2018

North Dakota
HIV AND HEPATITIS C COUNSELING, TESTING AND REFERRAL SITE POLICIES AND PROCEDURES

North Dakota Department of Health
HIV • STD • TB
VIRAL HEPATITIS PROGRAM

North Dakota Department of Health
HIV·STD·TB
VIRAL HEPATITIS PROGRAM

HIV & HCV CTR PROCEDURE & POLICY MANUAL

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Program Contact Information

The Counseling, Testing and Referral (CTR) Program is administered by the HIV.STD.Hepatitis program at the North Dakota Department of Health (NDDoH), Division of Disease Control. See below for information on the staff managing the program.

Title*	Phone
HIV.STD.TB.Viral Hepatitis Program Manager	701.328.4555
HIV.STD.Viral Hepatitis Prevention Coordinator	701.328.2366
HIV.STD.Viral Hepatitis Surveillance Coordinator	701.328.1059
Administrative Assistant	701.328.2378

*Current Personnel are listed at www.ndhealth.gov/HIV/Contact.

HIV.STD.TB.Viral Hepatitis Program Manager:

- Coordinates Contracts and Grant Applications.
- Processes Monthly Reimbursement Requests.

HIV.STD.Viral Hepatitis Prevention Coordinator:

- Provides Training on CTR Requirements and Expectations.
- Reviews and Analyzes MAVEN Data Entry for CTR Sites.
- Conducts Site Visits.
- Creation of Education Materials.

HIV.STD.Viral Hepatitis Surveillance Coordinator:

- Ensure Appropriate Case Follow-Up Occurs.
- Prepare Morbidity Reports, Including the Yearly Epidemiologic Profile.

Administrative Assistant:

- Ordering of Supplies and Educational Materials

Contact Information for Disease Control:

North Dakota Department of Health
Division of Disease Control
2635 E. Main Avenue
Bismarck, ND 58506
Email: disease@nd.gov

Phone: 701.328.2378 or 800.472.2180
Fax: 701.328.2499
Confidential Fax: 701.328.0355
HIV Confidential Fax: 701.328.0356
Website: www.ndhealth.gov/HIV/CTR

About CTR Program

The NDDOH Division of Disease Control CTR program offers HIV and hepatitis C testing to populations at risks. CTR sites aim to inform clients' knowledge of their HIV and hepatitis C status, counsel and support harm reduction and help to secure needed referrals for treatment and care.

CTR sites are chosen from among providers who routinely see patients at high and increased risk of HIV and hepatitis C infection. These types of providers include, but are not limited to local public health units, substance abuse and treatment centers, ND community action organizations, ND family planning sites, pregnancy clinics, corrections, homeless shelters, institutions of higher education, community health centers, tribal health, etc. CTR sites offer HIV and/or hepatitis C testing and prevention counseling and supplies. CTR sites may also offer hepatitis vaccination, other STD testing and community education.

Each year, up to 25 agencies are selected via a competitive procurement process to receive contracts to perform services at CTR sites. Additional sites are eligible to receive supplies to offer services without funding and are considered non-contract partners. A current list of CTR sites is available at www.ndhealth.gov/HIV/CTR.

Program Goals for CTR Sites

The HIV and Viral Hepatitis programs of the NDDoH Division of Disease Control aim to reduce the spread of HIV and viral hepatitis, reduce illness and death and promote the health and well-being of people with or at risk for these infections. Offering HIV and hepatitis C testing at CTR sites increases accessibility to healthcare services for populations at risk. CTR sites aim to inform clients' knowledge of their HIV and HCV status, counsel and support harm reduction and secure needed referrals (i.e. medical, social, prevention and partner services).

The program is committed to upholding the vision of the National HIV/AIDS Strategy, which states:

"The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination"

The program also focuses on completing activities of the National Viral Hepatitis Action Plan for the Prevention, Care and Treatment of Viral Hepatitis. Increasing the proportion of persons who are aware of their hepatitis C virus (HCV) infection status is one goal of the action plan that is accomplished at CTR sites through testing of at-risk individuals.

In addition to the National HIV/AIDS Strategy and the National Viral Hepatitis Action Plan, CTR sites should also aim to complete the goals in the ND Integrated HIV and Viral Hepatitis Prevention and Care Plan. This document highlights the objectives, strategies and activities that are the focus of the NDDoH HIV and Viral Hepatitis programs. The four goals of the integrated plan are:

1) **Reduce New HIV and Viral Hepatitis Infections.**
2) **Increase Access to Care and Improve Health Outcomes for People Living with HIV and Viral Hepatitis.**
3) **Reduce HIV and Viral Hepatitis Related Health Disparities.**
4) **Achieve a More Coordinate Response.**

The most current ND Integrated HIV and Viral Hepatitis Prevention and Care Plan highlights objectives and activities for 2017 - 2021. This plan is updated yearly with documented progress made towards each activity within the various strategies. Based on the activities within this plan and the two national documents addressing HIV and Viral Hepatitis, the NDDoH developed the required activities of the CTR program.

The following are core elements that are essential to all CTR sites:

1) Ensure that CTR is a voluntary service that can only be delivered after informed consent is obtained.
2) Provide information and education to the client about HIV and HCV.
3) Provide client-focused HIV/HCV prevention counseling.
4) Use HIV and HCV testing technology approved by the Food and Drug Administration (FDA).
5) Deliver test results in a manner that is supportive and understandable to the client.
6) Assess the need for referrals in support of risk reduction or medical care. Provide appropriate referrals, link clients to referral services and document referrals and their outcomes.

In addition to the required activities associated with the core elements, CTR sites are recommended to provide comprehensive services, which could include sexually transmitted disease (STD) testing, human papilloma virus (HPV) vaccination and viral hepatitis vaccination at every opportunity. In addition to providing services to incoming clientele, CTR sites, in partnership with the NDDoH and the North Dakota Community Planning Group for HIV and Viral Hepatitis Prevention, Care and Treatment (NDCPG), may offer outreach services in the community such as rapid testing at health fairs, community events or stand-alone testing events targeting high risk individuals. Table 1 below summarizes the required and recommended activities performed at CTR sites.

Table 1. Required and Recommended CTR Activities

Required Activities	Recommended Activities
Obtaining Consent	Outreach Events
HIV/Hepatitis C Rapid & Confirmatory Testing	Community Education
Pre- & Post-Test Counseling	STD Testing
Risk Reduction	Hepatitis A & B Vaccination
Data Submission for All Tests Performed	HPV Vaccination
Resource Referrals	Case Management
Provide Client Education	Partner Services

CTR Site Required Reporting

The CTR program requires certain information be reported to the NDDoH by all CTR sites, contracted and non-contracted. The following is a summary of the required information reported to the NDDoH:

- Testing Data:
  - Patient demographics, including patient name, address, gender, race, ethnicity, etc.
  - Previous testing history.
  - Specified risk factors.
  - Results of screening and confirmatory testing.
    - Positive rapid and confirmatory results reported separately.
  - Co-infection screenings.
  - Behavioral and social support services assessments and referrals.
- Rapid Test Quality Assurance:
  - Control logs.
  - Temperature logs.
  - Invalid test reports.
  - Current CLIA waiver.
- Hepatitis Vaccine
  - Doses administered.

Testing Data Reporting

For testing data, there is a form available, HIV/HCV Test Form, often referred to as the PEMS form, that has all of the information required to be reported on every individual who is tested for HIV and/or HCV. The paper version of this form is not required to be completed, as the data is required to be entered into a system called the North Dakota Electronic Disease Surveillance System, which is referred to as Maven. The Maven website is: https://apps.nd.gov/maven/login.do. A Required Data Elements and Maven User Guide and Maven tutorial are available on the CTR website.

To enter data into MAVEN, users need a username and password. New employees or facilities must contact the HIV.STD.Viral Hepatitis Prevention Coordinator to obtain user information before performing tests or entering data. ***Note:*** *MAVEN user information will expire if the user does not login at least once every 90 days.*

MAVEN Site and User Agreements

All users of Maven must sign a Maven User Agreement prior to receiving their username and password. This User Agreement is also signed in January each year. The Maven Users' Agreement describes policies and procedures related to maintaining confidentiality with the data in Maven. A user's access may be permanently denied for Maven if there is a violation of the User Agreement.

