

HIV/AIDS PROGRAM
HIV Counseling, Testing and Referral Policies

The policies on the following pages are applicable to all sites receiving reimbursement through the North Dakota Department of Health for HIV testing activities. The policies may or may not be applicable to other agencies involved in testing.



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Questions should be directed as follows:

Reimbursement issues	HIV/AIDS Program Manager
HIV Case Investigations	HIV Surveillance Coordinator
Ordering supplies and test forms	HIV/AIDS Administrative Assistant

All other programmatic issues and questions should be directed to the HIV Prevention Coordinator.

CTR Policy Revision Dates

CTR Policies	Approval Date	Current Revision Date
Instructions for CTR Forms	09/2002	08/2008
Guidelines for HIV CTR Testing	10/1996	04/2008
Protocol for HIV Counseling	10/1996	03/2009
Protocol for Rapid Test Intervention	03/2009	
Consent for HIV Testing	06/1995	08/2008
Spousal Notification Policy	06/1996	08/2008
Disclosure of HIV Status of an Inmate	11/2008	
Record Maintenance & Retention Policy	06/1995	04/2008
HIV Testing Schedule	10/1996	08/2008
OraSure HIV-1 Oral Specimen Policy	10/2001	04/2008
Clearview Complete HIV 1/2 Assay Procedure	03/2009	
Clearview Complete HIV 1/2 Reactive/Nonreactive Control Procedure	03/2009	
CTR Program Forms		
Informed Consent for HIV Testing	06/1995	08/2008
Sexually Transmitted Infection/Human Immunodeficiency Virus/Hepatitis Risk Assessment and Reduction Plan (SFN 58942)	08/2008	
Pre- and Post Test Counseling Assessment for HIV Testing (SFN 58941)	08/2008	
HIV Request for Reimbursement (SFN 8684)	07/2005	
HIV Prevention Supplies & Information Order (SFN 52281)	--	08/2008
Client Satisfaction Survey	08/2008	08/2008
Confidentiality Oath	08/2000	08/2008
HIV Test Form Part 1 (OMB No. 0920-0696)	01/2008	
HIV Test Form Part 2 (OMB No. 0920-0696)	01/2008	
Fahrenheit Temperature Log (SFN 53775)	--	01/2009
Celsius Temperature Log (SFN 58468)	--	01/2009
Clearview Complete Reactive/Nonreactive Control Log	03/2009	
Emergency Relocation Plan Template	--	03/2009
“Do Not Unplug” Warning signs	--	
Other Sections		
CDC Guidelines	--	04/2008
Laws	--	04/2008
Case Investigation	--	06/2008

Guidelines for Provision of HIV Counseling, Testing, and Referral Services

Publicly-funded HIV antibody counseling and testing was initiated in March 1985 to provide an alternative to the donation of blood as a means for high-risk persons to determine their HIV status.

In 1987, HIV counseling and testing was expanded. Persons seeking care for sexually-transmitted disease, family planning, childbirth or substance abuse were counseled and tested in an attempt to reduce their risk for HIV transmission. “The primary public health purposes of counseling and testing are to help uninfected individuals initiate and sustain behavioral changes that reduce their risk of becoming infected and to assist infected individuals in avoiding infecting others.”

In 2006, the Centers for Disease Control and Prevention (CDC) published revised recommendations for HIV testing in health care settings. The recommendations are designed to make HIV screening a routine part of medical care for all patients between the ages of 13 and 64, and to improve diagnosis of HIV infection among pregnant women.

- To normalize HIV screening as a routine part of medical care, all patients ages 13-64 should be screened. Screening that is universal, and not tied to risk behaviors, will help maximize opportunities for early diagnosis in medical settings and reduce the stigma associated with HIV testing.
- To reduce the mother-to-child HIV transmission rate, routine prenatal HIV screening of all pregnant women is recommended. Women with known risk factors should receive a second HIV test during the third trimester. Providers should consider repeat testing in the third trimester for other women on a case-by-case basis.

The revised recommendations address HIV testing in health care settings only. They replace CDC’s 1993 *Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings* and update portions of CDC’s 2001 *Revised Guidelines for HIV Counseling, Testing and Referral* and *Revised Recommendations for HIV Screening of Pregnant Women*. The new recommendations do not alter current recommendations on HIV counseling and testing in non-clinical settings, such as community centers or outreach programs.

CTR sites should conduct HIV counseling, testing and referral whenever possible, in accordance with the Centers for Disease Control and Prevention (CDC) Revised Guidelines for HIV Counseling, Testing and Referral (MMWR, September 22, 2006/Vol. 55/No. RR-14). See CDC Guideline Section for Complete guidelines.

Guidelines for HIV CTR Services, Cont.

Testing provided at HIV counseling, testing and referral (CTR) sites, funded through contracts with the North Dakota Department of Health, is available free of charge only to people considered to be at risk.

Testing should also be provided for people who are or have:

- Multiple sex partners
- Injecting drug users
- Partners of injecting drug users
- Partners of HIV-infected persons
- Diagnosis of tuberculosis disease

This includes individuals who are seeking care for:

- Sexually-transmitted disease
- Family planning
- Childbirth
- Substance abuse

Those not eligible for free publicly-funded testing include, but are not limited to, those who request testing for:

- Employee screening programs
- Insurance purchase requirements
- Travel
- Sport team screening programs
- Occupational exposure incidents

Patients with recognized risk factors should have a repeat HIV test every six months to a year. This includes, but is not limited to, individuals with HIV-positive sex partners, injection drug users and their sex partners, individuals who exchange sex for money or drugs, and individuals who have had, or whose sex partners have had more than one sex partner since their most recent HIV test. In addition, all patients initiating treatment for tuberculosis or seeking treatment for STDs should be screened.

Protocol for HIV Counseling

HIV prevention counseling is a client-centered exchange designed to support individuals in making behavior changes that will reduce their risk of acquiring or transmitting HIV. Client-centered means that counseling is tailored to the behavior, circumstances, and special needs of a person. Being client-centered is a process that is an important aspect of HIV prevention counseling.

Intensive HIV prevention counseling for high-risk populations will remain a vital component of community-based HIV prevention interventions. Prevention counseling will be provided by a trained counselor to all clients HIV tested through the publicly-funded CTR sites.

All CTR staff conducting HIV testing must have appropriate training and to ensure this, individuals performing HIV testing will attend the *Fundamentals of HIV Counseling* course at least once every five years.

