Rapid HIV Testing Protocol    (STD Clinic)

(Revised February 2, 2006)

Background
In late 2002 and early 2003, significant HIV testing developments occurred. First, the U.S. Food and Drug Administration (FDA) approved OraQuick, the first of the so-called "second generation" rapid HIV tests to be approved by the FDA. Second the CDC issued a new guidance, “Advancing HIV Prevention: New Strategies for a Changing Epidemic,” which specifically advocated for the use of rapid HIV testing to increase access to early diagnosis and referral for treatment and prevention services in high-HIV prevalence settings. The Colorado Department of Public Health and Environment (CDPHE) has provided funding to Denver Public Health for the implementation of HIV rapid testing.

Goals and Priorities for Rapid Testing

- Increasing the number of clients at increased risk who are tested.
- Increasing the number of clients who learn their test results.
- Decreasing the need for follow-up activities for clients who do not return for their HIV test results and associated prevention counseling.

Eligibility for Rapid HIV Testing

Clients must meet the following criteria to be offered a rapid test:

- Client must provide his or her name and address. Anonymous testing will not be allowed in the STD Clinic.

Note: The OraQuick Advance© test is approved for HIV 1 and HIV 2 screening.

HIV Counseling in Conjunction with Rapid Testing

In general, the same basic components of HIV counseling should be provided in conjunction with HIV rapid testing. The following aspects of counseling are unique to a rapid testing scenario:

Informed Consent

The patient must complete the consent statement during the triage process, and choose whether or not they are willing to be tested for HIV.

Information Conveyed to Patients

The following information must be conveyed to clients when using OraQuick Advance©:

1) Clients should be informed that the results of the rapid HIV test will be available quickly, approximately 20 minutes after administering the test.
2) The FDA requires that an information pamphlet on OraQuick Advance®, developed by OraSure Technologies, must be given to the client.

Client Readiness to Test

Just because clients request and accept rapid HIV testing does not necessarily mean that they are prepared for the result. It is important that counselors be attentive to client readiness and clearly explore the extent to which clients are prepared to receive results that same day. Counselors may offer the option of returning at a later date to receive their test results if the client is not ready to receive them.

Page 1 of 8
Completing the HIV Rapid Test Form

1) Detailed instructions on completing and submitting the HIV Rapid Test Form

The HIV Rapid Test Form has been developed by the Colorado Department of Public Health and Environment (CDPHE) to assist the counselor with quality client-centered counseling and the efficient collection of epidemiological information. Remember, the CDPHE Rapid Test Form should never be used to drive your counseling session. The majority of the information requested on the form should be gathered through the client-centered HIV prevention counseling and risk assessment process.

The HIV Rapid Test Data Collection Form:

The counselor accurately and legibly completes this copy. This copy is mailed directly to CDPHE regardless of test result. If the test result is negative, no additional paperwork is required. If the test result is positive, an additional form must be completed to send the confirmatory specimen to the CDPHE Laboratory.

Clarification of individual data items on the HIV Rapid Test Form

a. The HIV Rapid Test Form consists of an AGENCY SECTION and a CLIENT DEMOGRAPHICS SECTION. You must fully and accurately complete both sections.

b. FACILITY INFORMATION – Please indicate both physician name and agency or group name on the facility line. Also include the counselor name, your facility address and phone number on the indicated lines.

c. SITE CODE – The STD site code is 0173.

d. SPECIMEN COLLECTION – This section includes the date the specimen was collected.

e. DATE RECEIVED/SPECIMEN NUMBER – Do not fill in this field. The CDPHE lab will complete this field when you send in a specimen for confirmatory testing.

f. RAPID TESTING RESULTS – After verifying the result in HealthDoc, the clinician should bubble in the result on the form. Make sure this is completed prior to sending to CDPHE.

g. Remember, the epidemiologic portion of the HIV Rapid Test Form should always be completed at the end of your counseling session. A good “rule of thumb” to follow is: leave no question unanswered. Print firmly and legibly. Errors need to be erased or whited out.
Performing the Test
All clients who test for HIV in the STD Clinic will receive a rapid test. This method of testing will eliminate the need to provide HIV results by telephone, and ensure greater likelihood that patients will receive their results.

NOTE: For the most efficient use of time, the triage nurse should determine whether or not the patient is interested in the Rapid Test and ensure proper consent. The phlebotomist will collect the sample immediately following patient registration, and take to the laboratory immediately after collection for processing.

