POLICY AND PROCEDURES

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<td>SUBJECT: Rapid HIV Antibody Testing Procedure</td>
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**Policy:** Vista Community Clinic provides confidential HIV Testing utilizing rapid Clearview HIV 1/2 Stat Pak and confirmatory standard HIV tests at each clinic site. Testing is done on an appointment and walk-in basis.

**Purpose:** To provide same day confidential rapid HIV testing to Family Planning patients at all Family Planning visits, excluding Pregnancy Test Only visits.

**Procedure:**
1. Patient confidentiality will be strictly protected.
2. Patients will be verbally informed that the rapid HIV test will be performed.
3. Patient consent for HIV testing is incorporated into the patient’s general medical consent.
4. Assent is inferred unless the patient declines testing.
5. If patient declines rapid HIV testing, this decision will be documented in the In-House Lab Template of the electronic medical record.
6. Staff will note any high risk behaviors provided by the patient in the risk assessment of the electronic medical record (e.g. Injection Drug Use (IDU), multiple sex partners, etc.).
7. Referral information is available for medical, social, counseling, and mental health services.
8. Patients will receive their test results on the same day.
9. When a test result is preliminary positive (reactive), a confirmatory test will be performed. Patients will be counseled as to the meaning of the reactive test result, the importance of returning for the confirmatory test result, and the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of the confirmatory test.
10. Written infection control procedures are in place.
11. Universal precautions will be practiced.

**Billing:** Billing for the rapid HIV test for patients covered by HAP, Managed Care, and private insurance is described in the posting procedure below. Patients that are not covered by any insurance programs can self pay. The cost is $25.00.
Posting Procedure:
1. Obtain a Reservation number by logging on to Medi-Cal’s website and filling in the fields under the “LSRS” section. Use NPI only for the user name – not “HAP11710F”, etc.
2. Copy and paste the Reservation number into the Procedure template in the electronic medical record.
3. At the Service Item prompt in the charge posting screen of NextGen, select 86703.
4. An “S” code diagnosis is required for HAP patients only. DO NOT USE S60 code. It will be denied. Please refer to HAP benefits grid for additional diagnoses. Under service modifier, choose the ZS code.
5. Once the LSRS Printed Confirmation Form page is available, it is necessary to convert the file into a PDF to be saved. The directions are as follows:
   a. Print the LSRS Printed Confirmation Form from the Medi-Cal web page
   b. Select the “Bullzip” printer, your file will automatically transfer to the Reservation Holding Tank folder
   c. Double click on My Computer
   d. Double click on Vale Terrace “K” drive
   e. Double click on Home
   f. Double click on Clinical
   g. Double click on Operations
   h. Double click on Reservation
   i. Double click on Reservation Holding Tank
   j. Find your PDF File
   k. Right click and select rename
   l. Rename the file to actual encounter number and CPT code (EXAMPLE: “123456_58742”)
   m. Right click-Cut
   n. Select back
   o. Find your site folder
   p. Double click on your site folder
   q. Double click on the current year folder
   r. Double click on the current month folder
   s. Paste the document within the current months folder

CONSENT AND PRETEST INFORMATION
1. Patients will be verbally informed that a rapid HIV test will be performed unless they decline (opt-out screening).
2. Staff will note any high risk behaviors provided by the patient in the risk assessment of the electronic medical record (e.g. Injection Drug Use (IDU), multiple sex partners, etc.).
3. Oral and written information provided to patients tested with a rapid HIV test includes the following:
   a. Information about the HIV test.
b. Information about HIV transmission and prevention.
c. The meaning of the test results in explicit, understandable language.
d. Where to obtain further information and, if applicable, HIV prevention counseling.
e. Where to obtain other services including treatment, if applicable.
f. In addition, patients tested with rapid HIV tests should be:
   i. Advised that their rapid test results will be available during the same visit.
   ii. They should also be informed that confirmatory testing is needed if the rapid test result is reactive.

DOCUMENTATION AND LAB PROCEDURE
The test kit operation must occur in an appropriate setting away from the counseling area to avoid distracting the patients, and to allow the counselor/test kit operator appropriate opportunities to consult with other staff, if necessary, prior to delivering the result. Staff, including MA’s, screeners and Health Educators that have been trained on the Clearview HIV 1/2 Rapid Test, are able to perform rapid HIV testing with a limited phlebotomy certification.

Specimen collection may occur either in the testing area or screening room. After the test is performed the patient must be moved to either the screening room or waiting room.

