be referred for care outside of (*Agency*) if the client's needs progress beyond management capability.

Testing documentation

Confidential HIV testing records are included with the existing medical chart. HIV testing documentation is not kept separate within the client's chart unless the client requests that it be kept separate. If the client presents for STD testing which includes HIV testing, documentation will be on the STD testing form.

Release of records

Medical record documentation containing information pertaining to HIV testing and counseling or HIV status may only be released if the client gives permission to release the HIV related information. Otherwise, HIV relating information may not be released. Exceptions are listed in the AGENCY's Notice of Client Privacy (as required by law, public health risks, etc.).



Denver Indian Health and Family Services

HIV Protocol

Employees' Manual

Last Updated July 12, 2007

Table of Contents

1. Overview	2
2. Role of the Provider	3
A. HIV Prevention Counseling	
B. Information about the test	
3. Universal Precautions for infection control	4
A. Management of Exposure	
4. Education	4
A. Resources	
5. Works Cited.....	5
6. Resources	5
7. Appendix	
A. HIPAA Notice of Privacy	
B. HIPAA Notice of Privacy Acknowledgement Form	
C. HIV Testing Consent Form	

1. Overview

What is human immunodeficiency virus (HIV)?

Human immunodeficiency virus (HIV) is a virus that attacks the immune system, making it difficult for the body to fight infection and disease.

HIV is the same virus that causes acquired immunodeficiency syndrome (AIDS), which increases a person's risk of developing certain cancers and infections. AIDS is the last and most severe stage of the HIV infection. However, having HIV does not mean you have AIDS. The good news is that people who are being treated for HIV are living longer than ever before with the help of drugs that slow the rate at which HIV infection progresses to AIDS.

What causes HIV?

The infection is caused by the human immunodeficiency virus (HIV). Most people get HIV by having unprotected sex with someone who has HIV. Another common way of getting the virus is by sharing needles with someone who is infected with HIV when injecting drugs. HIV cannot be spread by casual contact such as kissing or sharing drinking glasses with an infected person.

Once HIV enters the body, it infects a type of white blood cell called CD4+ cells. These white blood cells are an important part of the immune system that helps your body fight infections. As HIV attacks and destroys CD4+ cells, the immune system weakens and becomes less able to fight off disease. ¹

HIV is not spread through everyday social activity. It is not spread through casual contact or through air or water. This means that intimate activities like hugging; touching, cuddling, kissing, and massage do not spread HIV, as long as there is no contact with a partner's blood, semen, or vaginal fluid. ²

You can't get HIV from:

Handshakes.
Coughs or sneezes.
Sweat or tears.
Being around an infected person.
Food.
Mosquitoes or other insects.

Or from using—

Swimming pools.
Toilet seats.
Phones or computers.
Straws, spoons, or cups.
Drinking fountains.

1. http://www.webmd.com/hw/hiv_aids/hw151411.asp

2. <http://www.redcross.org/services/hss/hivaid/>

2. Role of the Provider

A. HIV Prevention Counseling

The following are guidelines that should be taken into consideration when counseling a patient about HIV.

- a. Keep the focus on HIV risk reduction
- b. Complete a personalized risk assessment of the patient that includes sexual and drug use history.
- c. Provide support for positive steps already taken
- d. Clarify misconceptions or misinformation about HIV/AIDS risk
- e. Negotiate an achievable behavioral change step that will reduce risk
- f. Be flexible in the counseling approach
- g. Provide a referral for counseling and testing or upon request
- h. Provide appropriate education/resources (see Education Section)
- i. Follow strict confidentiality measures

B. Information about the HIV test

1. HIV Testing

The HIV test will detect any antibodies linked to HIV in the blood. The test determines if an HIV infection is present. HIV can be detected through a blood test between 2 weeks and 6 months after the infection. If a person is infected with HIV, it is still possible to transmit the disease if their blood work has returned with a negative result. Testing for the HIV virus is often done at 6 weeks, 3 months, and 6 months after exposure to determine that a person is not infected.

Several tests can find antibodies or genetic material (RNA) to the HIV virus. These tests include:

- **Enzyme-linked immunosorbent assay (ELISA).** This test is usually the first one used to detect infection with HIV. If antibodies to HIV are present (positive), the test is usually repeated to confirm the diagnosis. If ELISA is negative, other tests are not usually needed. This test has a low chance of having a false result after the first few weeks that a person is infected.
- **Western blot.** This test is more difficult than the ELISA to perform, but it is done to confirm the results of two positive ELISA tests.
- **Polymerase chain reaction (PCR).** This test finds either the genetic material DNA or RNA of HIV. PCR testing is not done as frequently as antibody testing because it requires technical skill and expensive equipment. This test may be done in the days or weeks after exposure to the virus. Genetic material may be found even if other tests are negative for the virus.
- **Indirect fluorescent antibody (IFA).** This test detects HIV antibodies. Like a Western blot test, it is used to confirm the results of an ELISA. However, it is more expensive than a Western blot test and not commonly used. ¹ <http://www.questdiagnostics.com/kbase/topic/medtest/hw4961/descrip.htm>

3. Universal Precautions for infection control

The universal precautions for infection control are recommended for all employees. These precautions are used to help prevent exposure to another person's blood or body fluids.