The following six steps should be used as a guideline when performing HIV counseling. When conducting conventional HIV testing as with the OraSure, pre- and post-test counseling will be provided. When conducting rapid HIV testing, the single session method for counseling will be utilized. These six steps apply to both types of counseling methods. The only difference is during conventional testing the counseling is provided over two sessions and for rapid testing the counseling is delivered in one session.

Step 1. Introduce and Orient Client to Session.

Introduce yourself as a health counselor. Describe the purpose of the session, the expected duration, and what you hope to achieve in the session. Seek consensus from the client as to the objectives of the session and agreement to maintain this focus throughout the session.

During the session, be polite, professional, and display respect, empathy, and sincerity to the client. Become involved and invested in the process and convey an appropriate sense of concern and urgency about the client's HIV risk behaviors. Seek to deal with the client's concerns.

Step 2. Identify Client's Personal Risk Behavior(s) and Circumstances.

With the client, identify the specific behaviors that place him or her at risk for HIV. Focus the client on specific behaviors, situations, and partner encounters that contribute to his or her risks. Attempt to build from the problem (symptoms, referral, etc.) and reasons that brought the client to the clinic. Establish an atmosphere that conveys a collaborative and creative exploration of the relevant issues.

Step 3. Identify Safer Goal Behaviors.

Reinforce the client's previous HIV risk-reduction efforts. Identify specific safer goal behaviors that the client is willing to try to adopt.

Protocol for HIV Counseling, Cont.

Step 4. Develop a Personalized Action Plan.

Help the client establish a personal plan to reduce his/her risks of HIV. The plan should be realistic, yet challenging, and should address the specific behaviors identified by the client during the risk assessment phase of the session. It should incorporate the client's previous attempts, perceived personal barriers, and perceived personal benefits to reducing HIV risk.

Discuss existing barriers to adopting the new behavior and what benefits there are. Identify concrete, incremental steps the client can start to take to achieve his/her goal. Discuss how the client will put the plan into operation, using specific and concrete steps. Establish a back-up plan. Confirm that this plan is personalized and acceptable to the client. Solicit questions and reinforce the client's initiative in agreeing to try to negotiate a risk reduction plan.

Step 5. Make Referrals and Provide Support.

Identify client peer and community support for HIV risk reduction, as well as provide referral to professional services directed at addressing specific issues the patient may have identified.

Step 6. Summarize and Close Session.

Briefly summarize issues and plans that have been discussed and identify the next steps that the client has agreed to take. Assist with any necessary follow-up appointments. Encourage and support the client in progress.

Suggested Open-Ended Questions

Step 1. Introduction

- Why did you come to the clinic today?
- What would you like to know before you leave here today?
- What have you heard about AIDS?
- How do you think the virus is passed from one person to another?
- How did you decide to take the HIV test today?

Step 2. Identify Client's Personal Risk Behavior(s) and Circumstances

- Risk Assessment Questions
- What makes you believe that you might be at risk for HIV?
 - What are you doing in your life that might be putting you at risk for HIV?
 - Tell me about the exposure incident that brought you to the clinic today (when was the last time you had unprotected sex? shared needles?)
 - If you were infected, how do you think you may have been infected?
 - Have you been tested before? If so, when and why? What were the results?
 - How many different people do you have sex with? How often?
 - What is your experience with shooting up drugs? How often do you do this?
 - When was the last time that you put yourself at risk for HIV?
 - What was happening then?
 - When do you have sex without a condom?
 - What are the riskiest things that you are doing?
 - What are the situations in which you are most likely to be putting yourself at risk for HIV?
 - How often do you use drugs or alcohol? How does this influence your HIV risk behaviors?

Step 3. Identify Safer Goal Behaviors

Questions to Explore Client HIV Risk Reduction Attempts and Safer Goal Behaviors

- Is there a specific time that you remember where you were able to practice safer sex (use needles safely)? What did you do? What made it possible for you to do it?
- How was that for you?
- What are you presently doing to protect yourself?
- What would you like to do to reduce your risk of HIV?

Statements Reinforcing Positive Change Already Made

- It's great that you are here!
- You've taken the first step; you're doing a great job; keep it up!
- The fact that you are concerned about HIV is important.
- It is important that you recognize that you've really been thinking about reducing your HIV risk.
- Look at how much you've already done to protect yourself (be specific).

Step 4. Develop a Personalized Action Plan

Questions to Explore Client HIV Risk Reduction Attempts and Questions to Explore Personal Barriers and Benefits to Adopting Safer Behaviors

- Is there a specific time that you remember when you were able to practice safer sex (use needles safely)? What did you do? What made it possible for you? How was that for you?
- What are you presently doing to protect yourself?
- What would you like to do to reduce your risk of HIV?
- What do you see as advantages or good things about adopting _____ (the safer behavior)?
- What do you see as disadvantages or bad things about adopting _____ (the safer behavior)?
- What makes it easy (what situations make it easier for you) to _____ (the safer behavior)?
- What makes it difficult (what situations make it difficult for you) _____ (the safer behavior)?
- Who (individuals or groups) would approve or support you in adopting _____ (the safer behavior)?
- Who (individuals or groups) would disapprove or object to you adopting _____ (the safer behavior)?

Questions to Use When Assisting the Client to Develop a Personal Risk Reduction Plan

- What one thing can you do to reduce your risk right now?
- What can you do that would work for you?
- What could you do differently?
- How would your sexual practices (drug use practices) have to change for you to stay safe?
- Now that you have identified some steps you could take, how can you go about making this happen?
- What could you do to make it easier to take these steps?
- Who would help to support you in taking these steps?
- When do you think you will have the opportunity to first try this (behavior, discussion, etc.)?
- How realistic is this plan for you?
- What will be the most difficult part of this for you?
- Who can help you?
- What might be good about changing this?
- What will you need to do differently?
- How will things be better for you if you . . . ?

Suggested Statements Supporting and Reinforcing the Client

- You have really done something good for yourself in putting this plan into place.
- You've taken very positive steps today to help meet some important personal goals.

Step 5. Make Referrals and Provide Support

- We've talked about a lot of issues today. Which of the things we've talked about would you like more help with?
- Would you like to talk with an individual counselor about . . . (issue that has been raised)?
- Would you be interested in a support group?
- Is there a particular kind of support or service that you would be willing to consider?

