POLICY AND PROCEDURE	
SUBJECT/TITLE:	HIV Antibody Testing Protocol
APPLICABILITY:	Nursing
CONTACT PERSON & DIVISION:	Diane Thompson, RN, MSN
ORIGINAL DATE ADOPTED:	06/2011
LATEST EFFECTIVE DATE:	02/27/2020
REVIEW FREQUENCY:	Every five (5) years and as needed
BOARD APPROVAL DATE:	N/A
REFERENCE NUMBER:	200-14-P

A. PURPOSE

To comply with the Ohio Department of Health (ODH) and the Centers for Disease Control and Prevention (CDC) which seek to increase the reliability of the data, target persons at higher risk for HIV infection, and improve and track HIV prevention education and referrals. Use of a rapid – rapid testing process with same-day results can substantially improve the delivery of counseling and testing services. Because most persons who are tested are not infected, they can receive counseling and learn their HIV status in a single visit. In addition, providing positive results also increases the number of infected persons who ultimately learn their infection status and can be referred for medical treatment and additional prevention services.

B. POLICY

This protocol is specific to the Nursing Division at Canton City Public Health when testing individuals for HIV. It is to be used in conjunction with the ODH HIV Prevention Program, HIV Counseling, Testing & Referral Protocol 2015 (for resource information) and more specifically, the Rapid/Rapid HIV Testing Protocol (6/2018). Noted here are deviations or details specific to Canton City Public Health clinical process.

C. BACKGROUND

Add any background clarification that might be needed. If none, indicate this section with N/A.

D. GLOSSARY OF TERMS

Include any terms and definitions. If none, enter N/A.

E. PROCEDURES & STANDARD OPERATING GUIDELINES

HIV testing occurs in STI clinic two mornings a week, SWAP (needle exchange program) Friday afternoons, Counseling and Testing Referral Site (CTR) clinic Wednesday afternoons and the 2nd Thursday of every month, and various outreach clinics as opportunities present throughout the year. The Sexually Transmitted Infection (STI) clinic has its own testing protocol, all other clinics will use the following steps.

Forms needed to complete the HIV testing process:

1. CDC HIV Test Form (EvaluationWEB® 2019 HIV Test Template), Pages 1 and 2. (Revised 01/23/2020)
2. HIV Consent Form – Rapid HIV Test (for confidential testing – ALL individuals are encouraged to confidentially test)
3. HIV Risk Reduction Plan (for high risk individuals)
4. HIV Test Self-Assessment Form (updated 1/30/2020)
5. HIV Test Self-Assessment Form Score Sheet
6. HIV Verification Form (for individuals testing positive)

7. 2-Part Laboratory Slip

See Couples HIV Testing and Counseling (CHTC) process for details specific to couples testing.

Testing Procedure

1. Effective 8/1/2018, the standard testing procedure at CCPH is the Rapid-Rapid using OraQuick Advance Rapid HIV 1/2 Antibody Test (or equivalent manufacturer approved rapid test) and if preliminary positive, a repeat test with a verification rapid test (currently INSTI HIV-1/HIV-2 Antibody Test).
2. OraQuick Advance is a rapid (20-40 minute) EIA screening test. Results are given to the patient on the day the test is administered (other possible test kits include Unigold – a 10 minute EIA screening test and Clearview – a 15 minute EIA screening test).
3. A reactive OraQuick Advance is a PRELIMINARY positive requiring a second rapid test for verification.
4. Verification INSTI HIV-1/HIV-2 Antibody Test with results in as little as 60 seconds.
5. A negative OraQuick Advance is a negative HIV test result.

Staff Training

1. All persons administering the OraQuick Advance (or equivalent) HIV antibody test and the INSTI HIV-1/HIV-2 Antibody Test must review the training video or read the training literature provided by the manufacturer; or,
2. Attend a training hosted by the manufacturer; or,
3. Be mentored by an existing trained clinician.

