

# SULLIVAN COUNTY PUBLIC HEALTH SERVICES

<p><b><u>POLICY:</u></b> HIV Counseling and Testing</p> <p>Rapid HIV Counseling and Testing shall be performed in accordance with New York State Department of Health AIDS Institute 2014 NYS Confidentiality &amp; Testing Law April 2014, Article 27F.</p> <p><b><u>PURPOSE:</u></b> To ensure staff adherence to NYSDOH AIDS Institute guidelines</p> <p><b><u>RESPONSIBLE PARTY:</u></b> SC Public Health Services Director (HIV Clinic staff, epidemiology staff, and SCHN Nursing staff )</p>	<p>Original Approval: 2003</p> <p>Revised 09/2005</p> <p>Revised 09/2018</p> <p>Revised 6/2020</p>
---	--

A current CLEP Limited Testing Laboratory Registration Certificate will be displayed in the HIV Rapid testing area. HIV rapid test modality will be listed as an approved test.

*In 2014 New York State (NYS) Education Law (Section 6527, subdivision 6 and Section 6909, subdivision 4) in regard to the use of non-patient specific orders for registered professional nurses (RNs) permits licensed physicians and certified nurse practitioners to issue non-patient specific orders for RNs who may be providing HIV and HCV rapid testing to patients. A current non-patient specific standing order signed by the Sullivan County PHS Medical Director for HIV Rapid test performance by department RNs will be kept on file in the HIV testing binder.*

**Rapid HIV tests will be performed on:**

- Persons who request HIV rapid testing by appointment.
- With consent, patients enrolled in the TB active or latent TB Article 28 programs
- Persons between the ages of 13 and 17, who may be tested without parental permission if they can demonstrate an understanding of HIV test purpose and the implications of the result. Persons under 17 should be informed that parental notification maybe needed in order to access medical care in the instance of a positive screening test result. The patient has the right to refuse parental notification, however, every effort will be made to assist the underage patient with access to care when deemed necessary.

**Appointments:**

- HIV rapid testing will be conducted by appointment without charge.
- Appointments may be scheduled by phone or in person.
- For clients who do not wish to give their name when making an appointment, they will have the option of making an anonymous appointment using initials of the client’s choice and this will be recorded by staff instead of a name in the schedule.
- *Documentation:* For both anonymous and confidential testing, an HIV clinic information card is completed for each client and staff documents his/her risk factor(s), age, sex, and zip code. A brief narrative and a coded identification number or initials are entered on the card. Included on the card is a field to enter the test lot number and the control lot

## SULLIVAN COUNTY PUBLIC HEALTH SERVICES

number, along with a field for expiration dates. The cards are kept in a binder in a locked cabinet in the epidemiology office and the office door is locked after business hours.

- **Staffing:** The nursing supervisor will assign qualified staff to perform rapid HIV test appointments. Staff assigned to testing are responsible for arranging substitute coverage if a scheduling conflict arises. In the event of an unforeseen absence, supervisory or program staff will arrange coverage.
- **Security:** Rapid HIV Testing will only be conducted during regular business hours or when at least 2 staff members are present in the clinic area.
- **Patient Bill of Rights:** Patient's Rights Poster are displayed in both English and Spanish in the testing waiting area. Every client offered an HIV rapid test will be offered a copy of the Patient Bill of Rights. Client's signature documenting receipt or refusal will be captured within the client's record. For anonymous testing, client may initial or use any other mark of his or her choice.
- **HIV rapid testing modalities:** Sullivan County offers both anonymous and confidential testing, as defined by New York State Department of Health's (NYSDOH's) AIDS Institute. Clients are first offered confidential testing. If a client refuses confidential testing, then the anonymous option will be offered. It must be explained in case of an anonymous test, that for a referral for care if a screening test result is positive the patient has the option of converting the record to a confidential one to facilitate timely medical diagnosis and treatment.
- **Risk Reduction Education/Counseling:**

It is explained to and confirmed with the client that an HIV test is going to be performed. HIV rapid testing is voluntary. Persons offered HIV rapid testing will be informed about the nature of the test and the implications of positive and negative results and have an opportunity to have all questions answered before the test is performed. HIV risk reduction education /counseling may be conducted via NYS AIDS Institute audio visual tool. Verbal consent is permitted under NYS law.

  - **STI Referrals:** If on the basis of patient history, symptoms or lab results, a client tested confidentially requires a referral for STI program follow up, a referral is made directly to STI program staff.
  - If the client tests anonymously, the client is advised to personally contact the STI program directly, or given other options for follow up with a private physician or clinic provider.
  - **Immunizations:** Many clients requesting HIV testing are considered at risk for Hepatitis A and B. Therefore, all clients at HIV testing appointments are offered the option of receiving Hepatitis A and B vaccine while here. The agency's normal immunization consent form and protocol are used.