Universal Precautions

1. Use protective barriers
 - A. Wear gloves when performing veinipuncture or when touching blood and body fluids. Gloves must be changed when torn and after contact with each person.
 - B. Use masks and protective eyewear whenever splashes, spray or spatter of blood drops may happen. When using a mask, change between each patient or when the mask becomes moist.
2. Hand washing
 - A. Wash hands thoroughly before placing gloves on and immediately after removing gloves. Hands should be washed immediately if bare hands have touched blood or any contaminated surface.
 - B. Hands should be washed after using the toilet, wiping runny nose, and after handling patient specimens. Wash hands before handling clean equipment and after handling dirty equipment.
3. Sharps protection
 - A. Do not bend, remove, recap, or purposely break needles. Disposal of needles should be placed in the appropriate puncture proof containers. Do not remove objects from sharps containers.

A. Management of Exposure

1. The following procedure should be followed if a worker has a puncture wound from a sharp object, (e.g. needle stick or cut) or exposure of an open wound or mucus membrane to blood/body fluids:
 - a. Workers who experience a possible exposure should have a baseline HIV Ab test to document current status. This should be done at a private medical doctor or through the employer, using the worker's legal name, so that the records can be accessed if necessary.
 - b. Obtain informed consent of the source client for HIV Ab and HbsAntigen (Ag) testing. If the client refuses, the agency should consult with legal counsel regarding the implications of the applicable statute.
 - c. If the source client is positive for either Ab or Ag, the worker should be advised and tested immediately at six weeks, 3 months and six months post exposure. If the worker's results remain negative six months post exposure then no further follow up is required. If the worker refuses testing, complete a release form and have the worker sign it.
 - d. The source client should be offered appropriate client-centered HIV pre – and posttest counseling, including results if desired, by an experienced HIV Ab test counselor.

- e. Workers performing exposure prone procedures should discuss AZT prophylaxis with their care provider in advance and decide if AZT would be desired in the event of a possible exposure.
2. An incident report should be completed each time a worker has a potential exposure and full documentation of the event and the follow-up should be included.¹

¹ <http://www.cdphe.state.co.us/pp/womens/FPmanuals/nursingPolicies/XIV-HIVPOLICY.pdf>)

5. Education

Educational resources can be downloaded from:

- American Red Cross: <http://www.redcross.org/services/hss/hiv aids/>
- AIDSinfo: <http://aidsinfo.nih.gov/>

6. Resources

American Red Cross Health and Safety Services

<http://www.redcross.org/services/hss/hiv aids/>

Last Retrieved: July 12, 2007

AIDSinfo A service of the U.S. Department of Health and Human Services

<http://aidsinfo.nih.gov/>

Last Retrieved: July 12, 2007

Colorado Department of Public Health

<http://www.cdphe.state.co.us/cdphehom.asp>

Last Retrieved: July 12, 2007

Human Immunodeficiency Virus (HIV) Test, Quest Diagnostics Incorporated

<http://www.questdiagnostics.com/index.html>

Last Retrieved: July 12, 2007

WebMD Human Immunodeficiency Virus (HIV) Infection

http://www.webmd.com/hw/hiv_aids/hw151411.asp

Last Retrieved: July 12, 2007



Denver Indian Health and Family Services

Notice of Privacy Practices

This notice describes how your medical information may be used and disclosed, and how you can get access to this information. Please review this carefully.

Denver Indian Health and Family Services has always considered physician-patient confidentiality an integral part of patient care.

As part of the Balanced Budget Act of 1997, new legislation regarding the privacy of your protected health information (PHI) will become effective April 14, 2003.

The law, known as HIPAA (Health Insurance Portability and Accountability Act), requires that all healthcare providers maintain the privacy of protected health information and provide individuals with notice of its legal duties and privacy practices with respect to protected health information. This office is required to follow the terms of the notice currently in effect.

We use health information about you for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive. Continuity of care is part of treatment and your records may be shared with other healthcare providers to whom you are referred. Information may be shared by paper mail, electronic mail, fax, or other methods.

In addition, we may disclose identifiable personal health information about you without your authorization for several reasons. Subject to certain requirements, we may give out health information without your authorization for public health purposes such as reporting of communicable diseases, birth, death, injury and child abuse or neglect; for auditing purposes; for research studies; and for emergencies. We may provide information when otherwise required by law, such as for law enforcement or by court order in specific circumstances. Contact with you may also take place in the form of appointment reminders, prescription refills, referrals, test results, etc.

In any other situation, we will ask for your written authorization before using or disclosing any identifiable personal health information about you. If you choose to sign an authorization to disclose information, you may later request to revoke either all or part of the authorization to limit or stop any future uses or disclosures.

You have the right to request to see and receive a copy of all information that is contained in your medical record or chart at this office by alternate means or at alternate locations. All such requests must be submitted in writing. This includes information that other providers may have sent to this office. If you request a copy of your medical record,

we will charge you only normal photocopy fees. Exceptions to this right of access include psychotherapy notes, information compiled in reasonable anticipation of, or for use in, civil, criminal, or administrative proceedings; and protected health information maintained by Denver Indian Health and Family Services that is subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C., 263a, to the extent the provision of access would be prohibited by law or exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 C.F. R., 493.3(a)(2).