CTR Testing Process

1. Numbers will be given to persons coming in for testing. The numbers determine the order of the testing.
2. *"What is the OraQuick Rapid HIVI-1/HIV2 Antibody Test* (appendix A)*, How is it performed?"* information sheet will be given to clients to read while waiting for the clinician. The differences should be reviewed with each client.
3. Confidential Testing is the standard. Anonymous Testing is optional by request from patient. The differences should be reviewed with each client.
4. Each client will receive the Consent Form – Rapid HIV Test (appendix B) and HIV Test Self-Assessment Form (appendix C) to be completed while waiting for the clinician. If the client chooses to test anonymously, he/she will not sign the Consent Form but will complete the HIV Test Self-Assessment Form

Sexual Health Walk-In Clinic Testing Process

Refer to the Sexual Health Walk-In Clinic Protocol

CTR Testing Procedures

1. Equipment
   a. absorbent drop sheet
   b. OraQuick Test kit
   c. sample collection device
   d. lancet
   e. alcohol
   f. gauze squares
   g. cotton balls
   h. band aids

i. gloves

2. Explain that the OraQuick test is a screening test and what it means.
3. Explain how the sample will be collected. The clinician will run the test in the clinic room.
4. Create a double lab slip with the patient's demographic information and OPSCAN number on the top of the lab slip for confidential testing. If an anonymous test, write the OPSCAN number in the "Name" section and the age in the date-of-birth area. In addition, mark the back of the HIV Self-Assessment form indicated that confidential testing was offered to the client.
5. Verify the information on the consent form with the patient's photo identification. If the patient does not have photo identification, the test can still be done but the patient is to be informed that they will not be able to receive a written copy of their results.
6. In front of the patient, open the test kit pouch which contains the developer solution vial. Leave the other pouch of the kit unopened.
7. Check expiration dates on the outside of the test kit, on the test device and the developer solution vial making sure none of the dates have passed. If any of the dates have passed, use another kit.
8. Place an Op-Scan number on the developer solution vial then open and insert the vial into the blue stand (this step can be skipped if testing the patient in the clinic room).
9. Using standard finger stick procedure lance the patient's finger; wipe away the first droplet of blood with a gauze pad and express another droplet.
10. Use the sample collection device to collect a blood sample being sure to completely fill the eyelet.
11. Completely mix the blood sample with the fluid in the developer solution vial, then place wand provided in kit into solution vial.
12. Begin the timer.
13. Conduct the risk assessment interview. Review the self-assessment form to determine if the client meets the ODH criteria for targeted higher risk
    a. Young Black men who have sex with men (YBMSM);
    b. Men who have sex with men (MSM);
    c. Substance abusers (people who inject drugs - PWID) or users of crack cocaine or "crack";
    d. Trans/nonbinary person (especially young, Black);
    e. Partners of PWID and MSM;
    f. Partner of a person living with HIV/AIDS (PLWHA);
    g. Prostitutes (sex exchange for drugs or money);
    h. Contact to an HIV positive partner;
    i. Lesions suspicious of syphilis or herpes;
    j. Had a Syphilis diagnosis in the last year;
    k. Have moved from the South and haven't been tested.

    If the client meets the criteria, the clinician will complete a Risk Reduction Plan (appendix D).
14. Once the test has developed, the clinician will read and record the result on the lab slip.
15. The clinician will compare the Op-Scan Number on the lab slip with the patient's Op-Scan number and then give the results.
16. Keep the Lab slip and other forms with the Op-Scan.
17. Op-Scan Number Labels should be on:
    a. Op-Scan Form
    b. Developer Solution Vial
    c. Test Device
    d. Consent Form
    e. HIV Self-Assessment Form (hand written)
    f. Risk reduction Plan (hand written)

18. After the testing is completed, the Op-Scan form is placed in the Results Given folder with one lab slip and the other lab slip is placed in the Stat Lab until after clinic – after clinic it is taken to the lab.
19. Complete the OPSCAN form – EvaluationWEB 2019 HIV Test Template (appendix E)
20. If using a test device other than OraQuick, follow manufacturer's directions for test administration.