All CTR sites must sign a Maven Site Agreement. Each CTR site must designate a Maven administrator. If a CTR agency has multiple locations, each site must complete a Site Agreement. The Maven site administrator authorizes new Maven users for their site, notifies the NDDoH is users terminate their CTR employment, is designated as the Maven point of contact and ensures Maven users utilize the system appropriately and follow the User Agreement.

Rapid Test Quality Assurance and Hepatitis Vaccine

Additional information on reporting requirements for rapid test quality assurance and hepatitis vaccine is detailed in corresponding sections of this manual.

Screening for HIV and HCV at CTR Sites

Rapid, point-of-care HIV and hepatitis C tests are the provided for use at CTR sites. These tests should be prioritized for uninsured or underinsured individuals as these tests and corresponding visits are covered by most insurance policies. Also, testing services at CTR sites are only available to individuals considered to be at risk for HIV and/or HCV. Services at CTR sites are considered confidential; anonymous testing is not available at CTR sites.

Risk Assessment

In order to determine if individuals are at risk for and should be screened for HIV and/or HCV, individuals seeking services must complete a risk assessment. NDDoH has developed a risk assessment tool however sites are not required to use it. The required risk assessment data elements are described in the document Required Data Elements and MAVEN User Guide. The HIV.STD.Hepatitis Prevention Coordinator can provide assistance to ensure the CTR site is utilizing the optimal tools for their testing program.

HIV Screening

Screening should be provided annually for people who are or have had:

- Men who have sex with men (MSM)
- Sex with people living with HIV (PLWH)
- More than one sex partner since last HIV test
- Injected drugs or shared needles or works with others
- Persons who exchanged sex for money or drugs
- Persons diagnosed with/or sought treatment for tuberculosis, HCV or a sexually transmitted disease (STD)
- Sex with an injection drug user
- Sex with someone who exchanged sex for money or drugs
- Sex with someone whose sexual history is unknown (i.e. anonymous sex partners, usually involves networking apps such as Grindr)
- Tattoos or body piercings in unsterile environments

Patients that are considered at high-risk for HIV infection may benefit from being screened every three to six months. Those at high-risk include:

- Sex partners of PLWH
- Persons who engage in unprotected anal sex
- Persons who use networking apps to meet their partners, i.e. have anonymous sex partners
- Persons who inject drugs (PWID) and their sex partners
- Persons who are or have partners whom exchange sex for money or drugs
- Persons who engage in unprotected anal sex

The above HIV screening recommendations are from CDC as well as informed by the epidemiology of HIV in North Dakota. CDC HIV screening recommendations can be found on www.cdc.gov/hiv.

Note: *Per CDC, everyone between the ages of 13 and 64 should be screened for HIV at least once in their lifetime without an assessment of risk. This strategy is to be implemented as opt-out screening and is recommended for healthcare facilities and age-based screening programs are not to be implemented in the CTR program.*

HCV Screening

Those that have current risk behaviors should be screened at least annually as recommended by CDC. People at risk include those who:

- Currently injecting drugs
- Ever injected drugs, including those who injected once or a few times many years ago
- Have certain medical conditions, including persons:
  - who received clotting factor concentrates produced before 1987
  - who were ever on long-term hemodialysis
  - with persistently abnormal alanine aminotransferase levels (ALT)
  - who have HIV infection
- Were prior recipients of transfusions or organ transplants, including persons who:
  - were notified that they received blood from a donor who later tested positive for HCV infection
  - received a transfusion of blood, blood components, or an organ transplant before July 1992
- HCV- testing based on a recognized exposure is recommended for:
  - Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
  - Children born to HCV-positive women

HCV screening may be considered for:

- Men who have sex with men (MSM)
- Intranasal cocaine and other non-injecting illegal drug users
- Sex partners of HCV-positive persons
- Sex partners of persons who inject drugs
- Persons who use illicit drugs, but do not admit to injection drug use, may still be considered for HCV testing due to the possibility that illicit non-injection drug users may be engaging in risky additional risky behaviors

HCV is not efficiently transmitted through sex, thus heterosexuals or those with multiple sex partners are not recommended for routine HCV screening. Studies of HCV transmission between heterosexual or homosexual couples have yielded mixed results, but generally have found either no or very minimally increased rates of HCV infection in partners of persons with HCV infection compared with those whose partners are not HCV-infected. Data indicate that sexual transmission of HCV can occur, especially among persons with HIV infection. Increasing incidence of acute HCV infection among MSM with HIV infection has been reported in New York City and Boston, along with multiple European cities. These men usually engage in high-risk and traumatic sexual practices and might have concurrent genital ulcerative disease or STD-related proctitis. Other common practices associated with new cases of HCV infection include group sex and use of cocaine and other nonintravenous drugs during sex. Certain studies have revealed that risk increases commensurate with increasing numbers of sex partners among heterosexual persons with HIV infection and MSM, especially if their partners are also coinfected with HIV.

Individuals that have been successfully treated for HCV or have resolved their infection without treatment, should be screened for HCV at least annually if they have continued risk factors. These individuals are not be screened with a HCV rapid test. In order to determine if individuals are currently infected, a HCV RNA test should be ordered.

Note: *The CDC recommends that everyone born during 1945 through 1965, also known as "baby boomers", get a one-time test for hepatitis C regardless of known risk factor. People born during 1945 through 1965 are 5 times more likely than other adults to be infected. At CTR sites, the focus is at risk testing and thus baby boomers are not included in this program unless they have another specified risk for HCV.*

Screening Services Not Provided

Individuals that are ineligible from receiving CTR testing include those who are seeking testing for employee screening, insurance purchase agreements, travel related purposes, sports team screening or occupational exposure incidents. The CTR program is also not meant for universal screening of pregnant women. Pregnant women are recommended to have HIV screening with each pregnancy and only recommended for HCV screening if they have a documented risk factor. *Note: HCV rapid tests are not approved for use on pregnant women.*

Screening at Correctional Facilities

Thera are two North Dakota Century Code subsections that describe requirements for HIV and STD screening in correctional facilities. Below are the subsections of the North Dakota Century Code:

- **23-07-07.5. Testing of inmates and convicted individuals for exposure to the human immunodeficiency virus - Reporting - Liability.**

  1. The following individuals must be examined or tested for the presence of antibodies to or antigens of the human immunodeficiency virus:
     a. 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;
     b. 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 and 12.1-20-13; and
     c. 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 the human immunodeficiency virus.
  2. The results of any positive or reactive test must be reported to the state department of health in the manner prescribed by the department and to the individual tested. Subsection 1 does not require the testing of an individual before sentencing or the testing of an individual held in a jail or correctional facility awaiting transfer to the state penitentiary.
  3. A licensed physician, nurse, technician, or employee of a hospital or clinic who draws blood from any person for the purpose of conducting a test required by this section is not liable in any civil action for damages arising out of such action except for an act or omission that constitutes gross negligence.

- **23-07-08. Persons in prison examined and treated for sexually transmitted diseases. Every person convicted of a crime who is imprisoned fifteen days or more in a state, county, or city prison must be examined for sexually transmitted disease and, if infected, must be treated therefor by the health officer within whose jurisdiction the person is imprisoned.**

Although century code only requires HIV testing of inmates if there were convicted and imprisoned for fifteen days or longer, all inmates regardless of length of imprisonment or conviction status can be tested for HIV and/or HCV in the CTR program. Although STD testing is not included in the CTR program, inmates should also be screened for STDs, including chlamydia, gonorrhea and syphilis.

Post-Exposure Prophylaxis (PEP)

When assessing risk, if there is a concern about a recent exposure, CTR sites should always consider if a referral to a healthcare provider for PEP is needed. Some situations that may require PEP referral include individuals who have been exposed to HIV during sex (ex. If the condom broke), sharing needles or other drug equipment or if clients were sexually assaulted. PEP for HIV is used only in emergency situations and must be started within 72 hours after a possible exposure. There is no PEP available for hepatitis C. CTR sites should determine a good referral source for PEP in their community, oftentimes that would be an emergency room or urgent care clinic. The NDDoH has a fact sheet available on body and bodily fluids exposure that CTR sites may use as a reference.