Step 6. Summarize and Close Session

Consent for HIV Testing

HIV testing must be voluntary and undertaken only with the patient's knowledge. Patients must be specifically informed that HIV testing may be part of their care and have the opportunity to decline testing. Before making this decision, patients should be provided basic information about HIV and the meaning of positive and negative test results and should have the opportunity to ask questions.

Consent for HIV testing can be incorporated into general consent for medical care. If a facility does not have a general consent for medical care, the client must sign the "Informed Consent for HIV Testing" form.

N.D.C.C. 14-10-17 states that minors 14 years of age or older may contract for and receive examination, care, or treatment for sexually transmitted diseases, which include HIV, without permission, authority, or consent of a parent or guardian.

Consent for HIV testing is not required from individuals who are mandated by law to submit to HIV testing. N.D.C.C. 23-07-07.5 states that the following individuals must be examined or tested for the presence of antibodies or antigens of HIV.

1. Every individual convicted of a crime who is imprisoned for fifteen days or more in a grade one or grade two jail, a regional correctional facility, or the state penitentiary;
2. Every individual, whether imprisoned or not, who is convicted of a sexual offense under chapter 12.1-20, except for those convicted of violating sections 12.1-20-12.1-20-13;
3. Every individual, whether imprisoned or not, who is convicted of an offense involving the use of a controlled substance, as defined in chapter 19-03.1, and the offense involved the use of paraphernalia, including any type of syringe or hypodermic needle, that creates an epidemiologically demonstrated risk of transmission of HIV.

Spousal Notification

In accordance with the requirements of Section 8 of Public Law 104-146, action must be taken to ensure that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to the human immunodeficiency virus and should seek testing.

A spouse is “any individual who is the marriage partner of an HIV-infected patient, or who has been the marriage partner of the patient at any time within the 10-year period prior to the diagnosis of HIV infection.”

In order to comply with the Section 8 of Public Law 104-146, it is the responsibility of the field epidemiologist to make such notifications. Notification will be documented. See the Case Investigation section for notification and documentation protocol.

Disclosure of HIV Status of an Inmate

The duty of the HIV counselor is to disclose the HIV status of an inmate to medical personnel providing direct care to the individual, the administrator of the correctional facility or as otherwise authorized by law. There should not be any disclosure beyond that, and to the extent there is, disclosure should only be made based on “legitimate penological purposes,” or as stated in the HIPAA privacy rule. Within the jail, further disclosure is up to the policies of the administrator and should be on a strictly “need to know basis.”

Except as otherwise provided by N.D.C.C. 23-07.5, the results of a test for the presence of an antibody to the human immunodeficiency virus may be disclosed only as follows:

To a correctional institution having lawful custody of an inmate, if the correctional institution represents that such protected health information is necessary for: (a) the provision of health care to the individual; (b) the health and safety of such individual or other inmates; or (c) the health and safety of the officers or employees of or others at the correctional institution. 45 CFR 164.512(k)(5).

To reduce the transmission of HIV, the correctional facility staff should be trained in universal precautions.

Record Maintenance and Retention Policy

The following record retention and maintenance guideline must be followed. In agencies where existing policies are more restrictive, local policies may be followed in lieu of these.

RECORD MAINTENANCE

N.D.C.C. 23-07.5-04 states that the health care provider that obtains a specimen of body fluids for the purpose of testing for HIV shall:

1. Obtain from the subject: the subject's parent, legal guardian, or custodian if the subject is a minor; or the subject's legal guardian if the subject is incapacitated, informed consent for testing or disclosure, unless testing and procedures for disclosure are otherwise provided by law.
2. Maintain a record of the consent received under subsection 1.
3. Maintain a record of the test results obtained.

CDC Standards for HIV Counseling, Testing and Referral require that client records also include:

1. Documentation of prevention counseling.
2. Result notification.
3. Formulation of risk-reduction plans.

Each individual testing site must retain these records according to the schedule provided below in the Record Retention Schedule.

CONFIDENTIALITY

N.D.C.C. 23-07-02.2 provides that a report of an individual's HIV seropositivity is strictly confidential information and may not be released even through subpoena, search warrant, or discovery proceedings, or otherwise, except that:

1. Release may be made of medical or epidemiologic information for statistical purposes in a manner such that no individual person can be identified;
2. Release may be made of medical or epidemiologic information to the extent necessary to enforce section 23-07-02.1 and this section and related rules concerning the treatment, control, and investigation of human immunodeficiency virus infection by public health officials; or

Record Maintenance and Retention Policy, Cont.

3. Release may be made of medical or epidemiologic information to medical personnel to the extent necessary to protect the health or life of any individual.

No officer or employee of the state department of health may be examined in any proceedings regarding the existence or content on an individual's report.

Anyone breaching confidentiality is guilty of a class C felony (5 years and/or \$5,000).

RECORD RETENTION SCHEDULE

1. Consent forms must be kept for five years.
2. Negative serology reports must be kept for five years.
3. Positive serology reports must be kept permanently.
4. Other records (e.g., counseling, risk-reduction plan, etc.) should be retained as is routine for other medical file information.
5. Serology reports for patients who do not return to get results should be kept:
 - Permanently, if positive.
 - One year, if negative.

LOCATION OF RECORDS

HIV records and reports will be kept in the patient's medical file, if there is one, to ensure health care providers have access to all relevant data when providing patient care. Separate HIV files shall not be kept.

If there is no medical file, records must be kept according to the schedule provided (see Record Retention Schedule above) in a manner that ensures confidentiality.

HIV Testing Schedule and Procedure

On average, it takes 3-12 weeks after infection to produce enough antibodies to register a positive test result. This is what is referred to as the window period. It may take as little as three weeks or as long as six months for an HIV-infected person to have a positive result. Appropriate recommendations for further testing and risk prevention depend on the understanding of the window period and the individual's risk history.

Recently infected persons whose test results are not positive are still infectious to others.

HIV TESTING SCHEDULE

A recently exposed person should be tested at 6-8 weeks after exposure, but no earlier than three weeks after exposure. The client should be advised to return for HIV antibody testing six months from the exposure incident. This assumes no other HIV risk behaviors or potential exposures have occurred in the meantime. Those with ongoing HIV risk behavior should be tested every 3-6 months.

Counseling should include recommendations for taking precautions against possible transmission through sexual or needle-sharing activity during this window period.

HIV TESTING PROCEDURE

North Dakota testing procedures include the EIA and the IFA. The EIA is used as a screen. If a sample is positive with EIA two times, the IFA is used as a confirmatory test.