Verification Testing - ALL Clinics

Permission from the patient to test for HIV includes a second rapid test when needed to verify a reactive OraQuick. Refer to the ODH Rapid/Rapid HIV Testing Protocol. Currently we are using the INSTI HIV-1/HIV-2 Antibody Test. At this time, Canton City Public Health allows anonymous testing and if the individual refuses to convert from an anonymous Oraquick to a confidential INSTI, the INSTI test will not be done. The individual will be encouraged to return when he/she is ready to complete the verification testing confidentially. All efforts are made to get the individual to consent to confidential testing; however, it is ultimately the decision of that individual. The Canton City Law Department has reviewed the Ohio Revised Code (ORC 301.242) and concurred that we do have a responsibility to provide anonymous testing whether the first rapid or second rapid test. If the second confidential rapid test verifies positive, the HIV Verification Form (appendix F) is completed in an effort to link the individual into care (for those testing confidentially). Page 1 and 2 of the OPSCAN Form (appendix E) is completed by the clinician testing the client. A referral is made to the Disease Intervention Specialist (DIS) for all verified positive HIV tests.

Outreach Testing

1. When providing testing off site, staff will make reasonable and prudent efforts to assure the privacy and confidentiality of the patients.
2. When transporting HIV test kits, they must be maintained within the temperature parameters established by the manufacturer. A portable temperature gauge is to be placed with the kits to monitor temperature. Environmental conditions should be considered. Kits are to be transported in a cooler and not to be left inside a vehicle. Cold packs to be used as necessary. The refrigerator temperature log (pg. 41 of ODH HIV CTR Protocol, 2015) will be maintained hourly while off site.
3. Persons being tested in an offsite setting will be given the HIV Consent Form and the HIV Test Self-Assessment Form to complete while waiting for a clinician. The client will return the forms to the outreach worker assisting the clinician.
4. All outreach testing is confidential testing. If the patient wants an anonymous test they are to be referred to a CTS Clinic (*In special circumstances, anonymous testing may be determined to be appropriate at an offsite clinic*)
5. Once a patient is called, they are to remain with a clinician until they are given their result. Therefore, testing should be done in the following sequence: (*In certain situations, a laboratory test setting may be established to provide a more efficient testing environment*)

a. Determine the patient's response to a positive result (this is always done by the clinician, not the laboratory staff)
b. Collect the sample
c. Take the sample for developing
d. Conduct Risk Assessment Interview (if laboratory setting, this is done by the clinician)
e. Give patient their result

Outreach Testing Procedures

1. Equipment
    a. absorbent drop sheet
    b. HIV Rapid (OraQuick and INSTI) Test kits
    c. sample collection device
    d. lancet
    e. sharps container
    f. alcohol
    g. gauze squares
    h. cotton balls
    i. band aid
    j. latex gloves
    k. Emergency Kit
    l. Reactive/Nonreactive Stamp
    m. Timers
    n. Pens
    o. Clipboards
    p. Lab Slips
    q. Hand Sanitizer
    r. Gloves – Small/Medium
    s. Release of Information Forms
    t. Security Paper – HIV Result Forms
    u. Additional Paperwork
2. Examine the space available that it is large enough, has appropriate lighting and is reasonably sanitary enough to do Rapid Testing.
3. Verify the information on the confidential test form and the patient's photo identification. If the patient does not have photo identification, the test can still be done but the patient is to be informed that they will not be able to receive a written copy of their results.
4. Explain how the sample will be collected and follow steps of the CTS Clinic Testing Procedure.

Quality Assurance

1. Positive and Negative controls will be done on each shipment or change in lot number by the laboratory personnel
2. Rapid Test Kit devices are to be stored at the temperatures established by the manufacturer.
3. Rapid Test Kit devices will be stored in the laboratory and maintained at the appropriate temperatures by the laboratory staff.
4. If temperatures go outside this range, a positive and negative control will be done and the HIV Prevention Coordinator and/or Director of Nursing will be informed.
5. A log of all controls shall be maintained by lab personnel.
6. All persons performing the test will be trained. A Training Log will be maintained.
7. The laboratory director will follow CLIA requirements for proficiency testing and will maintain the appropriate logs.
11. OpScans
    a. The office assistant reviews all OpScans each month
    b. OpScans are then reviewed by one of the following:
        i. Health Services Coordinator (HIV Prevention Coordinator)
        ii. HIV Prevention Team
        iii. Director of Nursing

iv. Clinical Nurse Supervisor

c. Errors found on OpScan reviews will be reported back to the clinic staff
d. Negative OpScans are faxed to the State monthly by the HIV Prevention Team
e. Positive OpScans (Pages 1 and 2) are faxed to the State within 24 hours of positive test result (1-614-728-0876). Pages 3 and 4 are faxed upon completion by the DIS.