STD Screening

Screening for STDs, such as chlamydia, gonorrhea and syphilis, is recommended to be performed by all CTR sites to ensure comprehensive sexual health services are offered to all clients. All individuals at risk for HIV should be tested STDs and all patients diagnosed with a STD should also be tested for HIV. Refer to the CDC STD Treatment Guidelines for the most complete and current STD screening recommendations. These recommendations also include screening recommendations based on site of exposure, i.e. site-specific STD screening. For example, MSM engaging in anal sex are recommended to have specimens collected from the rectum tested for chlamydia and gonorrhea. Always consider site of exposure for chlamydia and gonorrhea testing. The NDDoH has posters available that detail rectal and pharyngeal site-specific screening specimen self-collection instructions. Order these posters and other supplies here.

For sites that need standing orders for the screening and/or treatment of STDs, they are found at www.ndhealth.gov/HIV/CTR. These standing orders are utilized by healthcare agencies in which patients may be seen by a nurse and not by physician or advance practice nurse. These standing orders allow nurses to screen and provide treatment for asymptomatic patients.

Although reimbursement for STD screening or treatment is not included in the CTR program, CTR sites are eligible to receive reduced fee STD testing from the North Dakota Public Health Laboratory (NDPHL), Division of Laboratory Services. Please contact the HIV.STD.Hepatitis Prevention Coordinator if you are not receiving reduced fee STD testing at the NDPHL. The receipt of this reduced fee testing also qualifies agencies for eligibility for STD designation within the federal 340B pharmacy purchasing program. Agencies have found cost savings through the procurement of medications to treat STDs for their clients. This may include mediations for the treatment of chlamydia, gonorrhea, syphilis, bacterial vaginosis, trichomoniasis as well as antiretroviral medications currently authorized for pre-exposure prophylaxis for HIV infections (HIV PrEP) and hepatitis B and C treatment. For more information on the requirements and instructions on how to register for this designation, contact the HIV.STD.TB.Viral Hepatitis Program Manager.

A reference tool that summarizes HIV, HCV and STD screenings can be found at www.ndhealth.gov/HIV/CTR.

Counseling at CTR Sites

HIV and HCV 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 and/or HCV. At CTR sites, all individuals seeking HIV or HCV testing should be provided counseling. Client-focused counseling techniques should be used to help clients determine their readiness for testing and to provide support systems to access while waiting for and after receiving their test results. Client-focused counseling also assesses the client's ability to cope with a positive test result. At the conclusion of the counseling session, a risk reduction plan should be developed with a client and/or appropriate referrals are made based on results and risks.

There are four goals for every counseling session. These include 1) risk assessment, 2) educate client 3) risk reduction planning and 4) result disclosure. The session is typically described in terms of pre-test and post-test counseling. A summary of activities in the pre and post-test counseling session is provided in Table 2.

Table 2. Pre- and Post-Test Counseling Activities

Pre-Test Counseling	During Waiting Period or Post-Test Counseling
Welcome client and discuss what is going to happen in the session.	Ensure client is ready to receive results. Provide results if client is ready.
Establish rapport.	Describe test and results and clear indicate what those results mean.
Educate client on HIV and hepatitis C.	Awareness of risk. Review risk reduction plan and highlight goals for behavior change.
Assess client's risk and readiness for testing.	Provide referrals as necessary.
Provide information on HIV and HCV testing. Include STD testing if appropriate.	Provide recommendations for continual testing if client's continues to have risky behaviors.
Prepare client to receive result.	Establish the overall knowledge of the disease.
Engage client in risk reduction counseling.	Educating about prevention.

Pre-Test Counseling

The pre-test counseling sessions focus on welcoming the client, establishing rapport, providing education about HIV and HCV, risk assessment and engaging the client in risk reduction counseling. Education provided to the client should at least include the type of testing available, risks and benefits of testing, how to prevent and transmit HIV and hepatitis C, window period for testing and where to obtain more information or other healthcare services.

Post-Test Counseling

The post-test counseling can occur the same day as the pre-test counseling if a rapid test is performed or at a later date if a conventional test is performed. A post-test counseling session includes providing test results and an explanation of those results. Review HIV and HCV educational material and develop a client specific risk reduction plan and provide appropriate referral services.

Counseling Negative Individuals

Provide test result in a way that is sensitive and appropriate to the client's needs and level of comprehension. Help the client understand the meaning of the test result. Reemphasize staying negative by helping the client understand how to prevent HIV and/or hepatitis C infection and educate client on screening recommendations, i.e .annually or every more frequent screening.

Counseling Newly Identified HIV and/or HCV Confirmed Positive Individuals

Individuals with positive HIV or hepatitis C confirmatory tests, post-test counseling should ideally be offered face-to-face in a confidential setting.

Post-test counseling for positive individuals should include a discussion of:

- The test results and the reliability and significance of the results;
- Partner services for positive HIV cases;
- Facts about HIV or hepatitis C transmission, emphasizing how to protect close contacts;
- Referrals for medical evaluation, care and treatment including healthcare insurance enrollment and information and referrals for support services, including social and emotional support and substance abuse treatment programs, mental health services or other related programs

At the conclusion of the post-test counseling session, providing information to the client that they can take home is very important.

Additional Information

Providers should develop and maintain strong working relationships with other providers and agencies that might be able to provide needed services. Providers who offer HIV/HCV prevention counseling and testing but not a full range of medical and psychosocial support services should develop arrangements with other providers who can offer needed services. When referral resources are not available locally, providers should identify appropriate resources and link clients with them. Coordination and collaboration promotes a shared understanding of the specific medical and psychosocial needs of clients requiring services, current resources available to address these needs, and gaps in resources.

Test Methods Offered at CTR Sites

All tests performed at CTR sites are required to be approved by the FDA. Both rapid and confirmatory HIV and HCV testing are offered to CTR sites. Rapid tests are provided to CTR sites free of charge from the NDDoH. Specimens for confirmatory testing collected at CTR sites should be performed at the NDPHL Division of Laboratory Services. Contracted CTR sites are reimbursed for the expense of confirmatory testing. Non-contracted partners are responsible for the costs associated with confirmatory testing.

Rapid Testing

Prior to CTR sites initiating rapid testing at their facility, the CTR site needs to obtain a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. This waiver is required as the rapid tests are CLIA waived by the FDA and North Dakota Board of Clinical Laboratory Practice. Information on CLIA application can be found here. Copies of CLIA waivers will be requested prior to becoming a CTR program and at site visits. Ensuring compliance with CLIA standards is the responsibility of the CTR site. Ensure all testers are aware of requirements and training necessary prior to testing individuals for HIV and HCV. A HIV & HCV Rapid Assay Procedure documents is available at www.ndhealth.gov/CTR if CTR sites need to create their own policies and procedures.

Note: Rapid tests should not be used for confirmatory testing as rapid tests are not definitive for the diagnosis of HIV or HCV. Individuals who had a positive screening test, such as those testing positive at a plasma center or a blood bank, should be offered a confirmatory test. If patients are not at risk for HIV or HCV, they should be referred to their primary care provider or other healthcare provider for this confirmatory testing.

Control Logs

For all rapid HIV and HCV tests, controls are required to be performed for quality assurance. Chembio SURE CHECK® HIV 1/2 Assay and HCV OraQuick® rapid tests require controls to be performed for the following circumstances:

1) Each new operator prior to performing tests on patient specimens.
2) When opening a new test kit lot.
3) Whenever a new shipment of test kits is received.
4) If the temperature of the test storage area falls outside:
    a. HIV SURE CHECK®: 8° to 30°C (46° to 86°F)
    b. HCV OraQuick®: 2° to 30°C (36° to 86°F)
5) If the temperature of the testing area falls outside:
    a. HIV SURE CHECK®: 18° to 30°C (64° to 86°F)
    b. HCV OraQuick®: 15° to 37°C (59° to 99°F)
6) At periodic intervals as indicated by the user facility. ***CTR Program Requirement: 6 Month Interval***

Anytime controls are performed, performance should be documented on a HIV/HCV Rapid Test Control Log. Control logs should be submitted within seven days of control performance.