EIA (Enzyme-Linked Immuno Assay)

Negative Response to EIA Test

- If patient is low risk and has no exposure to HIV infection, end testing process.
- If patient has been exposed to HIV, repeat EIA every three months for one year after exposure. If negative after one year and no further exposure has occurred, stop testing. If further exposure is occurring, test every six months.

Positive Response to EIA Test

- Repeat EIA twice on same sample. Two positives require confirmation.

HIV Testing Schedule and Procedure, Cont.

IFA (Indirect Fluorescent Antibody) Confirmatory Test

Negative Response to IFA after Positive EIA

- Repeat test in 2-4 months with a new specimen. If patient is truly at low risk, a positive EIA is likely to have been a false-positive result.

Indeterminate Response to IFA after Positive EIA

An indeterminate response on the IFA is extremely rare. In the event there are indeterminate results, repeat the test in three weeks on a new sample.

Positive Response to IFA

HIV infection is diagnosed and no further testing is needed. Inform patient and continue the counseling process.

SOURCES

1. CDC, Revised Guidelines for HIV Counseling, Testing and Referral; November 2001
2. ND AIDS Education and Training Center. HIV: A Source Book for the Health Care Provider; 2005

Policy for *OraSure*[®] HIV-1 Oral Specimen Collection Device

STATE HEALTH LAB PROTOCOL

1. *OraSure*[®] devices submitted to the North Dakota Department of Health, Division of Microbiology, will be processed on Tuesdays and Thursdays of each week.
2. An initial Enzyme Immunoassay (EIA) will be conducted. If the initial EIA is negative, the test will be reported as “negative.” If the initial EIA is reactive, the EIA will be conducted again, in duplicate. If reactive, the test will be reported as “reactive” and the provider will be asked to collect and submit a serum specimen for EIA screen and Immunofluorescent Assay (IFA) confirmation, if necessary.
3. The North Dakota Department of Health, Division of Microbiology, will not test a specimen of insufficient volume.
4. Specimen vials submitted to the lab should be labeled in marker, not with labels.

PRECAUTIONS AND LIMITATIONS OF THE PROCEDURE

Precautions

1. The *OraSure*[®] device is not intended to collect saliva. Failure to carefully follow the collection procedure may cause erroneous results.
2. *OraSure*[®] HIV-1 specimen vials are breakable and should be handled with care.
3. Handle specimens and materials contacting specimens as if potentially infectious biological materials in accordance with *Universal Precautions for Prevention of Transmission of HIV, HBV and Other Bloodborne Pathogens in Health Care Settings* (CDC, MMWR, June 24, 1988).
4. Occupational Safety and Health Administration (OSHA) regulations apply to personnel collecting and handling specimens.
5. Use freshly prepared 10 percent bleach to decontaminate surfaces in the event of a spill of a collected specimen.
6. Avoid contamination of collection device and the specimen vial solution with foreign matter.

Policy for *OraSure*[®] HIV-1 Oral Specimen Collection Device, Cont.

7. Do not use the collection pad if the package has been opened.
8. Do not touch the collection pad with fingers before or after specimen collection.
9. Do not use the collection pad if it is wet.
10. Do not use the device beyond expiration date shown on the device package.

Limitations

1. Subjects must be counseled that false negative results and false indeterminate results occur more frequently when testing with *OraSure*[®] HIV-1 specimens compared with testing blood specimens.
2. Studies to determine the performance characteristics of the *OraSure*[®] HIV-1 Oral Specimen Collection Device in subjects younger than 18 years of age have not been performed.
3. False results (either positive or negative) may occur as a result of interfering substances being collected with the specimen.
4. False negative results (the subject is infected, but *OraSure*[®] HIV-1 is negative) may occur as a result of the absence of antibodies to HIV-1 in the early phase of the infection, or anti-HIV levels which are below the lower limit of detection of this procedure.
5. False positive results may occur, for example, as a result of nonspecific cross-reacting antibodies, and not from an HIV-1 infection.
6. A person who has antibodies to HIV-1 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

Clearview[®] Complete HIV 1/2 Assay Procedure

SPECIMEN COLLECTION/TREATMENT

A. Specimen

Acceptable: Fingerstick whole blood, venous whole blood.

Unacceptable: Specimens collected from other sources.

B. Specimen Collection

Prior to specimen collection, provide the test subjects with Subject Information Notice and pretest counseling according to CDC Guidelines for Rapid HIV Testing.¹

The Clearview complete HIV 1/2 assay is performed on fingerstick whole blood or venous whole blood specimens.

Fingerstick Whole Blood: Prepare to perform the fingerstick blood collection procedure. Clean the finger of the person being tested with an antiseptic wipe. 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 and wipe away the first drop with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid. Collect the sample from the second drop by touching the sampler tip of the device to the drop of blood until the sample tip is full. Test immediately, following Test Procedure Instructions.

Venous Whole Blood: Draw blood following laboratory procedures for obtaining venous blood. Collect sample in a tube containing citrate, heparin, or EDTA. Be sure the tube of blood is well mixed.

C. Specimen Storage

If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Venous whole blood specimens should be shipped refrigerated with cold packs or wet ice. **DO NOT FREEZE WHOLE BLOOD.**

D. Handling Precautions

Handle the specimens and materials contacting specimens as if capable of transmitting infection.

Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes, or mouth during specimen collection and testing. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens. Dispose of all specimens and materials used in the test

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions that contain bleach.

For additional information on biosafety, refer to “Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood borne Pathogens”² and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Post Exposure Prophylaxis.”³ Use 10 percent bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.

REAGENTS AND EQUIPMENT

A. Reagents and Materials Provided

Component	Content	Quantity
Pouches	Each pouch contains: <ul style="list-style-type: none">▪ 1 sampler with a test strip inside▪ 1 buffer vial attached to the sampler (350 µL)▪ 1 sterile safety lancet▪ 1 bandage▪ 1 desiccant packet	25
Subject Information Notice	Information regarding HIV infection, transmittance, options for testing and test results.	25
Disposable Test Stands	Stands for holding buffer vials upright during testing.	25
Product Insert		1

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

B. Materials Required and Available as an Accessory to the Kit

HIV Reactive/Nonreactive Controls

- Contains one HIV-1 reactive control, one HIV-2 reactive control, one nonreactive control, and one (1) product insert.