Denver Indian Health and Family Services may deny your access request provided that you are given the right to have such a denial reviewed in the following circumstances:

1. A licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of you or another person;
2. The protected health information refers to another person and a licensed health care professional has determined that the access requested is reasonably likely to cause substantial harm to that person; or
3. The request for access is made by your personal representative and a licensed health care professional has determined that the provision of access is reasonably likely to cause substantial harm to you or another person.

We may also deny you access without providing an opportunity for review in the following circumstances:

1. The protected health information is excepted from the right of access;
2. Access to the protected health information is contained in records that are subject to the Privacy Act, 5 U.S.C., 552a or
3. Access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

Denver Indian Health and Family Services will have 30 days to act on a written request for access to your records unless the requested information is not maintained or accessible on site in which case we may take up to 60 days to act on your request. We will respond in writing to your request and provide you with the anticipated date we will complete our action on your request. If access is granted, we will provide whatever access was requested including inspection, obtaining a copy, or both. If access is denied, we will inform you in writing and provide you with the reasons or basis for the denial, a statement regarding your right to request a review of the decision and information on how to issue such a request. We will also give you access to any other protected health information after excluding the portion of the information for which access is denied.

If you believe that information contained in your medical record is incorrect or if important information is missing, you have the right to request that we correct the existing information or amend the missing information. This request must be submitted in writing and must include a reason to support the requested amendment. Denver Indian Health and Family Services must act on a request for amendment within 60 days of the

receipt of the request. The acceptance or denial of a request to amend your protected health information will follow the same process as requests for access described above. Should you request and receive approval for an amendment to your personal health information from another physician, we will also amend our records to reflect any changes made to your medical record at the other physician's office.

You have the right to an accounting of disclosures of all protected health information that was released by this office in the past six years EXCEPT for disclosures for purposes of treatment, payment and healthcare operations; to individuals of protected health information about them; for a facility directory or to persons involved in your care; or other notification purposes; for national security or intelligence purposes; to correctional institutions or law enforcement officials; or that occurred prior to the compliance date of April 14, 2003. You have the right to a paper copy of this notice regardless of whether you have received a prior copy either in printed or electronic format.

The accounting will include the date of the disclosure, the name of the person who received the protected health information and their address; a copy of the written request for disclosure; a brief description of the PHI disclosed and brief statement of the purpose of the disclosure that reasonably informs you of the basis for the disclosure. If we have made disclosure of PHI for a particular research purpose for 50 or more patients, the accounting will provide additional information about the disclosure and the research purposes.

You have the right to request a restriction on the use and disclosure of some information, even those disclosures or uses related to treatment, payment or health care operations. This request must be submitted in writing. However, Denver Indian Health and Family Services is not required to automatically agree to such a restriction request. If Denver Indian Health and Family Services does agree to a restriction of PHI, we will document the specific requested restriction. Please be advised that Denver Indian Health and Family Services may still disclose the restricted information if the individual who requested the restriction is in need of emergency treatment and the restricted health information is needed to provide that treatment. In those circumstances, we may use restricted information or may disclose the information to a health care provider to provide emergency treatment for you. If we disclose or use restricted information in this manner, we will request that the provider not further use or disclose that information beyond the emergency treatment.

We may also terminate our agreement to a restriction if:

1. You agree to or request the termination in writing;
2. You verbally agree to the termination and the verbal agreement is documented;
3. Denver Indian Health and Family Services informs you that we are terminating our agreement to a restriction, except that such termination is only effective with respect to protected health information created, received or obtained after the date of the termination notice to you.

Denver Indian Health and Family Services will keep on file the titles of the persons or offices responsible for receiving and processing requests for access and amendments from all patients and will retain appropriate documentation of any and all requests.

Any and all documentation relating to requests for access, requests for restrictions, requests for amendments, and requests for accounting disclosures will be maintained in the Denver Indian Health and Family Services offices for 6 years from the date it was created or the date it was last in effect, whichever is later.

Finally, you have the right to complain about any perceived privacy violations or if you disagree with a decision we made about access to your records. You may contact the Secretary of the Department of Health and Human Services at 200 Independence SW, Washington D.C., 20201. Be assured that the law also prohibits retaliation in any form to any person who exercises this right.

We may change our policies at any time. Before we make significant change/s to our policies, we will modify this notice to reflect the changes and post the new notice in the waiting area. You can also request a copy of our notice at any time. For more information about our Privacy Practices, contact the Denver Indian Health and Family Services Practice Manager at this office.

We are required by law to protect the privacy of your personal health information, provide this notice about our information practices, follow the information practices that were described in this notice, and obtain your written acknowledgement that you have read this notice, been given the opportunity to ask any questions regarding the notice, and have been given a copy of the notice if you requested one.



Denver Indian Health and Family Services

Notice of Privacy Practices Acknowledgement of Receipt

The Denver Indian Health and Family Services Notice of Privacy Practices provides information about how we may use and disclose protected health information about you.