The NDDoH performs controls on all rapid tests when a new shipment is received. If CTR sites pick up or have tests hand delivered, controls may not be necessary. Temperatures indicators are included with the delivery that will indicate if the tests went outside the storage temperature during the excursion. If the rapid tests went outside the storage temperature range, the CTR site would need to perform controls upon receipt. If the rapid tests did not go outside the storage temperature range, controls are not required to be performed by the CTR site upon receipt if controls had been performed in the previous six months.

Whenever a CTR site receives a shipment of tests, it is recommended to document each box with the date of last control performance, date of receipt and method of receipt. If controls did not need to be performed at time of receipt, that should also be documented on the box. For example, if a CTR site received two boxes of HCV rapid tests via delivery by the HIV.STD.Hepatitis Prevention Coordinator during a site visit and temperatures were verified to be within the storage temperature range, each box is recommended to be labeled with the following: 1) latest date of control performance (typically done by the HIV.STD.Hepatitis Prevention Coordinator), 2) date of delivery, 3) method of delivery and 4) statement "storage temperatures verified upon delivery – initials of verifier.

Note: HIV controls expire on the date listed on the product. HCV controls expire on the date listed on the product or two months after they are first opened. All HCV controls should be labeled with the date of opening and expiration date. Also note that expired controls and test devices can be used to train new operators.

Temperature Logs

Controls are required to be stored at refrigerator temperatures. HIV and hepatitis C controls should be stored at temperatures of 2° to 8°C (36° to 46°F). If controls are stored in a refrigerator in which the temperatures are submitted as part of the NDDoH Immunization program, no daily temperatures need to be submitted to the CTR program. Otherwise, daily temperatures need to be recorded on a temperature log, Celsius or Fahrenheit. The temperature log is then submitted at the end of every month. If temperatures fall outside of the acceptable range for the storage of controls, contact the HIV.STD.Hepatitis Prevention Coordinator immediately.

Rapid HIV Test

The rapid HIV test provided to CTR sites is the Chembio SURE CHECK® HIV 1/2 assay. **This test is to be used on individuals older than 12 years of age**. The test is approved for use on fingerstick whole blood, venous whole blood, serum or plasma. The results are read between 15 to 20 minutes after test is initiated. This test is very accurate with a sensitivity of 99.7% and a specificity of 99.9%. The window period of the rapid HIV test is 23 to 90 days to reliably detect HIV infection. One requirement for this test is that patients must receive the subject information notice prior to specimen collection and appropriate information when test results are provided.

Rapid HCV Test

The rapid HCV test provided to CTR sites is the Orasure Oraquick® HCV Rapid Antibody Test. **This test is to be used on individuals older than 14 years and cannot be used on pregnant women**. The approved specimens include fingerstick whole blood or venipuncture whole blood. The test results are interpreted between 20 and 40 minutes following the introduction of the device into the developer solution vial. With a fingerstick sample, the percent positive agreement is 97.9% and the percent negative agreement is 98.5% indicating that results are reliable with greater than 98% accuracy. The window period for anti-HCV screening tests ranges from 4–10 weeks after infection. Anti-HCV can be detected in >97% of people by 6 months after exposure.

Per manufacturer's requirements, testers must:

- Correctly interpret the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test device.
- Read the package insert completely before using the product.
- Read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.

The above requirements for testers are also included in the Staff Development and Training Policy.

Rapid Test Competency

All CTR sites are required to have an annual competency policy. A sample competency policy is available for CTR sites to modify for their program at www.ndhealth.gov/HIV/CTR. Competency policies will be reviewed during site visits. Also available on the above website is a sample competency certificate. CTR sites are recommended to have documentation of competency education for the performance of rapid testing for new testers as well as others for continued professional development.

Confirmatory Testing

All positive rapids tests must be confirmed with a confirmatory test. All CTR sites are recommended to offering confirmatory testing. If CTR sites do not offer confirmatory testing, these sites are required to have a written document that details their plan for ensuring that these clients get the confirmatory testing that they need. In addition to referrals, follow-up process of the referral should be included in their plan. Sites are encouraged to develop relationships with other CTR sites in their area, if available, to offer referrals for blood draws.

All blood specimens should be spun utilizing a centrifuge prior to sending to NDPHL. The CTR program will provide centrifuges as needed to CTR sites if funding is available. Do not centrifuge immediately after drawing blood. Allow the blood to clot in an upright position for at least 30 minutes but not longer than 1 hour before centrifugation. Per NDPHL, blood specimens for HIV and HCV confirmatory testing should be spun at 3 (3,000) RPM for 10 minutes.

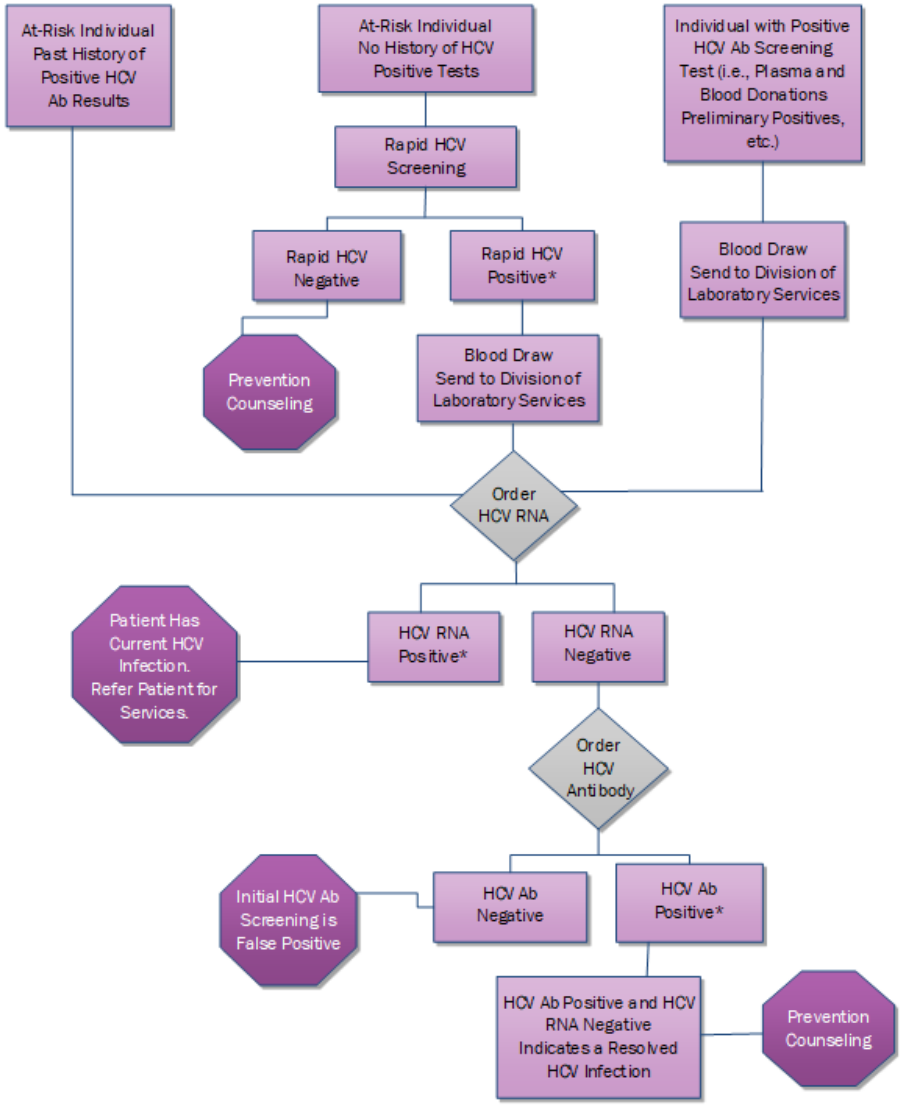
Confirmatory testing is performed at the NDPHL Division of Laboratory Services. When submitting specimens for confirmatory testing, ensure that correct procedures are followed. NDPHL Division of Laboratory Services provides specimen collection procedures and requires submission of completed laboratory request form with each specimen. The laboratory offers a courier service in several communities and healthcare facilities throughout North Dakota. Contact the HIV.STD.Hepatitis Prevention Coordinator if you are unsure if a courier location near your program. The courier service is free of charge and provides free shipping of specimens to the laboratory.