1. Document in electronic medical record and on the HIV Integration Form (Attachment 1) if patient declines a rapid HIV test.
2. Obtain blood sample. The used lancet and sample loop should be disposed of in the rigid, red puncture-resistant plastic containers marked “Biohazard” (Sharps Container).
3. Run rapid HIV test:
   a. Place the Clearview HIV 1/2 Stat Pak cartridge on a flat surface.
   b. Label the test device with patient name or identification number.
   c. Touch the 5 µL sample loop (provided in kit) to the specimen, allowing the specimen to fill the opening of the loop.
   d. Holding the sample loop vertically, touch it to the sample pad in the center of the sample (S) well of the device to dispense about 5 µL of specimen onto the sample pad.
   e. Invert the running buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (about 105 µL) of buffer slowly, drop by drop, into the sample (S) well.
   f. Record time on test device and wait 15 minutes.
4. Staff will check the result of the rapid HIV test between 15 to 20 minutes after test is done.
5. Results will be logged into HIV Integration Form.
6. If the test result is negative, the test kit should be disposed of in the white can marked “Solid Medical Waste”.

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7. If the test result is preliminary positive/reactive, the test kit should be disposed of in the rigid, red puncture-resistant plastic containers marked “Biohazard” (Sharps Container).

COMPLETING THE HIV INTEGRATION FORM
Mark Clinic Site with an “X”: VTB-Vale Terrace Branch, WC-Women’s Center, VCCW-Horne/West, PVW-Pier View Way, NRR-North River Road, or GV - Grapevine. (Complete for all patients)

Fill out visit date (month/day/year).

PATIENT INFORMATION
1. Attach patient label. (Attach for all patients) If no label available, fill out patient’s first and last name, medical record number, and date of birth.
2. Mark only one for Ethnicity with an “X”. (Complete for all patients)
3. Mark all that apply for Race with an “X”. (Complete for all patients)
4. Enter Age. (Complete for all patients)
5. Mark Gender with an “X”. (Complete for all patients)

TEST HISTORY
1. Mark only one for Have you been tested for HIV/AIDS before today with an “X”. (Complete for all patients)
2. If yes, mark only one for last test result received with an “X”.

IF PATIENT DECLINES TEST, SKIP TO DECLINED HIV TEST SECTION BELOW

RAPID/STANDARD HIV TEST INFORMATION

RAPID HIV TEST
1. Mark Rapid HIV Test with an “X”, if patient takes Rapid Test.
2. Fill out staff initials.
3. Mark Received Rapid HIV Test result with an “X”, if patient receives Rapid Test result.
5. Mark the correct test result: “Negative, Preliminary Positive, or Invalid” with an “X”.
6. If Preliminary Positive, go to Confirmatory HIV Test Information section and complete.
8. If patient chooses to retest, complete a second data collection form including the test result.
9. If patient chooses to decline, fill out Declined HIV Test section per instructions below.
10. If another staff person finishes testing, fill out staff initials.

**STANDARD HIV TEST**
2. Fill out staff initials.
5. Mark the correct test result: “Negative, Positive, or Indeterminate” with an “X”.

**CONFIRMATORY HIV TEST INFORMATION: ONLY TO BE COMPLETED IF RAPID HIV TEST IS PRELIMINARY POSITIVE AND PATIENT RECEIVES A CONFIRMATORY TEST**
1. Mark Confirmatory HIV Test with an “X”, if patient takes Confirmatory Test.
2. Fill out staff initials.
3. Mark the correct test result: “Positive, Negative, or Invalid” with an “X”.
5. If patient receives Confirmatory Test Result, mark Yes with an “X” and fill out the date and staff initials. If patient does not receive Confirmatory Test Result, mark No with an “X”.

**PATIENT DECLINED HIV TEST: ONLY COMPLETE IF PATIENT DECLINES HIV TESTING**
1. Mark Declined HIV Test with an “X”, if patient declines HIV test.
2. Fill out staff initials.
3. Mark reason declined HIV test with an “X”. If Other, specify reason given.

**RETRIEVING TEST RESULTS AND RESULT DISCLOSURE**
1. Confirm that the patient is prepared to receive her/his result.
2. Have the patient wait in the Screening Room while the Test Operator retrieves the results.
3. Be sure that the room where the results are retrieved is near the area used for counseling.
4. Do not allow the Counselor to be interrupted while reading the test.
5. After reading the test, the Counselor, then returns to the room.

**NEGATIVE TEST RESULT**
1. A negative test result is considered a “CONFIRMED” result and no further test is required.
2. A negative test result indicates that no antibodies to HIV were detected.
3. Patients whose rapid HIV test result is negative are informed that they are not infected, unless they have had a recent (within 3 months) known or possible
exposure to HIV. Retesting should be recommended for these patients because sufficient time needs to elapse before antibodies develop that can be detected by the test.

**PRELIMINARY POSITIVE (REACTIVE) TEST RESULT**
A preliminary positive result indicates that HIV antibodies were detected; all preliminary positive results require confirmation with a second independent test. Contact Rajni Lopez at 760.631.5000 ext, 7183 to inform her about any preliminary positive results.

This session must include the following:

1. Delivery of test result explaining the reactive test result in simple terms, avoiding technical jargon.
2. Time for patient to process the result.
4. Schedule a return appointment in 5 working days for the confirmatory test results.
5. Underscore the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of confirmatory testing.
6. Appropriate referrals.