I acknowledge that I have received the Notice of Privacy Practices.

Signature of Patient or Patient's Representative

Date

Print Name

Relationship to Patient

Interpreter (if applicable)



Denver Indian Health and Family Services Informed Consent to Perform HIV Testing

My health care provider has answered any questions I have regarding HIV testing and has given me written information with the following details about HIV testing:

- HIV is the virus that causes AIDS.
 - The only way to know if you have HIV is to be tested.
 - HIV testing is important to your health, especially pregnant women.
 - HIV testing is voluntary. Consent can be withdrawn at any time.
 - Several testing options are available including anonymous and confidential.
 - State law protects the confidentiality of test results and also protects test subjects for discrimination based on HIV status.
 - My health care provider will talk with me about notifying my sex or needle-sharing partners of possible exposure if I test positive.
-

I agree to HIV testing for the diagnosis of possible HIV infection. If I am found to have HIV, I agree to additional testing to determine the best treatment for me and to monitor the epidemic.

Signature: _____ Date: _____

Printed Name: _____

Oraquick Advance Rapid HIV-1/2 Antibody Testing Guidelines

Table of Contents

I. Introduction

II. Working with the Client

- A. Structure of the Client Visit for Rapid Testing
 1. Pre-Test Counseling and Informed Consent
 2. Administration of OraQuick Test
 3. HIV Prevention/Risk Reduction Counseling
 4. Disclosure of the Test Result and Follow-Up as Needed
- B. HIV Counseling
 1. The Role of an HIV Counselor
 2. Components of Pre-Test Counseling
 3. Components of Post-Test Counseling
- C. Policies Regarding HIV Antibody Testing

III. Running the Test

- A. Materials Required to Perform the OraQuick Test
- B. Directions for Using OraQuick
 1. Preparing Your Work Space
 2. General Test Preparation
 3. Specimen Collection and Testing Procedure
 4. General Test Clean Up

IV. Quality Control

- A. Storage and Use
- B. Internal Controls
- C. External Controls
- D. What to do if...

V. Protocol for Reactive Test Results

- A. Before Giving the Result
- B. Giving the Result
- C. Making Referrals
- D. Confirmatory Test Results

VI. Protocol for Repeat Rapid HIV Testing

I. INTRODUCTION

As the AIDS epidemic continues to grow, HIV antibody testing should be a routine part of STI screening. HIV testing cannot only bring peace of mind to those who test negative but also provide the opportunity for counseling about risk reduction practices and prevention. For those who test positive, new treatment options are available that may significantly prolong survival and counseling can be directed toward seeking case management, antiretroviral therapy, and support services for transmission prevention.

While men who have sex with men continue to comprise the greatest number of positive HIV cases, the number of cases among women, minorities, and young adults is increasing rapidly. These cases are primarily attributable to heterosexual transmission and injection drug use.

Although millions of traditional HIV tests are conducted annually in publicly funded counseling and testing programs, many of the persons who are tested do not return to receive their results. One of the largest benefits of the OraQuick Advance Rapid HIV-1/2 Antibody test is that almost all clients will receive their test results since they can be provided during a single counseling and testing session. By reducing the potential of losing clients to follow-up, rapid testing may substantially improve the counseling and referral services we are able to provide to our clients.

OraQuick Advance is a simple, rapid immunoassay that detects antibodies to HIV-1/2 in oral fluid, finger stick whole blood, venipuncture whole blood and plasma specimens and provides results in as little as 20 minutes. Clinical studies have demonstrated that the sensitivity and specificity of rapid HIV tests are comparable to those of the enzyme immunoassays (such as the OraSure test) currently used for screening. The negative predictive value of this screening test is high; as a result, a client with a negative rapid HIV test result can generally be told he or she is not infected. However, because HIV antibodies take time to develop after exposure to the virus, persons with a recent possible exposure (sexual contact or needle sharing within the previous six weeks) might need retesting at a later time. As with any screening test, the positive predictive value of a reactive rapid HIV test is low in populations with low prevalence. Because some reactive test results may be false positive, every reactive rapid HIV test must be confirmed by a supplemental western blot.

Prior to specimen collection, each client must be given the "Subject Information Pamphlet" provided with each device. The client must also be counseled (refer to counseling protocol for rapid HIV testing) and provide consent for rapid HIV antibody testing (refer to the "Informed Consent for Rapid HIV-1/2 Antibody Testing" form).

II. WORKING WITH THE CLIENT

A. Structure of the Client Visit for Rapid Testing

1. Pre-Test Counseling and Informed Consent
2. Administration of OraQuick Test
3. HIV Prevention/Risk Reduction Counseling
4. Disclosure of the Test Result and Referrals as Needed

1. Pre-Test Counseling and Informed Consent

- Recommend testing and introduce the rapid testing process.
- Provide streamlined counseling, including information about the test's benefits and limitations.
- Provide information on the ways in which HIV is transmitted.
- Obtain informed consent.
- Assess the client's readiness to receive the result, e.g. ask about support systems, history of domestic violence, depression, etc.
- Explain the testing method.