HIV Confirmatory Testing

The type of HIV confirmatory test performed at NDPHL is a fourth generation HIV-1/2 antigen/antibody combination immunoassay. This fourth-generation test detects the P24 antigen which is produced even before HIV antibodies. The window period for this confirmatory test is 13 to 42 days after infection. If the rapid HIV test is positive, the fourth-generation test is negative, a HIV nucleic acid test is then recommended. The NDPHL will ensure that this test happens along as the rapid reactive test result is reported to the NDDoH Division of Disease Control immediately. The window period for the HIV NAT test is 10 to 33 days after an exposure. It is very important that CTR sites immediately report all rapid reactive HIV tests results to the NDDoH to ensure appropriate confirmatory testing occurs.

HCV Confirmatory Testing

The HCV confirmatory test available is a confirmatory antibody test as well as a quantitative RNA viral load test. Traditionally, all rapid reactive HCV tests would be confirmed with a confirmatory HCV antibody test followed by a HCV RNA test. The CTR program is recommending a non-traditional algorithm for confirmatory HCV testing. In the CTR program, the first confirmatory test ordered should be the HCV RNA. If the HCV RNA test is nonreactive, then a confirmatory HCV antibody test should be ordered. The below diagram illustrates the recommended HCV testing algorithm at CTR sites:



*Report Positive Result to Disease Control

When submitting samples for hepatitis C testing, there are temperature requirements for the performance of the HCV RNA testing. Whole blood or serum stored at ambient temperatures must be to the laboratory within 24 hours of collection and specimens that are refrigerated must be to the laboratory within 48 hours. If the time from collection to arrival at the laboratory will be greater than 48 hours, the sample needs to be frozen at ≥-20°C.

Blood Draw Supplies

CTR sites may order blood draw supplies free-of-charge from the NDDoH. Blood draw supplies that are available include vacutainer tubes, eclipse needles for blood collection 21G x 1 ¼", angel wing collection sets 23G x ¾", one-use vacutainer holders, tourniquets and 2'' x 2" gauze pads. These supplies can be ordered at www.ndhealth.gov/HIV/Supplies.

Reporting & Documentation

All testing and screening results need to be reported on every test performed, both rapid and confirmatory tests. These results are entered in MAVEN. Results should be documented within a patient's chart either via a paper form or electronically. The CTR program does not specify which documentation method is used by the site.

If an invalid test result is observed, it must be reported to the HIV.STD.Hepatitis Prevention Coordinator. The invalid test report form is available here. Invalid tests should be reported within seven days of specimen collection.

All HIV rapid and confirmatory positive results must be reported to the NDDoH within one business day. Positive HIV results must reported by calling the Division of Disease Control at 701.328.2378. When reporting a positive HIV or hepatitis C, you may speak to anyone in the HIV.STD.TB.Hepatitis Program or contact the local field epidemiologist. All HCV rapid and confirmatory positive results must be reported to the NDDoH within seven business days. HCV results can be reported by 1) submitting a North Dakota Morbidity Report Card, 2) submitting an online disease report card or 3) emailing the MAVEN Event ID to the HIV.STD.Hepatitis Prevention Coordinator. Submitting the information in MAVEN as a CTR event is not considered reporting a positive test result.

STD Testing & Treatment

CTR sites are eligible to receive reduced fee STD testing from the NDPHL Division of Laboratory Services. Please contact the HIV.STD.Hepatitis Prevention Coordinator if you are not receiving reduced fee STD testing at the NDPHL. Another benefit to the CTR program is that CTR sites are eligible to receive 340B pricing on STD medications. More information on the 340B program is available here: https://www.hrsa.gov/opa/index.html. As a CTR site, the agency is then considered a safety net provider and can receive significantly reduced prices on medications for STD treatment. For more information on the program or how to get registered, please contact the HIV.STD.TB.Hepatitis Program Manager.

Resources and Additional Information

- Hepatitis C Test Interpretation, CDC
- Hepatitis C Testing Algorithm, CDC
- Hepatitis C Testing Algorithm, NDDoH
- Rapid HIV and HCV tests, controls and blood draw supplies ordered online: www.ndhealth.gov/HIV/Supplies.
- Supplies for STD testing are provided by NDPHL, including swabs for site-specific testing. Contact 701.328.6272.
- Disease reporting forms that are available:
    - STD Reporting Form - Health Care Providers
    - STD Reporting Form – Patient Interview
    - Syphilis Case Report Form
    - HIV Confidential Case Report Form

Policies and Statutes for CTR Programs

Consent

Consent for HIV and HCV testing can be incorporated into general consent for medical care; a separate consent form specific to HIV or hepatitis C is not needed. Consent can be given orally or written as long as it is documented in the client's medical record. Clients shall still have the opportunity to decline testing. Recommendations around consent were described based on the opinion of ND Office of Attorney General. Please contact the HIV.STD.Hepatitis Prevention Coordinator if your facility needs assistance in development of a consent form or policy.

Minor Consent

North Dakota Century Code 14-10-17 states that "*any person of the age of fourteen years or older may contract for and receive examination, care, or treatment for sexually transmitted disease or substance use disorder without permission, authority, or consent of a parent or guardian*". This century code indicates that all adolescents 14 years or older may consent to STD testing (chlamydia, gonorrhea, syphilis, HIV, etc.) without parental consent. Per opinion received by he HIV.STD.TB.Viral Hepatitis Program from the ND Office of Attorney General, hepatitis C testing and HPV vaccination also are applicable under this century code. ***Note**: Rapid hepatitis C testing is only approved for those 15 years and older.*

Record Location and Retention Policy

Location of Records

HIV and HCV records and reports shall 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 or HCV files shall not be kept. If there is no medical file, records must be kept confidential.

Record Retention Schedule

The NDDoH does not have requirements for record retention at CTR sites. CTR sites are encouraged to establish their own record retention policy. If records are kept electronically, there is no recommendation to keep additional paper records of HIV or HCV records.

Confidentiality

All patient information collected for the CTR program shall be considered protected health information (PHI). All PHI is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule. All CTR sites should ensure that staff are properly trained in maintaining and protecting PHI.

Note: North Dakota Century Code (NDCC 23-07-21) indicates an individual who releases or makes public confidential information may be found guilty of a class C felony. NDCC 23-07-02.2 addresses breaching confidentially of an individual's HIV seropositivity status. According to this NDCC, anyone breaching this confidentiality is guilty of a class C felony (5 years and/or $5,000).

Viral Hepatitis Vaccine

All CTR sites enrolled in the Vaccines for Children (VFC) program through the Immunization Program are eligible to receive adult viral hepatitis vaccine. Twinrix, single antigen hepatitis A and single antigen hepatitis B vaccine are available through the CTR program. The vaccine is available to CTR sites free-of-charge. Contracted CTR sites are also able to request reimbursement for vaccine administration. Current rates of reimbursement are equal to that of the administration fee cap. This fee is located on the reimbursement worksheet in PRS.

All clients at risk for hepatitis C are recommended to be vaccinated for hepatitis A and B. Thus, all clients whom are tested for hepatitis C should also be screened for a history of hepatitis A and hepatitis B vaccination and/or history of or current infection. If the client has no prior history of hepatitis A or B vaccination and/or history of or current infection, appropriate viral hepatitis vaccine should be offered to the client. CTR sites should strive to ensure that all clients receive a completed vaccine series. To remind patients of subsequent doses required to complete the series, CTR sites could use reminder phone calls, letters, post cards or even utilize incentives when the client comes in for additional doses in the series.

The vaccine in the CTR program is considered 317 vaccine, thus individuals receiving the vaccine must meet the eligibility requirements of the immunization program. Eligible **18 years and younger** clients include those that are one of the following:

1. Medicaid eligible
2. Uninsured
3. American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
4. Underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC - eligible for non-covered vaccines only).

Eligible **adults**, 19 years and over, include those that are one of the following 1) Uninsured or 2) Underinsured.

All clients receiving vaccine provided at the CTR sites must be entered in the North Dakota Immunization Information System (NDIIS) along with documentation of the appropriate vaccine lot number and other information required by the NDDoH Immunization Program. Contact the Immunization Program to request NDIIS access information.