### Providing HIV Rapid test results

## SULLIVAN COUNTY PUBLIC HEALTH SERVICES

- For clients testing **positive** for HIV, see “**Procedure for Giving Positive HIV test results**” under **HIV RAPID TEST PROCEDURE**
- Clients testing negative will be offered a follow up test appointment if potential HIV exposure has occurred within the 3 months prior to the current HIV test
- Clients who test negative and whose HIV exposure falls into the identified risk category recommended for Pre- Exposure HIV antiviral prophylaxis, will be encouraged to accept referral to ID specialist or other participating HIV Pre-Exposure HIV antiviral prophylaxis provider. (see NYS AIDS Institute provider list on NYSDOH website).

### **HIV RAPID TEST PROCEDURE**

Only staff with rapid HIV test training and documented test control performance observation will conduct rapid HIV tests. Clients being tested with Alere Determine HIV-1/2 Ag/Ab rapid technology will receive the “NYSDOH Testing: What you need to know” handout. *Appendix A English, A-2 Spanish*

**For complete testing protocol with images refer to Package insert** *Appendix B*

#### **Each staff member conducting a rapid test will:**

1. Establish Test Area readiness:
  - HIV test candidate will be brought into a private area for testing. A medical record will be completed as previously described under “**Appointments: Documentation**”.
  - Ensure lighting is acceptable for test procedure.
  - Ensure that temperature requirements for testing have been met. Check temp last recorded. View thermometer in HIV kit storage area on temp log posted on storage cabinet. If temperature has been out of range, perform an external control to ensure quality of product. Inform nursing supervisor when temperature falls out of range. Nursing supervisor will secure appropriate modifications for temperature control
  - (Controls will be stored in the refrigerator between 35 and 46 degrees F. Daily reading of refrigerator temperature shall be recorded on temp log posted on the refrigerator *Appendix C* )
  - Obtain all testing supplies and PPE equipment
  - Record HIV kit lot number on *Master Result inventory log sheet (Appendix D)*

**NOTE:** In the event the temperature of room or the refrigerator falls out of range, testing will cease, the nursing supervisor will be notified and corrective action will be taken.

2. Conduct HIV test (*refer to Appendix B*) Provide an explanation of test procedure and the nature of preliminary results and process for confirmation if positive.
  - *Provide FDA manufactures’ test hand out to test candidate*
  - *Label testing devise components with patient identifier name or anonymous test ID number*

## SULLIVAN COUNTY PUBLIC HEALTH SERVICES

- Don appropriate PPE
  - Set up all supplies in same private area where patient history was documented
  - Conduct HIV test procedure according to manufacturer's specifications (*Appendix B*)
3. While test is processing:
- Conduct HIV Risk assessment and exposure dates
  - Provide Risk reduction education/counseling according to NYSDOH AIDS Institute guidelines
  - Offer appropriate barrier devices (condoms, dental dams, lubricants)
4. Discard all used test supplies in red bag waste container. Lancet must be discarded in sharps container
5. Record results on patient record, on Master Test Results log.
6. Explain test result and provide copy to client.
7. Provide Follow up appointment if client is inside sero-conversion window
8. Provide referral for complete STI/HCV screening as appropriate

### **Procedure for Giving Positive HIV test results:**

- Positive HIV Alere Determine HIV - 1/2 AG/AB test must be reflexed for HIV Ab differentiation. (LABORATORY-BASED HIV DIAGNOSTIC ALGORITHM)
- Positive test results must be provided in person to the client.
- Clients testing preliminary positive via finger stick rapid test require a confirmatory venous blood sample done via Western Blot. Provide immediate onsite referral for HIV confirmatory test and complete STI screen with an Infectious Disease (ID) specialist as soon as possible. The ID specialist will perform a venous specimen and forward it to Wadsworth Lab for confirmatory testing. (Reminder: the Health Care Provider who performs the confirmatory test must complete the Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF) (DOH-4189) within 14 days after confirmatory results have been obtained.)
- If test was performed anonymously, offer the client the opportunity to convert his or her identification to a confidential test so that a healthcare provider can see the results with client's identification present.
- Inform patient about HIV antiviral PEP that is available for sex and needle sharing partners
- NOTE: A client may be very distraught and the counselor must dedicate the time to offer support and to listen to the client's concerns, and if the client is willing, will be assisted to set the follow up appointment with a provider for the confirmatory test before leaving clinic. The client will also be provided with a packet of educational materials in their primary language including referral information for specialty health care providers, mental health counseling, crisis intervention, legal aid, domestic violence hot line, social services, and contact information to access ADAP and other health insurance options, should the confirmatory test confirm a positive result.