2. Administration of OraQuick Test

- Obtain client's signature or bar code number on the informed consent form.
- Collect the specimen and perform the test.
- Document all phases of the testing visit on the **OraQuick Advance Rapid HIV-1/2 Test Sheet**. This form will become part of the client's chart or put on file.

3. HIV Prevention/Risk Reduction Counseling

- Explain how risk assessment will assist in interpreting the meaning of the result.
- Help the client identify behaviors that place him/her at risk.
- Help the client develop a realistic and incremental plan to reduce risk, regardless of test result.

4. Disclosure Of The Test Result And Follow-Up As Needed

Disclosure of a Non-Reactive Test Result

- Explain the test result – non-reactive for HIV-1/2 antibodies.
- Discuss the window period and, based on client risk, the need for subsequent testing.
- Make an appointment for a subsequent visit if the client is at high risk for HIV.
- Reinforce the prevention plan.

Disclosure of a Reactive Test Result

- Explain the meaning of the test result, using language to convey a preliminary result.
- A reactive rapid HIV test result suggests that antibodies to HIV may be present.
- Reinforce the necessity of confirmatory testing via the western blot.
- Provide the client with support. Provide crisis intervention and referrals as indicated.

Confirmatory HIV Testing

- Arrange for confirmatory serum HIV antibody test (western blot specific testing) either on site, by referral, or by appointment at Tapestry's HIV/AIDS Services.
- Advise the client to adopt the behaviors discussed in the prevention plan until the rapid test result is confirmed.
- If the rapid test result is reactive and the confirmatory test result is negative, advise the client to follow-up by repeating the rapid test in 2-3 months.

Invalid Result

- An invalid test result means that there was a problem running the test, either related to the specimen or to the device. An invalid result cannot be interpreted. Repeat the test with a new pouch and a new sample. See the "what to do if..." section for answers to additional questions.

B. HIV Counseling

1. The Role of Staff Performing HIV Testing:

- Provide accurate and basic information about HIV, transmission and prevention
- Help clients examine their risk behavior
- Create a non-judgmental atmosphere in which clients can speak openly about their concerns
- Be able to identify and offer support services for clients
- Make appropriate referrals when necessary
- Manage the testing process safely and accurately

2. Components of Pre-Test Counseling:

- Introduce yourself and your role
- Address the client privately
- Identify the client's reasons for testing
- Advise no food, drink or smoking for at least 20 minutes prior to testing
- Assess the client's knowledge of HIV and modes of transmission
- Explain basics of HIV infection, AIDS, and risk factors associated with infection
- Evaluate risk status
- Develop a risk reduction plan with the client
- Explain confidential versus anonymous testing
- Discuss OraQuick HIV-1/2 antibody test, procedure, window period, accuracy, and the need for confirmatory testing on reactive results
- Discuss pros and cons of testing, benefits of early testing and treatment
- Explain the meaning of a non-reactive, reactive or invalid test result
- Identify client's support network to determine if client wants support after results are given
- Assess client's readiness to test, reconfirm decision to test
- Give client the "Subject Information" pamphlet
- Obtain informed consent
- Initiate use of the Rapid HIV-1/2 Documentation Form

3. Components of Post-Test Counseling:

- Re-establish rapport with client
- Address any concerns the client may have
- Assess client's readiness for test result
- Give result promptly unless client indicates ambivalence
- Allow response time for client
- Address client's feelings about result
- Give essential information
- Facilitate appropriate referrals

If result is non-reactive:

- Emphasize that a non-reactive result does not mean that one is immune to HIV
- Reassert safe sex practices and risk reduction to avoid future exposure
- Assess the need to re-test depending upon window period and last exposure
- Retesting should occur approximately 2-3 months after a client's last exposure

If result is reactive:

- Allow client to express a range of reactions
- Address client's concerns
- Help client make plan for the following 24 hours to prioritize needs and obtain support
- Address the importance of confirmatory serum HIV testing by western blot to confirm reactive test result and arrange for testing
- Discuss benefits of early intervention and treatment
- Discuss risk behavior and avoidance of transmission, re-infection
- Discuss referrals for on-going medical care and HIV case management/supportive services if the confirmatory test is positive

C. Policies Regarding HIV Antibody Testing

The agency family planning sites will offer *confidential* testing using the OraQuick testing method. Persons requesting *anonymous* testing will be referred to HIV/AIDS Services. Persons receiving testing do not need to be established clients. All persons requesting testing must pay at the time of the counseling and testing visit. The decision to receive testing rests solely with the client. Testing will not be provided unless the client is able to understand and provide informed consent.

Under no circumstances shall an employee provide rapid or serum HIV antibody testing to any family member (including extended relatives and step family) or to one's self. If an employee is found to have provided HIV antibody testing to a family member or to one's self, disciplinary action will be taken by their supervisor.

For confidential testing, all documentation related to rapid testing (including the OraQuick Test Sheet, Risk Assessment, Informed Consent, and Medical Record Release Form and counseling notes) will be kept in the back of the client's chart or on file. All staff with access to client records will have signed Statement of Confidentiality Form.