C. Materials Required but not Provided

- Clock, watch, or other timing device.
- Pipettor capable of delivering 2.5 µL of sample (for other than fingerstick or venipuncture whole blood specimens).
- Disposable gloves.
- Sterile gauze.
- Antiseptic wipes.
- Biohazard disposal container.
- Collection devices for samples other than fingerstick or venipuncture whole blood specimens.

D. Storage and Stability

The Clearview[®] Complete HIV 1/2 assay should be stored in its unopened pouch at 8° to 30°C (46° to 86° F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch.

E. Quality Control

1. Internal Built-in Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the control area if the test has been performed correctly and the device is working properly. (Please see section: Interpretation of Test Results.)

2. External Quality Control

Good laboratory practice (GLP) necessitates testing external control material along with the test samples to ensure proper performance of the test kit. Clearview Complete HIV reactive/nonreactive controls are available separately for use with the Clearview Complete HIV 1/2 assay. The HIV controls are used to verify the operator's ability to

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

properly perform the test and to interpret the results. Each reactive control will produce a reactive test result and has been manufactured to produce a faint line in the test area. The nonreactive control will produce a nonreactive test result. Run the controls as per the test procedure and follow the instructions as described in Interpretation of Results sections of this product insert. It is the responsibility of each facility using the Clearview Complete HIV 1/2 assay to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

3. Run the Kit Controls Under the Following Circumstances

- ♦ Each new operator prior to performing tests on patient specimens.
- ♦ When opening a new test kit lot.
- ♦ Whenever a new shipment of test kits is received.
- ♦ If the temperature of the test storage area falls outside of 8° to 30°C (46° to 86°F).
- ♦ If the temperature of the testing area falls outside of 18° to 30°C (64° to 86°F).
- ♦ At least once every month.

If the HIV control reagents do not produce the expected results, contact Inverness Medical Technical Support at (800) 637-3717.

F. Precautions

1. Safety Precautions

- a. Handle the specimens and materials contacting specimens as if capable of transmitting infection.
- b. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
- c. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
- d. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of one hour at 121° C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10 percent bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

- e. For additional information on biosafety, refer to “Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens”² and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.”³
- f. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.

2. Handling Precautions

- a. The Clearview complete HIV 1/2 assay device has a sample filter in the lower part of the device and an absorbent pad in the upper part of the device within the barrel that encloses the test strip. Confirm the presence of the sample filter and absorbent pad prior to performing the test. If either is missing, DO NOT USE.
- b. Do not use any device if the pouch has been perforated. Do not use the device if the desiccant packet is missing.
- c. Each device is for single use only.
- d. Do not use the reagents beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
- e. Do not mix reagents from different lot numbers of kits.
- f. To ensure accurate test results, the sampler must be inserted into the buffer vial immediately after the sample application.
- g. Adequate lighting is required to read the test results.

TEST PROCEDURE

A. Kit Component Preparation

All components for the Clearview Complete HIV 1/2 assay are ready to use as supplied. Follow directions as indicated. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18° to 30°C: (64° to 86°F) prior to testing.

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

1. **Open Pouch, Remove and Identify Components.**

Identify test device, buffer cap and test stand.

Note: If desiccant packet, absorbent pad (at top of sampler) or sample filter (at bottom of sampler) is missing, DO NOT USE. Discard device and use a new test.

2. **Write Patient ID on Stand.**

3. **Separate Buffer Cap from Test Device.**

4. **Place Buffer Cap in Test Stand.**

On firm surface, drop the buffer cap in the test stand

5. **Specimen Application Waived Procedures.**

- For fingerstick whole blood, touch blood drop with sampler tip until the tip is full.
- For venous whole blood, pick up a drop of whole blood from the inside of a blood tube cap.

6. **Start the Test.**

With buffer vial in stand, firmly press the device tip (sampler tip) through foil cover. Push hard until device is fully seated in the buffer cap.

It will “snap” 3 times when properly seated.

Snap 1: through foil

Snap 2: into cap

Snap 3: fully seated

7. **Confirm Device is Fully Seated.**

- The blue line directly above the arrows must line up with the clear line in the stand.
- You will see pink/purple buffer solution begin to flow upwards.

IF YOU DO NOT SEE PINK/PURPLE FLOW WITHIN 3 MINUTES, PUSH AGAIN! (then start timer).

8. **Start Timing – Wait for 15 minutes.**

Note: the sampler/buffer cap vial should be kept upright in the test stand.

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

9. Read Test Results.

Read the test between 15 and 20 minutes.

Note: Reactive test results (See interpretation of test results section) may be observed and read earlier than 15 minutes. To verify a nonreactive test result, wait the entire 15 minutes after starting the test. **Do not read results after 20 minutes.**

INTERPRETATION OF RESULTS

When the Clearview complete HIV 1/2 assay is properly performed, the appropriate pink/purple lines will become visible. These are:

- **The Control Line**, which appears closer to the top of the test strip, indicates that specimen was adequately applied and there was proper hydration and migration of reagents. The control line will become visible within 15 minutes after starting the test regardless of the HIV antibody status of the specimen.
- **The Test Line**, which appears closer to the bottom of the test strip (below the control line), indicates the presence of HIV-specific antibodies. The test line will only become visible within 15 minutes after starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.

Nonreactive

One pink/purple line in the control area, with no line in the test area indicates a nonreactive test result. A nonreactive test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test result is interpreted as negative for HIV-1 and HIV-2 antibodies. However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the test result and its interpretation.^{1,4}

Reactive

Two pink/purple lines, one in the test area and one in the control area indicate a reactive test result. The line in the test area may look different from the line in the control area. Intensities of the test and control lines may vary. A test result with visible lines in both test and control areas, regardless of line intensity, are considered reactive. A reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as preliminary positive for HIV-1 and/or HIV-2 antibodies. Follow CDC guidelines to inform the test subject of the test result and its interpretation.^{1,4}

If the test is reactive then a confirmatory test must be conducted and sent to the State Lab for processing. If the confirmatory comes back negative, then the initial screen was more than likely a false-positive and the client is negative for HIV. If the patient has had a known

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

exposure to HIV, then testing should be repeated in 2-4 months. If the confirmatory test comes back positive, then the initial screen was a true positive and HIV infection is diagnosed and no further testing is needed.

Note: The HIV surveillance coordinator or the HIV Program manager must be notified on all screenings that are reactive.

Invalid

A pink/purple line should always appear in the control area, whether or not a line appears in the test area. If there is no distinct pink/purple line visible in the control area, then the test is invalid. Any lines that appear outside of the control area or test area is an invalid test. An invalid test cannot be interpreted. One pink/purple line in the control area with a test line outside the test area is an invalid test. It is recommended that an invalid test be repeated with a new device.