Vaccine will be ordered on the last day of every month. CTR sites must complete the most current vaccine order form and submit via fax or email to the HIV.STD.Hepatitis Prevention Coordinator by the last day of the month. The current vaccine order form is available at: www.ndhealth.gov/HIV/CTR.

CTR sites are responsible for ensuring their in-stock vaccine does not expire. If the vaccine at a CTR site is going to be expiring soon, the CTR site should contact the HIV.STD.Hepatitis Prevention Coordinator for assistance in finding a facility that would be able to use the vaccine prior to expiration. CTR sites should contact the HIV.STD.Hepatitis Prevention Coordinator at least three months prior to their vaccine expiring to ensure adequate time to arrange for transfer to another facility. Sites that have wasted doses of vaccine may not receive vaccine in the future as a CTR site.

All CTR sites are recommended to include HPV vaccine as part of their comprehensive sexual health services. CTR sites are excellent locations to vaccinate at risk individuals for HPV that may have been missed in their adolescent years. HPV vaccine is available through the VFC and Adult 317 Immunization Programs. Contact the Immunization Program at 701.328.2378 for additional information.

Staff Development and Training Policy

New Employee Training Requirements

All testers and counselors must adhere to the training requirements of the NDDoH. Individuals entering in Maven also have required training. The following are requirements that should be completed within 30 days of hire for CTR staff based on their role within the program:

Required Training	Role Required
1. Watch Online Rapid Training Videos a. **OraQuick® Rapid HCV Video:** orc.orasure.com/default.aspx?pageid=1995 b. Chembio SURE CHECK ® HIV 1/2 Assay: chembio.com/sure-check-hiv-12-assay/	Tester
2. Read Product Inserts for HIV and Hepatitis C Testing Devices.	Tester
3. For Hepatitis C Rapid Testing, view Hepatitis C Visual Reference Panel.	Tester
4. Receive In-Person Training on Rapid Test Performance by Qualified Individual. ***Note: Only a new CTR site needs to be trained by the NDDoH; otherwise all new employees can be trained by a qualified (i.e. previously trained) employee.***	Tester
5. Read Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings published by CDC. *MMWR* 1988; 37(24):377 to 388.	Tester
6. Read CTR Manual.	Tester & Counselor
7. Watch the Following Presentations (Available at www.ndhealth.gov/HIV/CTR: • **HIV 101, Viral Hepatitis 101, STD 101 , Counseling Overview** • **0.5 CEUs are available for each of these ½ hr. presentations.**	Counselor
8. View *Delivering HIV Rapid Test Results From the Field.* DVDs are available from the HIV.STD.Hepatitis Prevention Coordinator.	Counselor
9. View Maven tutorial and read Required Data Elements and Maven User's Guide, both available at www.ndhealth.gov/HIV/CTR.	Maven Data Entry Staff

Optional: Participate in role playing exercise. Role playing exercises are extremely helpful in practicing asking open vs. closed ended questions. Role playing exercises also provide valuable insight into areas of the counseling and client education that counselors need to prioritize. Nonverbal communication cues can also be observed during role playing exercises. An example of a role play exercise is available at: www.ndhealth.gov/HIV/CTR.

Continuing Education

Every three years, it is required that CTR staff complete the following requirements based on their role in the CTR program:

Required Training	Role Required
1. Ensure Test Competency for Rapid HIV and HCV Testing.	Tester
2. Review Current CTR Manual.	Tester & Counselor
3. View Three Presentations or Attend One Conference on HIV, STD or HCV Every Three Years.	Counselor

The CTR site is responsible for collecting and maintaining records on all staff. Staff training records need to be retained for at least three years as these records will be reviewed by HIV.STD.Hepatitits Prevention Coordinator during the CTR site visit. A staff development and training form is available at www.ndhealth.gov/HIV/CTR.

HIV Prevention and Viral Hepatitis Site Visit

All CTR sites will have a site visit conducted by the HIV.STD.Hepatitis Prevention Coordinator once every three years. The goal of these sites visits is to ensure compliance with protocols and policies from the CTR program. These site visits will highlight strengthens and areas of improvement for each CTR site. All site visits will be coordinated at least three weeks in advance with the point of contact indicated for each site.

The following is minimum list of items that will be discussed at each site visit:

1) Staff Development and Training
   - Documentation of staff completing training requirements.
   - Note: CTR shall provide a list of employees that were new employees since the previous site visit and a list of employees that were due for continuing education.
2) CTR Site Staff Assessment
   - All current staff of the CTR site will need to attend a short presentation and review an assessment to ensure all staff are educated about CTR site policies and procedures.
3) Testing Data and Submission
   - Goals for performance standards and metrics.
   - Target population being tested and missed.
   - Timeliness and completeness of data submission.
   - Reporting of positive rapid and confirmatory HIV and HCV test results.
4) Quality Control
   - Control logs.
   - Control storage and handling.
   - Test kit storage.
   - Temperature logs.
5) Testing Protocol
   - Risk assessment.
   - Documentation of consent.
   - Documentation of test results.
   - Reviewing facility policy and procedures.
   - CLIA Certificate of Waiver. A copy of current waiver will be requested.
6) Vaccination
   - Doses in NDIIS.
   - Completion of series.
7) Educational Materials
   - Availability of brochures, safe sex kits, condoms, etc.
8) Referral Services
   - Referrals offered by facility to both high-risk negative patients and those diagnosed with HIV or HCV.
9) Community Outreach
   - Efforts made or desired by the CTR site to increase community education or awareness.

Quality Management and Quality Improvement

The purpose of the CTR quality management program is to assess current practices and ensure best practices are being followed to offer high quality sexual health services at CTR sites. Quality management metrics can be used to identify areas for quality improvement, areas in which services may be deliver more efficiently and effectively. Also, CTR sites can request technical assistance to ensure that desired target outcomes are met and there is continued success of the CTR program. A quarterly report will be sent to CTR sites on these quality management metrics.

The following are the goals and performance standards of the CTR program:

Goal	Performance Standard	Measure	Data Source	Target
CTR Services Provide Tests to People At Risk	Tests are Provided to Individuals At Risk or are from Disproportionately Affected Populations.	Proportion of Total Tests That Were Performed Among At Risk Populations.	Data Submissions in Maven	90% of HIV Tests Performed are Among At Risk Populations.
				90% of HCV Tests Performed are Among At Risk Populations.
	Individuals Tested More Than Once per Year are at High-Risk for HIV or HCV.	Proportion of Total Tested More Than Once per Year That Were Performed Among High Risk.	Data Submissions in Maven	80% of Repeat HIV Tests are Among High-Risk Populations.
				80% of Repeat HCV Tests are Among High-Risk Populations.
CTR Services Identify People Who Are HIV and/or HCV Positive And Don't Know Their Status	CTR Sites Maintain a Seropositivity Rate Consistent with CTR Program Standards	Proportion of Total Tests That Had Confirmatory Positive HIV Test Results or Confirmatory HCV Antibody or RNA Positive Test Results.	Data Submissions in Maven	HIV: 0.5% Seropositivity Rate.
				HCV: 5 % Seropositivity Rate
	Counselors Give Rapid Test Results to Individuals in a Timely Manner.	Proportion of Total Rapid Tests Results Provided to Clients Within 48 Hours of Specimen Collection.	Data Submissions in Maven	95% of All Rapid Test Results are Provided Within 48 Hours.
	Counselors Give Confirmatory Test Results to Individuals in a Timely Manner.	Proportion of Total Rapid Tests Results Provided to Clients Within 3 Days for HIV and 7 Days for HCV Specimen Collection.	Data Submissions in Maven	100% of All Confirmatory Test Results are Provided within 3 Days for HIV and 7 Days for HCV.
Link HIV and HCV Positive Individuals to Care and Services	Individuals Newly Diagnosed with HIV or HCV are Linked to Medical Care.	Proportion of Individuals Confirmatory Positive for HIV or Current HCV Infection that are Linked to Care and Attend a Medical Care Appointment within 90 Days of Result Notification.	Data Submissions in Maven; NDDoH Surveillance System; Health Information Network	90% of Individuals Diagnosed with HIV are Linked to Care and Attends a HIV Medical Care Appointment within 90 Days.
				40% of Individuals Diagnosed with Current HCV Infection are Linked to Care and Attends a HCV Medical Care Appointment within 90 Days