### **Quality control procedures:**

## SULLIVAN COUNTY PUBLIC HEALTH SERVICES

The Alere Determine HIV-1/2 Ag/Ab HIV-1 Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control (C) zone of the result window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device. The control line will appear on all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1. (Refer to *Test Results and Interpretation of Results* section below.)

Alere Determine HIV-1/2 Ag/Ab Combo kit Controls are available separately for use only with the Alere Determine HIV-1/2 Ag/Ab Antibody Test. The Kit Controls are used to verify your ability to properly perform the test and interpret the results. See appendix B for full quality control specifications

### **Kit Controls should be run under the following circumstances:**

- by each new operator prior to performing testing on patient specimens,
- whenever a new lot of the Alere Determine HIV-1/2 Ag/Ab Combo Antibody Test is used for the first time,
- if there is a change in the conditions of testing (e.g., new location, lighting, temperature, etc.), and at periodic intervals specified in your quality assurance program.

*NOTE all temperature deviations for storage room and refrigerator must be reported to the supervising nurse and corrected before testing continues. Consult manufacturer's specification for Control kit performance*

### **Storage:**

- HIV test kits must be stored in a locked cabinet in a room with a temperature range between 20-27°C (35-80° F). If stored in the refrigerator, test kit must be brought to ambient temperature for 15 minutes before use. If stored in refrigerator temperature range must be maintained within 35 to 46 degrees F.
- Prior to beginning test procedure document temperature of room on temperature log posted on storage cabinet. Do not perform if temperature is out of range. Notify supervising nurse.
- A daily temperature reading will be recorded by an assigned member of the epidemiology (D&TC) staff on the temperature log posted on the HIV supply storage cabinet and for the refrigerator where HIV kit controls are stored.
- If temperature check reveals temperatures above or below the prescribed range. The HIV test kits are to be removed and control performed prior to continued use of stored kits. The supervising nurse must be notified and corrective action taken before next patient test is performed.

### **Procedures for proper disposal of regulated medical waste.**

All lancets, rapid paddle tools will be disposed of in sharps containers. Gauze or gloves visibly contaminated with blood will be discarded in red bag waste

# SULLIVAN COUNTY PUBLIC HEALTH SERVICES

## Staff training

1. **Client confidentiality:** All staff shall complete HIPPA training and NYS Aids institute HIV testing specific confidentiality training. Refer to: *Article 27-F section of New York State Public Health Law.*
2. Staff will use the 'HIPAA Compliant Authorization for Release of Medical Information and Confidential HIV Related Information' revised in 2014, will be used to request permission for all referrals provided for the client *Appendix F English; F-2 Spanish*
3. **Infection Control:** HIV clinic staff receives annual updates on prevention of blood borne pathogen transmission and BBP exposure control. This training will be required for new employees intended to perform HIV Rapid testing and reviewed annually during the first staff meeting of the year. In addition, RNs are required by law to take a 4 hour course on Infection Control by a NYS approved provider every 4 years and to have documentation as such available to be presented upon NYSED's request.
  
4. **Alere Determine HIV-1/2 Ag/Ab Rapid HIV test performance.**
  - All staff conducting HIV rapid tests will review the manufacture's test kit and control kit performance specifications *Appendix B*
  - The supervising nurse will review the manufacturer's test conduction specifications while demonstrating the performance of a rapid test or control test to staff
  - Following a thorough review and demonstration of test procedure, each staff member new to performing HIV rapid tests will be observed by the supervising nurse while performing a control test
  
5. **Risk assessment and risk reduction education/ counseling:**
  - All staff members performing HIV rapid tests will be trained in risk reduction counseling in accordance with NYSDOH AIDS Institute recommendations
  - Each staff member will be observed conducting HIV Risk Reduction education/ counseling once a year. The supervisor will refer staff for additional training when deemed appropriate.

## Quality Assurance:

### *Procedural Deviations*

All procedural deviations shall be immediately be reported to the nursing supervisor. A verbal report will be followed by a written report and shall include: a description of the problem that occurred, the time and date, client identifiers if a client is involved and names of staff conducting testing at the time of the protocol deviation.

The supervising nurse will conduct an investigation of the procedural deviation and initiate the corrective action required.

## SULLIVAN COUNTY PUBLIC HEALTH SERVICES

***Staff meeting:*** In accord with agency quality assurance practices, agendas shall allow for discussion time for HIV testing protocol and/ or compliance concerns. Problems with any aspect of HIV clinic policy or procedure or adverse events with clients shall be reported to the supervising nurse as soon as possible and, if relevant for the staff, subsequently added to the next epidemiology (D&TC) Staff meeting agenda . The issue will be discussed, resolutions identified and shared with all staff present and those staff who are absent via ***meeting minutes*** distribution.