This test has been approved for use with whole blood collected by venipuncture or fingerstick, plasma, and oral fluid. To limit the amount of confusion in the stat lab, the phlebotomist will not perform a finger-stick on patients who request a rapid test. Instead, the phlebotomist will draw a small purple-top tube. The anticoagulant in the purple tube will allow the lab staff ample time to inoculate the OraQuick test solution.

Once the patient is registered, the designated phlebotomist will call individuals back for the blood draw.
   1) The phlebotomist will verify that the patient understands that he/she is having a rapid HIV test performed.
   2) A lab order for a HIV Rapid test will be created in the patient's visit in HealthDoc.
   3) The unique serology number on the patient's HIV form will be entered into the lab order.
   4) A demographic label will be placed on the HIV form. The patient's age, date of birth and collection date will be filled in by the phlebotomist.
   5) The phlebotomist will draw a purple top and a red top tube for the HIV and syphilis testing. (The purple top tube will be used for the rapid HIV test. The large red tube can hold sufficient serum to perform the RPR, a confirmatory HIV Western Blot if indicated, and serum for any research projects the patient chooses to participate in.)
   6) The phlebotomist will apply a specimen with serology label on the blood tube, and loosely attach the specimen serology sticker to the top of the tube. The HIV serology form will be placed in the box where it can be retrieved by the clinician.
Instructions for collecting a sample via VENIPUNCTURE:

1) Set up your workspace.
   • Gather the materials you will need.
   • Allow the test kit to come to room temperature before use.

2) Open the two chambers of the OraQuick Divided Pouch by tearing at the notches on the top of each side of the Pouch. To avoid contamination, leave the Test Device in the Pouch.

3) Remove the Developer Solution Vial from the Pouch.

4) Remove the cap from the vial by gently rocking the cap back and forth while pulling it off. Carefully place the vial in the blue stand.

5) Collect the sample
   • Put on exam gloves.
   • Apply tourniquet to patient’s upper arm.
   • Locate vein for sample collection.
   • Using an antiseptic wipe, clean the area surrounding venipuncture site.
   • Allow the skin to dry thoroughly or wipe dry with a sterile gauze pad.
   • Insert a sterile needle into the vein and collect a sample in a purple top tube.
   • Remove tourniquet.
   • Apply cotton over venipuncture site and remove needle.
   • Immediately place needle in a biohazard waste container.
   • Affix cotton to arm with Coban or tape.
   • Carefully remove the purple top from the specimen tube.
   • Pick up an unused Specimen Collection Loop by the hand end.
   • Put the rounded end of the Loop into the blood tube. Make sure that the Loop is completely filled with blood. (Note: If the Loop is dropped or comes in contact with any other surface, discard and collect another sample with a new Loop.
   • Immediately insert the blood-filled Loop all the way into the test vial. Use the Loop to stir the blood sample in the Developer Solution. Remove the Loop and dispose in a biohazard waste container.
   • Check the Solution to make sure that it appears pink. If the Solution is not pink, discard all test materials in a biohazard waste container and start the test over with a new kit.
Instructions for collecting a sample via FINGER-STICK:

1) Set up your workspace.
   - Gather the materials you will need.
   - Allow the test kit to come to room temperature before use.

2) Open the developer solution chamber of the OraQuick Divided Pouch by tearing at the notches on the top of each side of the Pouch. To avoid contamination, leave the Test Device in the Pouch.

3) Remove the Developer Solution Vial from the Pouch. Write the collection time on the patient’s label, and affix it to the Vial.

4) Remove the cap from the vial by gently rocking the cap back and forth while pulling it off. Carefully place the vial in the blue stand.

5) Collect the sample
   - Put on exam gloves.
   - Using an antiseptic wipe, clean the patient’s finger.
   - Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
   - Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward.
   - Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to bleed.
   - Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
   - Pick up an unused Specimen Collection Loop by the hand end.
   - Put the rounded end of the Loop on the drop of blood. Make sure that the Loop is completely filled with blood. (Note: If the Loop is dropped or comes in contact with any other surface, discard and collect another sample with a new Loop.
   - Immediately insert the blood-filled Loop all the way into the Vial. Use the Loop to stir the blood sample in the Developer Solution. Remove the Loop and dispose in a biohazard waste container.
   - Check the Solution to make sure that it appears pink. If the Solution is not pink, discard all test materials in a biohazard waste container and start the test over with a new kit.
   - Carefully replace the cap on the Vial to avoid spilling the inoculated solution.
   - Do not remove exam gloves.
   - Transport the Vial and the Pouch containing the Testing Device to the stat lab. Inform lab personnel that you are delivering a rapid test specimen.
   - Take off exam gloves and wash hands.
   - Laboratory personnel will record the result in HealthDoc.
Instructions for collecting a sample via ORAL FLUID:

1) Set up your workspace.
   • Gather the materials you will need.
   • Allow the test kit to come to room temperature before use.