HIV & HCV CTR PROCEDURE & POLICY MANUAL

Goal	Performance Standard	Measure	Data Source	Target
Link HIV and HCV Positive Individuals to Care and Services	Individuals Diagnosed with HIV are Linked to Partner Services within 2 Weeks of Diagnosis.	Proportion of All Confirmatory Positive HIV Patients Linked to Field Epidemiologists for Partner Services	Data Submissions in Maven; NDDoH Surveillance System	100% of Newly Diagnosed HIV Positive Cases are Linked to Partner Services within 2 Weeks of Diagnosis.
	Individuals Diagnosed with HIV are Referred to Medical Case Management within 2 Weeks of Diagnosis.	Proportion of Individuals Diagnosed with HIV that were Referred to Medical Case Management	Data Submissions in Maven Ryan White Program	100% of Newly Diagnosed HIV Cases Referred to Medical Case Management within 2 Weeks of Diagnosis.
CTR Counselors will Provide High Quality Services	CTR Staff are able to Accurately Interpret Test Results.	Proportion of Staff Performing Rapid Testing that are Trained and Proficient.	Training Records, Reviewed at Site Visit.	100% of CTR Staff are Appropriately Trained and Maintain Proficiency in Rapid Testing.
	CTR Counselors have Received Training to Deliver Results and Provide Prevention Counseling.	Proportion of Counseling Staff Properly Trained in Delivering Results and Providing Counseling.	Training Records, Reviewed at Site Visit.	100% of Counselors are Appropriately Trained to Deliver HIV and HCV Results and Prevention Counseling.
	Individuals At Risk for HIV and/or HCV are Tested Appropriately.	Proportion of All Individuals Screened for HIV, HCV and other STDs without Missed Opportunities.	Data Submissions in Maven	90% of Individuals Screened at CTR Sites are not Identified as a Missed Opportunity for HIV, HCV, Chlamydia, Gonorrhea or Syphilis Testing
CTR Sites are Compliant with Contract Requirements	CTR Events are Complete in MAVEN.	Proportion of CTR Events Submitted with all Required Fields Complete.	Data Submissions in Maven	95% of CTR Events have all Required Fields Complete
	Requests for Reimbursement are Submitted Timely and with Required Documentation.	Proportion of All Reimbursement Requests Submitted Timely and with Appropriate Documentation.	PRS.	80% of all Reimbursement Requests Submitted by the 15th of the Following Month and with Required Documentation.
	CTR Sites Shall Submit all CTR Events in Maven Timely.	Proportion of CTR Events Submitted within 30 Days of Session Date.	Data Submissions in Maven	80% of CTR Events Submitted within 30 Days of Session Date.
	CTR Sites Report Positive Rapid and Confirmatory Results Timely.	Proportion of All CTR Positive Rapid or Confirmatory Results that were Reported Timely.	Data Submissions in Maven; NDDoH Surveillance System	95% of Positive Rapid and Confirmatory Results were Reported Timely, HIV within 24 Hours and HCV within 7 Days, by the CTR Site

Grant Awards & Contracts for CTR Program

Once per year, the HIV.STD.Hepatitis program awards funds to CTR sites. To receive funds, sites must submit an application to participate in the program for the next upcoming calendar year. This grant opportunity is typically made available in November or early December each year. The HIV.STD.Hepatitis Program distributes the grant notice to all current sites and other potential partners via email as soon as the grant notice can be made available. Contracts and funding will be awarded for the time period January 1 - December 31.

In the yearly application, sites are required to submit a project narrative and proposed budget that focuses on accomplishing the goals and scope of the CTR program. The CTR program is designed to screening individuals for HIV and HCV who are at risk for infection and are uninsured and underinsured at no cost to them. For patients who are insured and at risk, CTR sites may use the supplies of the CTR program, however the cost of counseling and test administration should be billed to that patient's insurance and not billed to the CTR program. The project narrative may also include supplemental activities of the CTR program include providing viral hepatitis vaccination and linkage-to-care for individuals diagnosed with HCV.

The funding amount awarded to CTR sites is variable from year to year based on federal and state funding. CTR sites are awarded funding based on their submitted application and their capacity to offering screening for HIV and HCV. CTR sites may use their awarded dollar amount for reimburse of counseling sessions, blood draws, confirmatory fees, hepatitis vaccine administration fees, HCV linkage-to-care activities and other related expenses. The current reimbursement rate for these activities is found on the CTR Request for Reimbursement Form.

Items not included in the funding awarded to the CTR site include rapid HIV and HCV test kits and controls, blood draw supplies and viral hepatitis vaccine. These items are available to contract and non-contracted CTR sites free-of-charge at any time if supplies/funding is available.

Non-Contract Partners

Sites may choose to be in the CTR program as a non-contract partner. Non-contract partners do not receive funding from the NDDoH. Thus, these sites are not reimbursed for counseling sessions, blood draws, confirmatory fees, hepatitis vaccine administration fees, HCV linkage-to-care activities or other related expenses.

All non-contract partners are still eligible to receive free rapid HIV and HCV test kits and viral hepatitis vaccine. In return, all policies and procedures must be followed within this manual, including the submission of data on every rapid HIV and/or HCV test performed.

Sites may choose to join the CTR program at any time during the year. Also any site that submits an application, but is not awarded funds, may still choose to be in the CTR program as a non-contract partner. Non-contract partners are all eligible to apply for grant funds in the next calendar year.

Reimbursement for Services at CTR Sites

All contract partners are eligible to receive reimbursement for certain allowable expenses. Those expenses include:

- Rapid Testing
  - HIV & HCV Rapid Test with Counseling
  - HIV Rapid Test with Counseling
  - HCV Rapid Test with Counseling
- HIV/HCV Confirmatory Testing
  - Blood Draw
  - HIV Laboratory Test
  - HCV Antibody Laboratory Test
  - HCV RNA Laboratory Test
  - Counseling Sessions for Confirmatory Results
- HAV/HBV Vaccination Administration Fee
- Outreach Events
  - Rapid Testing for HIV/HCV. ***Note: Reimbursement is lower for rapid testing at outreach events.***
- Travel
  - Per diem, lodging and mileage are reimbursable for CTR related travel, ex. workshops or conferences
- HCV Linkage-to-Care
  - Hours of time spent on linking-to-care for individuals diagnosed with hepatitis C
- Additional Expenses
  - Supplies, incentives, Facebook advertising, educational materials, etc.
  - Contact the HIV.STD.TB.Hepatitis Program Manager if there are questions on approved additional expenses

To submit reimbursement for the above expenses, CTR sites are required to submit a completed reimbursement form on a monthly basis to the North Dakota Department of Health HIV.STD.TB.Viral Hepatitis Program Manager via the Program Reporting System (PRS). The reimbursement form details the current level of reimbursement for each activity and must be included as an attachment to the request for reimbursement in order for it to be processed. This document serves as the monthly progress report for each site. The reports are due 15 days after the end of the month. If reimbursement is not requested for the month, a report should be submitted showing a zero amount request to ensure consistent requests. The final expenditure report ending December 31st must be received by February 15th.

New users to the PRS system can request a login here. Please contact the HIV.STD.TB.Hepatitis Program Manager for additional instructions on submitting reimbursement expenses in PRS.

Billing for CTR Services

CTR sites are encouraged to bill insurance for HIV and HCV testing and counseling. By billing for services, CTR sites may increase their revenue for these services. If grant funds are unavailable or client is not at risk, CTR sites may charge the client for counseling, confirmatory testing and other expenses as long as client's are not billed for the rapid test. If CTR program rapid testing supplies are used, even if the client is billed for the counseling session, event data must still be reported in Maven.

HIV and HCV Testing at Outreach Events

Counseling, testing and referral sites can partner with NDDoH Division of Disease Control to coordinate HIV, STD and hepatitis C testing at various locations across North Dakota such as at health fairs, homeless shelters, veteran's events, etc. Outreach should target at-risk populations. **All outreach events need to be approved by the NDDoH at least 14 days prior to scheduled event.** Outreach events will not be approved to test populations not at-risk, ex. baby boomer screening events for HCV.