Documentation of HIV test results for Confidential testing will only be released when the form, “Authorization to Release HIV Medical Record Information”, is signed and dated by the client. All clients with reactive tests (and receiving confidential testing) will be asked to sign this form. Documentation of HIV test results for Anonymous testing may only be given to the client and will not be released to any third party.

III. RUNNING THE TEST

A. Materials Required to Perform the OraQuick Test

Included in the OraQuick Test Kit:

- OraQuick Divided Pouch (includes test device and developer solution vial)
- Reusable Test Stand
- Specimen Collection Loop
- Subject Information Pamphlet

Required Materials Not Included in OraQuick Test Kit:

- Disposable Latex, Vinyl, or Nitrile Gloves
- Timer or Watch capable of timing 20 to 40 minutes
- Clean, Disposable, Absorbent Workspace Cover
- Antiseptic Wipes
- Sterile Gauze Pads
- Biohazard Waste Container
- Sterile lancet if performing a finger stick

B. Directions for Testing Using OraQuick

General Preparation Procedure

1. Prior to any testing for a given day, complete the Quality Assurance Record as outlined in Quality Assurance Section for OraQuick:
 - Record Temperature on Temperature Log
 - Perform External Controls as outlined in QA
2. Document the following on the Log Record for OraQuick:
 - Client’s ID or Barcode Number
 - Date of Specimen Collection
 - Kit Lot Number (number on external packet, not vial)
 - Kit Lot expiration Date (date on external packet, not vial)

Preparing Your Work Space:

- Gather all of the required materials listed above.
- Check the expiration date on your testing kit.
- Allow the test kit to come to room temperature (59°-99° F) before use.
- Set up an OraQuick reusable test stand on your workspace.
- Put on your disposable gloves.

General Test Preparation:

- Provide the OraQuick “Subject Information” pamphlet to the client being tested.
- Open the side of the OraQuick divided pouch that contains the developer solution vial by tearing at the notches on the top of the pouch and remove the developer solution vial.
- Holding the vial firmly in your hand, carefully remove the cap from the vial by gently rocking the cap back and forth while pulling it off. Set the cap on your workspace cover.
- Slide the vial into the top of one of the slots in the stand. Do not force the vial into the stand from the front of the slot as splashing may occur.
- Make sure that the vial is pushed all the way to the bottom of the slot in the stand.

Complete the OraQuick Test Log and Test Sheet:

- The actual incubation time of the test is the length of time that the sample was in the developer solution before you read the results.

Specimen Collection and Testing Procedure: ORAL FLUID

Step 1: Collect

- Have the client remove the device from its pouch.
- Do not allow the client to touch the flat pad.
- Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch.
- Direct the client to place the flat pad above the teeth against the outer gum. Direct the client to gently swab completely around the outer gums, both upper and lower.
- **Do not** allow the client to swab the roof of the mouth, the inside of the cheek or the tongue.

Step 2: Test

- Instruct the client to insert the flat pad of the device all the way into the vial.
- Make sure the flat pad touches the bottom of the vial and the result window faces toward you.
- *Do not cover the holes on the device once placed in the vial.*
- Start timing the test. *Do not remove the device or the vial stand* while the test is running. Pink fluid will appear and travel up the result window. The pink fluid will gradually disappear as the test develops.
- Read the test results after 20 minutes but not more than 40 minutes in a fully lighted area.

Specimen Collection and Testing Procedure: FINGERSTICK

Step 1: Collect

- Using an antiseptic wipe, clean the client’s finger. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
- Using a sterile lancet, puncture the skin just off the center of the finger pad.
- Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed.
- Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
- Pick up an unused specimen collection loop by the thick handle end.

- Put the rounded end of the loop on the drop of blood. Make sure that the loop is completely filled with blood. Note: if the loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new loop for the collection of the blood sample.
- Specimens should be handled as if potentially infectious in accordance with the protocol for Universal Precautions.

Step 2: Mix

- Immediately insert the blood filled end of the loop all the way into the vial.
- Use the loop to stir the blood sample in the developer solution.
- Remove the used loop from the solution. Throw the used loop away in a biohazard waste container.
- Check the solution to make sure that it appears pink. This means that the blood was correctly mixed into the solution. If the solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new pouch and collect a new blood sample.

Step 3: Test

- Open the chamber of the OraQuick divided pouch that contains the test device by tearing at the notches on the top of the pouch. Remove the device from the pouch. Do not touch the flat pad of the device.
- Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch for testing.
- Insert the flat pad of the device all the way into the vial containing the blood sample. Make sure that the flat pad touches the bottom of the vial. The result window on the device should be facing towards you.
- Start timing the test. *Do not remove the device or the vial stand* while the test is running. Pink fluid will appear and travel up the result window. The pink fluid will gradually disappear as the test develops.
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

Test Interpretation

NON-REACTIVE:

The test is **Non-Reactive** if a reddish-purple line appears next to the triangle labeled “C” **and** **NO** line appears next to the triangle labeled “T”.

A **Non-Reactive** test means that HIV-1/2 antibodies were not detected in the specimen. A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several weeks to months to reach detectable levels.

REACTIVE:

A test is **Reactive** if a reddish-purple line appears next to the triangle labeled “C” **and** a reddish-purple line appears next to the triangle labeled “T”. One of these lines may be darker than the other.