Please indicate all invalid tests on the HIV Test Form--Part 1 under HIV Test 1. In the Test Result section there is a field to indicate invalid tests. The second time the test is conducted, it will be recorded under HIV Test 2. This will allow the HIV prevention coordinator to track the rate of invalid tests for North Dakota.

LIMITATIONS

- A. The Clearview complete HIV 1/2 assay test must be used in accordance with the instructions in the product insert to obtain accurate results.
- B. The Clearview complete HIV 1/2 assay must be used with capillary (fingerstick) or venous whole blood, serum or plasma only. Use of other types of specimens or testing of venipuncture whole blood specimens collected using a tube containing an anticoagulant other than citrate, heparin, or EDTA may not yield accurate results. For serum samples, collect blood without anticoagulant.
- C. Reading nonreactive test results earlier than 15 minutes or any test result later than 20 minutes may yield erroneous results.
- D. Do not open the sealed foil pouch until just prior to use.
- E. Do not use kit contents beyond labeled expiration date.
- F. For collection of a fingerstick whole blood specimen, ensure that finger is completely dry before performing fingerstick.

Clearview[®] Complete HIV 1/2 Assay Procedure, Cont.

- G. Read results in a well-lit area.
- H. A reactive test result using the Clearview Complete HIV 1/2 test suggests the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The Clearview Complete HIV 1/2 assay is intended as an aid in the diagnosis of infection with HIV-1/2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
- I. For a reactive test result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
- J. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.
- K. A nonreactive test result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
- L. This assay has not been evaluated for newborn screening, cord blood specimens.

REFERENCES

1. CDC. Revised Guidelines for HIV Counseling, Testing and Referral and Revised Recommendations for HIV Screening of Pregnant Women. *MMWR* 2001; 50(19):32-35.
2. Centers for Disease Control and Prevention (CDC) Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-care Settings. *MMWR* 1988; 37(24):377-388.
3. CDC: Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV Recommendations for Postexposure Prophylaxis. *MMWR* 2001; 50(RR-11):1-42.
4. CDC: Approval of a New Rapid Test for HIV Antibody. *MMWR* 2002 51 (46) 1051-1052.

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure

INTENDED USE

The Clearview HIV reactive/nonreactive controls are quality control reagents for use with the Clearview Complete HIV 1/2 assay.

Run the kit controls under the following circumstances:

- Each new operator prior to performing tests on patient specimens.
- When opening a new test kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test storage area falls outside of 8° to 30°C (46° to 86°F).
- If the temperature of the testing area falls outside of 18° to 30°C (64° to 86°F).
- At least once a month.

If the control reagents do not produce the expected results the test should be repeated with a new test device. If they still do not produce the expected results contact Inverness Medical Technical Support at (800) 637-3317.

SUMMARY AND EXPLANATION OF HIV REACTIVE AND NONREACTIVE CONTROLS

Clearview HIV reactive/nonreactive controls are human, plasma-based reagents. The controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results. The Clearview HIV-1 and HIV-2 reactive controls will produce a reactive test result and have been manufactured to produce a faint test "T" line. The Clearview nonreactive control will produce a nonreactive test result. Use of control reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the Clearview complete HIV 1/2 assay.

MATERIALS PROVIDED

Each HIV rapid test control pack contains a product insert and three vials (one HIV-1 reactive control, one HIV-2 reactive control and one nonreactive control) as described.

Clearview Complete HIV 1/2 Assay

Pipettor Method: Each control vial contains sufficient volume to run 100 tests.

Transfer Pipette Method: Each control vial contains sufficient volume to run 20 tests.

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure, Cont.

HIV-1 Reactive Control

One vial containing 0.25 mL of heat inactivated human plasma positive for antibodies to HIV-1, diluted in normal human plasma. Negative for hepatitis B surface antigen, hepatitis C antibody and HTLV I/II antibodies.

HIV-2 Reactive Control

One vial containing 0.25 mL of heat inactivated human plasma positive for antibodies to HIV-2, diluted in normal human plasma. Negative for hepatitis B surface antigen, hepatitis C antibody and HTLV I/II antibodies.

Nonreactive Control

One vial containing 0.25 mL of normal human plasma negative for antibodies to HIV-1 and HIV-2. Negative for hepatitis B surface antigen, hepatitis C antibody and HTLV I/II antibodies.

MATERIALS REQUIRED AND PROVIDED

Clearview Complete HIV 1/2 Assay

Each kit contains the components to perform 25 tests:

- Product insert
- 25 subject information notices
- 25 disposable test stands
- 25 pouches, each containing:
 - o 1 sampler with a test strip inside
 - o 1 buffer vial attached to the sampler (~350µL)
 - o 1 sterile safety lancet
 - o 1 bandage
 - o 1 desiccant packet
- Pipettor capable of delivering 2.5µL of sample or transfer pipet and clean non-absorbent disposable

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure, Cont.

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch or other timing device.
- Disposable gloves.
- Biohazard disposal container.

WARNINGS

For In Vitro Diagnostic Use

1. Read this product insert and the Clearview HIV 1/2 Complete HIV 1/2 assay product insert(s) completely before using this product. Follow the instructions carefully as not doing so may result in inaccurate test results.
2. Users of this test should follow the CDC Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne pathogens,¹ and "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV Recommendations for Postexposure Prophylaxis."²
3. Handle the Clearview HIV reactive/nonreactive controls, and materials contacting the controls, as if capable of transmitting infectious agents.
4. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact with hands, eyes or mouth during specimen collection and testing.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling specimens.
6. Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. The recommended method of disposal of biohazard waste is autoclaving for a minimum of one hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10 percent bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.**
7. Use 10 percent bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure, Cont.

8. Use of kit control reagents manufactured by another source may not produce the required results, and therefore will not meet the requirements for an adequate quality assurance program for the Clearview complete HIV 1/2 assay.

STORAGE AND HANDLING

The Clearview HIV reactive/nonreactive controls should be stored at 2° to 8°C (36° to 46°F). Do not use beyond the indicated expiration date. Open the control vials only when you are performing tests. Recap and store the control vials in their original container at 2° to 8°C (36° to 46°F) after use. The test devices should be stored in individual unopened pouches at 8° to 30°C (46° to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch.