**POST-DISCLOSURE COUNSELING**
Post-disclosure sessions are to be used to provide confirmatory test results after the initial disclosure of preliminary positive results for Rapid testing patients. Direct referrals should be provided to the patient directly.

**CONFIRMATORY RESULT DISCLOSURE**
The confirmatory result for preliminary positives is disclosed to the patient at the post-disclosure session. This session will consist of informing the patient that the preliminary positive result was confirmed, checking in with the patient about her/his emotional needs, reactions, and intentions and following up with appropriate referrals, including medical referrals and referrals to Partner Services (PS) if appropriate.

If the confirmatory test result (Western Blot) is either negative or indeterminate, the best way to resolve the difference between the preliminary and confirmatory test results and figure out the correct answer is to collect a follow-up blood specimen at least four (4) weeks after the initial reactive Clearview result. The patient should return for that extra blood work. After four (4) weeks, a patient in the window phase should now be clearly positive. If confirmatory testing is still negative after one month, the Clearview was probably false.

If clinic staff needs assistance in giving a confirmed positive result, contact HIV Integration Project staff as soon as possible to schedule a certified counselor from the Health Promotion Center.
Contact the HIV Medical Case Managers at VCC Grapevine (GV) to set up an initial appointment. Every effort will be made to schedule the Adult HIV Initial appointment at GV within two weeks of the confirmatory results disclosure appointment.

If the patient has a positive confirmatory test result and does not return for the test results, clinic staff should make two attempts to contact the patient via the telephone. If the patient is contacted, they should be asked to return to the clinic to receive their results. If unable to reach, clinic staff can contact the Bridge Worker at the Health Promotion Center (760.631.5000 ext. 2209) to assist with patient follow-up and results disclosure.

If a patient is unable to make their Adult HIV Initial appointment at GV due to time conflict, staff should contact the HPC Counseling and Testing Staff to reschedule the appointment.

CONFIRMATORY TESTING PROTOCOLS
The CDC recommends that for all confirmatory testing, the current standard of testing algorithm will be followed, with the following exceptions.

1. All Clearview HIV 1/2 Stat Pak reactive preliminary positive results must be followed up with either Western Blot or Immunofluorescent Assay (IFA) for confirmation.
2. Confirmatory testing needs to be done with blood specimens. Urine testing should not be performed due to its lower sensitivity.
3. With blood specimens, Enzyme Immunoassay (EIA) screening tests prior to the Western Blot or IFA confirmatory test is optional. If an EIA is performed, even if it is non-reactive, the specimen must proceed to Western Blot or IFA testing.

REPORTING
1. All confirmed positive HIV results are reported to the San Diego Public Health Department within seven days as mandated by the State of California. The HIV Case Report Form can be found at:
   http://www.sdcounty.ca.gov/hhsa/programs/phs/documents/HAEU_HIV_Case_Form.doc

QUALITY CONTROL PROCEDURES
Purpose: To ensure that kits are operating properly and confirming that, prior to conducting the tests, the test site is suitable.

Storage and Stability
Test kits are to be stored within the manufacturer’s recommended range of 46 degrees Fahrenheit and 86 degrees Fahrenheit. Do not freeze. Do not open the pouch until you are ready to perform test. When stored as indicated, test devices are stable until the expiration date marked on the pouch. Running Buffer should also be stored
between 46 degrees Fahrenheit and 86 degrees Fahrenheit in its original vial. Existing temperature log currently used in lab should be used to track temperature.

**Quality Control**

**Purpose:** To verify that the test kits are working as expected, operators are performing the test properly, and that the results are accurate.

1. **Built In Control Feature:** The control line serves as a built-in positive internal control and gives confirmation of sample addition and proper test performance. A pink/purple line will appear in the Control (C) area if the test has been performed correctly and the device is working properly.

2. **External Quality Control:** Good Laboratory Practices (GLP) necessitates testing external control material along with the test samples to ensure proper performance of the test kit. Clearview HIV Reactive/Nonreactive Controls are available separately for use with the Clearview HIV 1/2 STAT-PAK assay. The HIV Controls are used to verify the operator’s ability to properly perform the test and to interpret the results. Each Reactive Control will produce a REACTIVE Test Result and has been manufactured to produce a faint line in the TEST (T) area. The Nonreactive Control will produce a NONREACTIVE Test Result. Run the Controls as per the TEST PROCEDURE and follow the instructions as described in the INTERPRETATION OF TEST RESULTS sections of the Product Insert. It is the responsibility of each facility using the Clearview HIV 1/2 STAT-PAK assay to establish an adequate quality assurance program to ensure the performance of the device under specific locations and conditions of use.

3. Run the Kit controls under the following circumstances:
   a. Each new operator prior to performing tests on patient specimens.
   b. When opening a new test kit lot.
   c. Whenever a new shipment of test kits is received.
   d. If the temperature of the test storage area falls outside of 8 to 30°C (46 to 86°F).
   e. If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F).
   f. At periodic intervals as indicated by the user facility – Once a month.

4. An External Quality Control Log (Attachment 2) must be completed and maintained in the lab where controls are run.