A **Reactive** test result means that HIV-1/2 antibodies may have been detected in the specimen. A follow-up confirmatory serum sample by western blot must be obtained either on-site, by referral, or at Tapestry's HIV/AIDS Services to confirm a reactive result.

General Test Clean Up:

- Dispose of the used test materials in a biohazard waste container.
- Change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
- Use a lab cleaning product to clean up any spills.

Limitations:

1. Clinical data has not been collected to demonstrate the performance of the OraQuick Rapid HIV-1/2 Antibody Test in persons less than 13 years of age.
2. A Reactive result using the OraQuick Rapid HIV-1/2 Antibody Test must be confirmed with a follow-up serum sample by western blot.
3. A Non-Reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several weeks to months to reach detectable levels.
4. For a Reactive result, the intensity of the test line does not correlate with the titer of antibody in the specimen.

IV. QUALITY CONTROL

A. Storage and Use

- With each new shipment, document the lot number(s), date of receipt and expiration date(s) on a separate Reagent Log for each lot number. Rotate stock to ensure that kits with the earliest expiration dates are used first. Throw out any kit past its expiration date.
- On a daily basis, check the temperature of the storage area. Document the temperature on the **Daily Temperature Log Sheet**. The acceptable ranges are as follows:

Test Kits – between 35° F and 80° F

Control Kits – between 35° F and 46° F

Testing Area – between 59° F and 99° F

Materials must be maintained at proper temperatures to ensure adequate results.

If temperatures fall outside of acceptable range, run an external control and follow external control procedures.

- When performing tests, check the kit lot number and the kit lot expiration date. Make sure that the lot numbers of reagents are the same. Do not mix reagents with differing lot numbers. Document on the OraQuick Control Log Sheet.

B. Internal Controls

Each test device has a built-in (internal) control to ensure that the client's specimen has been correctly loaded and that it has traveled through the test device. A reddish-purple line which

develops next to the “C” on the test device indicates a valid test. This line will appear on all valid tests regardless of whether the sample is reactive or non-reactive. If no line develops next to the “C”, that test should be considered invalid and a second test should be run. If the line appears outside of the “C” or “T” triangle, the test is invalid. If a second test is invalid, run external controls. Internal controls should be documented on the OraQuick Test Log Record.

C. External Controls

External controls are used to ensure the accuracy of the test in detecting the antibody to HIV and to verify that personnel are able to perform the test and read the results correctly. External controls include one vial of an HIV 1 and one vial of HIV 2 antibody-positive human plasma control and one vial of an HIV antibody-negative human plasma control. The positive control should yield a reactive result while the negative control should yield a non-reactive result.

When an external control kit is opened, it can be used for up to 8 weeks and then discarded.

External controls should be run under the following circumstances:

- By each new operator prior to performing testing on clients – this is part of proving competency in the performance of the rapid test.
- When opening a new lot of test kits.
- When a new shipment of test kits is received.
- If the temperature of the storage area falls outside of the acceptable range (35°F – 80°F).
- If the testing area falls outside of the acceptable range (59°F –99°F).
- At each new outreach site.
- If two consecutive invalid tests are obtained on the same patient.
- If a test result is reactive.

If either external control produces an incorrect result, another trained staff person should run a second set of controls. If the second set of controls produces incorrect results, contact the test manufacturer for additional information on how to proceed. Discuss with the client the invalid result and offer the client the traditional HIV test.

If – ***after running two sets of external controls and contacting the manufacturer*** – the problem appears due to malfunctioning test devices, all Rapid Tests performed since previous correct control results should be considered invalid. Clients with invalid results should then be contacted for re-testing.

Document all information on external controls (when controls are run, their results and remedial/corrective actions) on the **OraQuick Kit Control Log Sheet**. Logs should be reviewed every month by the site supervisor.

D. What do I do if...

The Kit Controls do NOT produce the expected results.

If the test result for either the Negative Control or the Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and appropriate control specimen. If the test result for either control is not as expected upon repeat testing, discontinue

testing and contact OraSure Technologies Customer Service (800-869-3538). All patients who were tested after the last time the controls were run successfully must be retested.

The test kit storage area falls out of the required temperature range. (35 °F to 80 °F) (2 °C to 27°C) Follow the Kit Control Procedure for all lot numbers in storage. If the controls produce the expected result (positive control is positive and the negative control is negative) continue with patient testing. If they do not produce the expected result repeat Kit Controls. If they still do not produce the expected results contact OraSure Technologies Customer Service (800-869-3538).

The testing area falls out of the required temperature range. (59 °F to 99 °F) (15 °C to 37 °C). Follow the Kit Control Procedure. If the controls produce the expected result (positive control is positive and the negative control is negative) it is okay to run patient samples at the current temperature of the testing area for a limited time (e.g. the rest of the day). If they do not produce the expected result repeat Kit Controls. If they still do not produce the expected results DO NOT proceed with patient testing and contact OraSure Technologies Customer Service (800-869-3538).

The pouch is expired.

Discard and use a new Pouch with a valid expiration date. Kit Controls must be run first if starting a new lot number.