TEST PROCEDURE

All components for the Clearview complete HIV 1/2 assay are ready to use as supplied. Instructions for use are given in the Clearview complete HIV 1/2 assay product insert(s). Follow directions as indicated. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18° to 30°C (64° to 86°F) prior to testing.

Procedure for Using Controls with Clearview Complete HIV 1/2 Assay

1. Open a control vial containing the control reagents. **Note:** The control reagents are clear to straw-colored. Do not use if the control reagents appears visually cloudy or discolored.
2. Remove buffer vial – separate from top of sampler and place in a disposable test stand provided with complete HIV 1/2 assay.
3. For control reagent, turn sampler upward and using a calibrated pipettor, pipette 2.5µL of the control reagent into the sampler tip. Use separate pipette tips for each control reagent.
 - a. Alternatively, using a transfer pipet draw the control reagent into the pipet to the position shown. To draw up the sample, squeeze the pipet bulb very gently to avoid drawing up too much control material.
 - b. Carefully dispense one drop of the control reagent into the weigh boat or a clean, dry surface.
 - c. Touch the tip of the sampler to the drop of control reagent allowing the reagent to travel into the sampler tip.

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure, Cont.

- d. Use a separate pipet and weigh boat for each control reagent.
4. With buffer vial in disposable test stand, firmly press the sampler tip through foil cover. Press hard until the device is fully seated in the buffer cap. It will “snap” three times when properly seated.
 - Snap 1: through the foil.
 - Snap 2: into the cap.
 - Snap 3: fully seated.
5. Start timing – wait for 15 minutes. Read the test results between 15 and 20 minutes. In some cases a test line may appear in less than 15 minutes. However, 15 minutes are needed to report a nonreactive test result. Read test results in a well-lit area. **Do not read Test Results after 20 minutes.**
6. Discard all test materials including the test device into a biohazard waste container.
7. Reseal the control reagent vials and store them in their original container at 2 to 8°C (36 to 46°F).

QUALITY CONTROL

Built-in Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the control area if the test has been performed correctly and the device is working properly. (Please see section: Interpretation of Test Results.)

INTERPRETATION OF TEST RESULTS

Please refer to the complete HIV 1/2 assay product insert for pictorial examples of reactive, nonreactive and invalid test results.

The **Control Line**, which appears closer to the top of the test strip, indicates that specimen was adequately applied, and there was proper hydration and migration of reagents. The control line will become visible within 15 minutes after starting the test regardless of the HIV antibody status of the specimen.

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure, Cont.

The **Test Line**, which appears closer to the bottom of the test strip (below the control line), indicates the presence of HIV-specific antibodies. The test line will only become visible within 15 minutes after starting a valid test when HIV-specific antibodies are present at detectable levels in the specimen.

Invalid - A pink/purple line should always appear in the control area, whether or not a line appears in the test area. If there is no distinct pink/purple line visible in the control area, then the test is invalid. Any lines appearing outside of the areas to the control or test is an invalid test. An invalid test cannot be interpreted. It is recommended that the test be repeated with a new device.

EXPECTED RESULTS

Clearview Complete HIV 1/2 Assay

Nonreactive Control

The nonreactive control will produce a nonreactive test result. One pink/purple control line should be present closer to the top of the strip for complete HIV 1/2 assay. There should be no visible line in the test area of the device. This indicates a nonreactive test result.

HIV-1 Reactive Control

The HIV-1 reactive control will produce a reactive test result and has been manufactured to produce a faint pink/purple test line. Two pink/purple lines, one line should be present closer to the bottom of the strip (test area) and a second line should be present closer to the top of the strip (control area) for the complete HIV 1/2 assay. This indicates a reactive test result. The intensities of the test and control lines may vary. If any visible line appears in the test and control areas, the result is reactive.

HIV-2 Reactive Control

The HIV-2 reactive control will produce a reactive test result and has been manufactured to produce a faint pink/purple test line. Two pink/purple lines, one line should be present closer to the bottom of the strip (test area) and a second line should be present closer to the top of the strip (control area) for the complete HIV 1/2 assay. This indicates a reactive test result. The intensities of the test and control lines may vary. If any visible line appears in the test and control areas, the results are reactive.

Note: If the test result for the nonreactive control, HIV-1 reactive control or HIV-2 reactive control is not as expected, the test should be repeated using a new test device and control

Clearview[®] Complete HIV Reactive/Nonreactive Controls Procedure, Cont.

specimen. If the HIV control reagents do not produce the expected results, contact Inverness Medical Technical Support at (800) 637-3717 if you are unable to obtain a valid test result upon repeat testing.

LIMITATIONS

The Clearview HIV reactive/nonreactive controls are quality control reagents for use **only** with Clearview HIV 1/2 stat-pak assay and/or complete HIV 1/2 assay.

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-care Settings. MMWR 1988; 37(24):377-388.
2. CDC: Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV Recommendations for Postexposure Prophylaxis. MMWR 2001; 50(RR-11):1-42.

Protocols for Handling and Storing Controls

Temperature logs will be maintained in accordance with the North Dakota Department of Health's Vaccine for Children (VFC) program. If a CTR site is already following these policies for vaccines then no further action is necessary. If a CTR site does not give vaccines, then the following is the procedure for handling, storing, and receiving the Clearview complete reactive/nonreactive controls.

STORAGE AND STABILITY

The Clearview complete HIV Reactive/Nonreactive Controls should be stored at 2° to 8°C (36° to 46°F). Do not use beyond the indicated expiration date. Open the control vials only when you are performing tests. Recap and store the control vials in their original container at 2° to 8°C (36° to 46°F) after use. The test devices should be stored in individual unopened pouches at 8° to 30°C (46° to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch.

PERSONNEL

Sites should designate a primary coordinator and at least one back-up. These people must be responsible for the following:

1. Monitoring and recording twice daily the temperatures on the temperature logs for each storage unit containing state-supplied HIV test controls and vaccine..
2. Adjusting the temperature of the control storage unit.
3. Reviewing temperature logs. The primary coordinator should review temperature logs weekly, if daily monitoring is being conducted by a back-up person, to ensure proper temperature recording. The back-up staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
4. Checking expiration dates of the controls.
5. Receiving all controls shipments or ensuring that others who may receive the order are aware of the procedure for receiving controls.

Training of other staff who are responsible for conducting controls should be the responsibility of the primary coordinator.

The coordinator can be the same person who orders the controls.

Protocols for Handling and Storing Controls, Cont.