Outreach events are a key component in HIV, STD and hepatitis prevention as high-risk individuals may not access testing and education in typical healthcare settings. Awareness days or months are excellent opportunities to host events. Some commonly used awareness events include:

- April: STD Awareness Month
- May: Hepatitis Awareness Month
- May 19: Hepatitis Testing Day
- June 27: National HIV Testing Day
- December 1: World AIDS Day
- Here is a list of additional awareness events.

When planning on outreach or testing event special considerations are needed for event advertisement, ensuring confidentiality, specimen collection, result delivery and other logistics concerns. The HIV.STD.Hepatitis Prevention Coordinator can help in organizing and hosting an event. Free STD testing may be available at outreach events, but sites must contact the HIV.STD.Hepatitis Prevention Coordinator prior to the event.

An outreach toolkit is available at www.ndhealth.gov/HIV/CTR. This toolkit discusses and provides ideas and considerations for the organization and management of an outreach event. After the outreach event, CTR sites shall report the number tested and positivity for HIV, HCV, chlamydia, gonorrhea or other offered screenings to the HIV.STD.Hepatitis Prevention Coordinator: Please contact the HIV.STD.Hepatitis Prevention Coordinator with any questions regarding outreach testing.

Ordering Prevention and Testing Supplies

All supplies, including condoms, educational materials, rapid tests, controls and other prevention supplies are ordered by submitting an online order form found at www.ndhealth.gov/HIV/Supplies/. Orders are typically processed within 1 to 2 business days. Longer delivery times may be imposed when the weather is extremely cold or hot. Many prevention supplies, including HIV and hepatitis C rapid tests cannot be shipped in freezing temperatures.

If CTR sites would like to pick up supplies in Bismarck, please submit an order at least two business days prior to scheduled pick up.

If there are any questions regarding ordering, please call 701.328.2378.

CTR Services at Correctional Facilities

Correctional facilities are eligible to be contract and non-contract CTR sites. Contract CTR sites are also able to provide CTR services at correctional facilities.

Screening

Thera are two North Dakota Century Code (NDCC) subsections that describe requirements for HIV and STD screening in correctional facilities. Below are the subsections of the North Dakota Century Code:

- **23-07-07.5. Testing of inmates and convicted individuals for exposure to the human immunodeficiency virus - Reporting - Liability.** ***Note: Refer to page 9 of this manual for full text of this subsection.***
- **23-07-08. Persons in prison examined and treated for sexually transmitted diseases. Every person convicted of a crime who is imprisoned fifteen days or more in a state, county, or city prison must be examined for sexually transmitted disease and, if infected, must be treated therefor by the health officer within whose jurisdiction the person is imprisoned.**

Although century code only requires HIV testing of inmates if there were convicted and imprisoned for fifteen days or longer, all inmates regardless of length of imprisonment or conviction status can be tested for HIV and/or HCV in the CTR program. Although STD testing is not included in the CTR program, inmates should also be screened for STDs, including chlamydia, gonorrhea and syphilis.

Counseling

Counseling expectations for inmates are not required for screening in correctional facilities. If inmates are only screened for HIV and/or HCV because of the century code, risk-reduction counseling may not be appropriate. Also, the time available per client may not be available for counseling following screening in the correctional facility. Because of these limitations, the reimbursable amount in a correctional facility for rapid testing is smaller than that which occurs in other CTR settings.

The CTR site can determine the length and content of a counseling session in a correctional facility. It is recommended that providing education about disease transmission and prevention and understanding of tests results be prioritized in the counseling session.

Disclosure of HIV & Viral Hepatitis Status of an Inmate

It may be the duty of the counselor to disclose the HIV, HBV or HCV status (protected health information, PHI) 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 NDCC 23-07.5, the results of a HIV or HCV may be disclosed only as follows per the U.S. Department of Health and Human Services HIPAA privacy rule:

> *To respond to a request for PHI by a correctional institution or a law enforcement official having lawful custody of an inmate or others if they represent such PHI is needed to provide health care to the individual; for the health and safety of the individual, other inmates, officers or employees of or others at a correctional institution or responsible for the transporting or transferring inmates; or for the administration and maintenance of the safety, security, and good order of the correctional facility, including law enforcement on the premises of the facility (45 CFR 164.512(k)(5)).*

Linkage-to-Care for Hepatitis C

All CTR sites screening for hepatitis C are encouraged to offer linkage-to-care services for individuals diagnosed with acute or chronic HCV infection. The goal of linkage-to-care services is to ensure the client is receiving appropriate medical care by attending their first medical appointment after their diagnosis. For those diagnosed with HCV, the Services that would be considered linkage-to-care include, but are not limited to:

1) Scheduling referral appointments.
2) Following-up with client or referral provider after their appointment.
3) Additional counseling sessions to ensure client is understanding HCV and their diagnosis.
4) Follow-up with client throughout care, i.e. HCV treatment or substance abuse treatment.
5) Assisting clients with overcoming barriers to accessing care, ex. navigation to patient assistance programs or signing up for health insurance.

All time spent on linkage-to-care for hepatitis C must be documented within Maven. Additional information on this required document is found within the Required Data Elements and Maven User's Guide. CTR sites may provide linkage-to-care services for individuals that were diagnosed with HCV at a location other than a CTR site. Even if the client was not tested at the CTR site, an event in Maven should be created to properly document the linkage-to-care activities.

CTR sites are only reimbursed for linkage-to-care services for those diagnosed with HCV. Linkage-to-care services are available to individuals diagnosed with HIV from Ryan White Case Managers and Field Epidemiologists; CTR sites should refer individuals diagnosed with HIV to those providing linkage-to-care.

Reimbursement

The confirmatory counseling is reimbursed at a rate of $30.00 per session. This session is expected to last approximately one hour. Linkage-to-care services would then include any time beyond the one-hour confirmatory counseling session. CTR sites are reimbursed for linkage-to-care services by the hour in a minimum of 15-minute increments. This expense is included on the CTR reimbursement form.

Summary of CTR Responsibilities

The following is a summary of the forms and/or responsibilities within a CTR site:

1. **Program Design.**
    a. Design program to comply with CTR program goals and quality management metrics.
    b. Follow current CTR program policies and procedures.
2. **Risk Assessment.**
    a. Screen all client's for risk for HIV and/or HCV.
    b. Utilize risk assessment form, HIV/HCV test form or similar form to collect information. Sites may use electronic medical record instead of maintaining a paper record.
    c. Submit all required information into Maven.
3. **Counseling.**
    a. Provide client-centered risk reduction counseling when appropriate.
4. **Rapid Testing.**
    a. Ensure quality assurance on rapid test kits.
        i. Store test kits in approved temperatures.
        ii. Perform controls on test kits when indicated.
        iii. Document and report control performance within 7 days.
        iv. Submit monthly temperature logs for the storage of controls.
        v. Report invalid test results.
        vi. Maintain competency for staff performing rapid HIV and HCV testing.
        vii. Report all positive rapid results to the Division of Disease Control.
        viii.
5. **Confirmatory Testing.**
    a. Ensure site is following guidelines from the NDPHL Division of Laboratory Services for proper specimen collection and handling.
    b. Follow CTR designated testing algorithms.
    c. Report all positive confirmatory results to the Division of Disease Control.
    d. If able, provide linkage-to-care for individuals diagnosed with HCV.
6. **Staff Training.**
    a. Complete the Staff Development and Training worksheet for all new employees and employees requiring continuing education.
7. **Hepatitis Vaccination.**
    a. Order vaccine as needed by submitting order form to HIV.STD.Hepatitis Prevention Coordinator.
    b. Ensure vaccine supply does not expire before it is utilized.
    c. Enter doses administered into NDIIS.
8. **Reimbursement.**
    a. Contract sites shall submit monthly reimbursements timely in PRS.
9. **Grant.**
    a. Submit grant application for CTR program in November/December each year.

There is more information on the above activities found within this manual. If there any questions, please contact the HIV.STD.Hepatitis Prevention Coordinator.