Developer vial spills (any amount) before adding the sample.

Discard all elements of the opened Pouch in a Biohazard Waste Container and start the test from the beginning using a new complete unused Pouch containing a Vial, Device, and Absorbent Package.

Developer vial spills (any amount) after adding the sample.

Discard all elements of the opened Pouch (including the Developer Vial containing the sample) into a Biohazard Waste Container and start the test from the beginning using a new complete unused Pouch containing a Vial, Device, and Absorbent Package. A new sample must be collected.

If blood or any other debris is present on the oral swab after swabbing.

Discard all elements of the opened Pouch (including the Developer Vial containing the sample) into a Biohazard Waste Container and start the test from the beginning using a new complete unused Pouch containing a Vial, Device, and Absorbent Package. A new sample must be collected.

If using finger stick, the blood does not flow by placing gentle pressure next to the puncture site. Clean a new site with a new antiseptic wipe and perform a new puncture.

The collection device containing a sample is dropped or comes in contact with any surface.

Discard the device in a Biohazard Waste Container. Get a new unused device to collect the sample.

There is no absorbent package with the device.

Discard all elements of the opened Pouch (including the Developer Vial containing the sample) and start the test from the beginning using a new complete unused Pouch containing a Vial, Device, and Absorbent Package. A new sample must be collected.

You touch the flat pad.

Discard all elements of the opened Pouch (including the Developer Vial containing the sample) and start the test from the beginning using a new complete unused Pouch containing a Vial, Device, and Absorbent Package. A new sample must be collected.

You suspect that the flat pad has become contaminated by touching another surface.

Discard all elements of the opened Pouch (including the Developer Vial containing the sample) and start the test from the beginning using a new complete unused Pouch containing a Vial, Device, and Absorbent Package. A new sample must be collected.

The two holes on the back of the device were covered while the test was running.

See instructions for an INVALID test.*

The device was removed from the vial while the test was running.

See instructions for an INVALID test.*

The vial was moved while the test was running.

See instructions for an INVALID test.*

The test was read less than 20 minutes after the test began.

See instructions for an INVALID test.*

The test was read more than 40 minutes after the test began.

See instructions for an INVALID test.*

There is no reddish-purple line within the “C” triangle 20 to 40 minutes after the test has begun.

See instructions for an INVALID test.*

Any of the lines present are outside of the “C” or “T” triangle areas.

See instructions for an INVALID test.*

A red background in the result window makes it difficult to read after 20 minutes.

See instructions for an INVALID test.*

*** Instructions for an INVALID Test**

If the test is invalid, discard all elements of the opened pouch and start the test from the beginning using a new, complete, unused kit. A new oral fluid sample must be collected. If you receive two consecutive invalid test results on a client, the Kit Controls must be run prior to any further testing. If the Kit Controls produce the expected results (positive control is reactive and negative control is negative) then a blood sample must be collected and submitted to the

reference lab for follow-up testing. If you are unable to draw blood at the time of the invalid test, refer the client to a confirmatory blood test site.

V. PROTOCOL FOR REACTIVE TEST RESULTS

This protocol is written to guide the counselor who must give a client a reactive test result and then begin the process of referring the client into services they will need for confirmatory testing as well as medical and supportive care.

Before Giving Result

- Take a deep breath. You can help the client best by staying calm.
- Notify your supervisor. The supervisor will help walk you through the following steps.
- Determine where and when a confirmatory blood test can be drawn. All confirmatory tests are done solely by western blot.

Giving the Result

- Give the result to the client right away after sitting down with them in a private room.
- When giving the results, clearly state that this is a reactive test result. It is a preliminary result and is not conclusive until a confirmatory blood test result is received.
- Sit with the client and allow them to react. If they wish, allow a support person to come join them.
- Explore the client's support system, who they will tell, and what they will do between now and their next appointment.
- Give the client numbers for mental health emergency services and supportive services.

Making Referrals

- Conduct confirmatory testing on site, by referral, or by appointment.
- All confirmatory testing will be done via western blot.
- Make the appointment for as soon as possible.
- Help insure transportation, if necessary.
- If the client is concerned about lack of money or health insurance, they can be assessed for eligibility for Medicaid or other state-funded programs.

For Confidential Testing:

- Fill out and give the client the "Medical Referral Form" form to bring to their appointment if receiving confirmatory testing off site. Write the phone number, address, directions, and the name of the location to which they will be going.
- Have the client sign an "Authorization to Release HIV-Related Information form.
- In addition, provide a referral for HIV Case Management. Have the client sign a release form for this referral as well, and then call the appropriate case management program for the county where the client wants to receive services.

Confirmatory Test Results

- All confirmatory tests are done via western blot.
- All confirmatory test results must be given in person.
- If the confirmatory test result is negative, advise the client to repeat a rapid HIV test in 2-3 months (and at designated intervals thereafter if negative).
- Offer referral to an HIV care specialist for further testing.

VI. PROTOCOL FOR REPEAT RAPID HIV TESTING
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Repeat Rapid HIV testing is advised with discordant results, on an annual basis or with each new risk factor. It is advised to test for HIV antibodies 2-3 months from the time of potential exposure.