HIV Testing By Appointment:

1. Front desk staff will transfer callers inquiring about HIV testing by appointment to the HIV prevention team voice mailbox (#8120) informing the client to leave information on how and when a HIV prevention team member can return the call and schedule the appointment.
2. HIV prevention team members will monitor the HIV prevention team voice mailbox periodically throughout the day.
3. When returning the call, the HIV prevention team member will reinforce to the caller that ODH-funded testing and screening programs prioritize testing for those at highest risk for HIV and that we offer free HIV risk screenings and education to everyone.
4. The HIV prevention team member should ask the caller what he/she believes places them at risk for HIV. The following table can be used to guesstimate a caller's risk.

The following table is a tool that can be used by the HIV prevention team member to estimate a caller's risk for HIV. These questions are NOT to be asked of the caller.

Priority Populations (45 points)	10 point questions
Young Black MSM or MSM in general	Have you or a partner been diagnosed with syphilis?
PWID	How often do you use condoms?
Trans and nonbinary persons	Anonymous partners?
Partner of: Person living with HIV PWID MSM	Partners inject drugs?
Had a syphilis diagnosis in the last year	Partners have sex with gay/bi men or TGNC people?
Has moved from the South and hasn't been tested.	Sex for money/drugs?

5. The HIV prevention team member returning the call will attempt to schedule the caller based on the prevention team member's availability. If the prevention team member and caller cannot coordinate a time, then a different prevention team member will schedule the appointment. The HIV prevention team member will only schedule tests that are convenient for his/her schedule.
6. On the day of the appointment, the HIV prevention team member will inform the front office staff of the appointment time.
    a. Appointments will NOT be made during scheduled CTS clinic or during sexual health walk in clinic as these are already scheduled times that clients can be seen.
    b. If an HIV prevention team member has a client scheduled and needs to be out of the office (called off, emergency field visit, etc.) the prevention team member will either ask another prevention team member to handle the appointment or will call and reschedule.

Record Retention

Follow the retention policy for Canton City Public Health

Security

1. Anonymous and Confidential testing records shall be stored in a locked file.
2. Access to the records is restricted to clinical staff and the health commissioner.
3. All staff will be aware of the Canton City Public Health confidentiality policy.
4. All staff will sign the Canton City Public Health statement of confidentiality.
5. Discipline for violations of the confidentiality policy are as set forth in the Canton City Health Code as adopted by the Board of Health.

F. CITATIONS & REFERENCES

N/A

G. CONTRIBUTORS

The following staff contributed to the authorship of this document:

1. Diane Thompson, RN, MSN, Director of Nursing
2. Pamela Gibbs, Health Services Coordinator
3. Jon Elias, MD, Medical Director
4. Ashanti Parker, Office Assistant

H. APPENDICIES & ATTACHMENTS

Appendix A: What is the OraQuick Rapid HIVI-1/HIV2 Antibody Test

Appendix B: Consent Form – Rapid HIV Test

Appendix C: HIV Test Self-Assessment

Appendix D: Risk Reduction Plan

Appendix E: EvaluationWEB 2019 HIV Test Template (Pages 1-4)

Appendix F: HIV Verification Form

Appendix G: HIV Test Self-Assessment Score Sheet

I. REFERENCE FORMS

ODH HIV Counseling, Testing & Referral Protocol, 2015

ODH Rapid/Rapid HIV Testing Protocol, 2019

J. REVISION & REVIEW HISTORY

Revision Date	Review Date	Author	Notes
10/2/2019	10/02/2019	David McCartney Diane Thompson	Addition of HIV Testing by Appointment section.
02/27/2020	02/27/2020	Diane Thompson	Page 1 of 7 – updated CDC HIV Test Form to current revision date of 01/23/2020 Page 1 of 7 – updated HIV Test Self-Assessment form to current revision date of 1/30/2020 Page 5 of 7 – Changed Quality Assurance, #11, b., ii. from Disease Intervention Specialist to HIV Prevention Team Page 6 of 7 – Changed Quality Assurance, #11, d. from Health Services Coordinator to HIV Prevention Team.

K. APPROVAL

This document has been approved in accordance with the “800-001-P Standards for Writing and Approving PPSOGFs” procedure as of the effective date listed above.