STORAGE REQUIREMENTS

All CTR sites are required to have appropriate equipment that can store and assist with the maintenance of proper conditions of Clearview complete reactive/nonreactive controls. Refrigerators without freezers and stand-alone freezers may be better at maintaining the required temperatures. However, combination refrigerator/freezer units are acceptable for storage of the controls if the refrigerator and freezer components each have a separate external door.

Refrigerators and freezers used for storage of the controls must comply with the following requirements:

1. Be able to maintain required, stable controls storage temperatures year-round.
2. At minimum, have a working certified thermometer inside each storage compartment.
3. Be dedicated to the storage of biologicals. Food and beverages must not be stored in the storage unit because this practice results in frequent opening of the door and destabilization of the temperature.

CTR sites must monitor the temperature of their refrigerator/freezer with certified thermometers.

1. Thermometers must be certified in accordance with National Institute of Standards and Technology or the American Society for Testing and Materials standards. Minimum/maximum thermometers are available from the NDDoH for storage units containing state-supplied vaccine or HIV testing controls.
2. The optimal system for monitoring refrigerator/freezer temperatures is an automated temperature-sensing device. If a sensing device is not feasible, a min/max thermometer is recommended. Thermometers should be placed in the center of the refrigerator, next to the controls.
3. Monitor and log temperatures (preferably using a min/max thermometer) at least twice a day (beginning and end). Post a temperature-recording chart on your refrigerator/freezer to record the temperatures. Copies of temperature recording charts must be sent in to the NDDoH at the end of every month for each unit containing the controls. **(For temperature recording charts, see Section 2: Forms, pp. 2.24-25.)**
4. Temperature logs must be saved for a minimum of three years.

Protocols for Handling and Storing Controls, Cont.

5. **Action must be taken and recorded on every out-of-range temperature.** If refrigerator or freezer temperatures are out-of-range, record the temperature on a temperature log and immediately isolate the affected controls. Mark “do not use” until the NDDoH HIV program has been contacted. Do not assume that the control is not viable and do not discard the controls until the NDDoH has been contacted. Recorded actions should be sent monthly to the NDDoH along with the temperature logs.
6. Do not store food or beverages in a refrigerator that contains biologicals.
7. Place the controls in the storage unit so there is enough air space to allow cold air to circulate around the pouch.
8. Do not stack the controls next to coils in the refrigerator. The coils are extremely cold and could result in the controls being frozen.
9. Never store the controls in the refrigerator door. Opening and closing doors in refrigerators causes unnecessary temperature changes and could cause the controls to fail.
10. Once a month, check controls for expiration and usage to anticipate needs.
11. Place filled plastic water jugs in the refrigerator to help maintain temperature stability. This helps keep temperatures uniform and provides additional cold mass, both of which are useful, particularly if there is a power failure.
12. Unofficial studies have indicated some biologicals will retain their potency when left at room temperature for short periods of time. Please contact the control manufacturer for efficacy of controls not stored properly.
13. Place a warning sign to prevent unplugging the refrigerator/freezer by the plug/outlet to help ensure that the refrigerator/freezer is not turned off. **(See Section 2: Forms, p. 2.28.)** Also place a warning sign on the circuit breaker for the refrigerator/freezer.

Other Suggestions

1. Lock storage facilities and equipment. This prevents unauthorized removal of controls and use of storage for other purposes.
2. Remove vegetable bins from the refrigerator; replace with cold water bottles.
3. Store all opened and unopened controls boxes inside the appropriate storage unit so that their contents and expiration dates are easily identifiable.

Protocols for Handling and Storing Controls, Cont.

4. Stabilize refrigerator and freezer temperature with proper placement and use of water bottles and frozen packs.
5. Follow manufacturer's recommended schedule for recalibration of the certified thermometers.

Emergency Storage and Handling

In the event of a freezer/refrigerator failure, power failure, natural disaster or other emergency that may compromise the storage condition of the controls, each facility must have a written emergency controls storage and handling plan. **(For an example, see Section 2: Forms, p. 2.27.)** This plan should be reviewed and updated as needed and at least annually. NDDoH staff making site visits will ask to see this plan. This plan must include:

1. Person(s) responsible for preparing and transporting including contact information.
2. How this person will be notified that the controls need to be moved.
3. Location that will receive the controls.
4. How receiving location will be notified of transport.
5. How to pack controls for transport.
6. Worksheet to document controls involved in power or equipment failure.
7. It is the responsibility of the facility to arrange for someone to be available in your office to immediately receive and properly store the controls. This employee must be trained in proper controls storage and handling. A back-up employee also should be trained. The National Immunization Program created a Vaccine Storage and Handling Toolkit that is available online at www2a.cdc.gov/nip/isd/shtoolkit/splash.html. This material is relevant to the storage and handling of the Clearview reactive/nonreactive controls as well. The NDDoH recommends that all clinic staff involved in storage and handling the controls view this toolkit online.
8. Providers should have written protocols in place for receiving controls.
9. Immediately upon arrival of a controls shipment, the temperature monitor contained in the shipment should be checked to determine that the vaccine has remained at proper storage temperature. Notify the NDDoH **immediately** if the temperature monitor indicates that proper temperatures were not maintained during shipment of vaccine.

Protocols for Handling and Storing Controls, Cont.

- a. If compromised controls are received, the NDDoH will arrange for a pickup of the compromised vaccine and for a replacement shipment to be sent as soon as possible.
 - b. All contents of the shipment (including the compromised controls, packing slip and thermometers) should be returned to the cooler.
10. Compare the received shipment with the information on the invoice. Notify the NDDoH **immediately** if there are any discrepancies in the order, including lot numbers and expiration dates.
 11. Controls must be refrigerated immediately at 2° to 8° C or 35° to 46° F.

Clearview Complete Reactive/Nonreactive Controls Packaging/Shipping

Controls are shipped on Mondays, Tuesdays and Wednesdays only. This ensures the controls will arrive at the CTR site before the weekend.

A variety of materials is available to ensure that the controls are protected and are kept at the appropriate temperature during shipment.

1. Do not ship controls if the daytime temperature is expected to exceed 90° F.
2. Do not ship controls if the nighttime temperature is expected to be below 0° F.
3. Controls must stay adjacent to the cold packs in order to maintain the desired internal temperature range when the outside temperature is extremely high.

Consider outside temperatures when traveling with biologicals. Do not leave controls in a vehicle for extended periods of time in either very cold or very hot temperatures.