2) Open the chamber of the OraQuick Divided Pouch containing the collection device by tearing at the notch on the top the Pouch.

3) Collect the sample
   
   • Label the pouch kit with:
     i. The specimen serology sticker from the HIV testing form
     ii. A patient specimen with serology label
   
   • Have the person being tested remove the device from its pouch. **Do not** allow the person to touch the flat pad. Check to make sure that an absorbent packet is included with the device. Discard the absorbent packet. (If no absorbent packet is present, discard the device and obtain a new pouch for testing.)
   
   • Direct the person to place the flat pad above the teeth against the outer gum. Have the person gently swab completely around the outer gums, both upper and lower, one time around, using the flat pad. **Do not** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. Both sides of the flat pad may be used during this procedure.
   
   • Instruct the person being tested to replace the swab back into the test kit pouch.
   
   • Immediately transfer the specimen/test kit to the stat laboratory for processing. Inform lab personnel that you are delivering a rapid test specimen. Note: Specimen must be received by the stat lab within 10 minutes of collection. If this does not occur, discard kit and specimen and begin procedure over.

The risk data on the HIV form will not be filled out until the clinician has gathered the information in the risk interview.

The lab tech will set up and record the test in HealthDoc per usual procedure.

In the instance of a reactive OraQuick result, the charge nurse will be immediately notified. These results will never be openly discussed in the lab among the clinicians, under any circumstances, beyond what communication is needed to coordinate efforts to get the result to the patient. The CDPHE DIS staff and Linkage to Care staff will be immediately notified of the positive result.

In the instance of multiple patients waiting to be seen, a clinician will call the patient out of order to begin the exam. This is to prevent a positive client from leaving the clinic without receiving their test results. In this scenario, the interview will proceed as if it were not known that the person has tested HIV+. The result will be given at the end of the visit, as per the usual routine, with the clinician tailoring the visit to meet the needs of the individual as would be routinely done. The positive results will be given, and the usual mechanism for HIV+ results will be followed. (See sections on ‘Reporting Rapid Results’, ‘Confirmatory Testing’ and ‘Instructions for Viral Load and CD4 Testing’.)

In the instance of a patient leaving before being given their positive result, CDPHE field staff will be contacted and informed of this, and given all contact info available on the patient’s chart.
Reporting Rapid Test Results to the Patient

1) If the test result is negative, clients should be told that they are not infected with HIV, unless they have had a recent (within 3 months) known or possible exposure to HIV. Retesting should be recommended for clients who have had risk exposure in the three preceding months because sufficient time needs to elapse before antibodies develop that can be detected by the test.

2) If the test result is preliminary positive (reactive), the counselor should explain the meaning of the reactive test result in simple terms. An example of such a message could be “Your preliminary test result is positive, but we won’t know for sure if you are infected with HIV until we get the results from your confirmatory test. In the meantime, you should take precautions to avoid transmitting the virus.” The counselor should emphasize the importance of confirmatory testing and schedule a return visit for the confirmatory test results. An oral specimen may be collected for the confirmatory test if the patient declines venipuncture. A DIS staff member from CDPHE should be paged to interview any client with a positive Rapid result.

Confirmatory Testing

For confirmatory testing the current standard testing algorithm should be followed, with the following exceptions:

- **All OraQuick reactive (preliminary positive) results must be followed up with a Western Blot for confirmation.**
- Confirmatory testing can be done on blood (plasma or serum) or oral fluid specimens.
- With blood specimens, enzyme immunoassay (EIA) screening tests prior to the Western blot is optional. For oral fluid testing, both EIA and Western blot testing should be performed to confirm results.
- A **large red top** tube should be collected for confirmatory testing while the ARDVRT study is in process. Counselors should use their best judgment to determine client readiness for this and other forms and referrals.
- The HIV laboratory form “Request for Analytical Services” should be completed to send with the confirmatory specimen. The STD Clinic code on the upper left corner of this form is: HV000152.
- **DIS personnel from CDPHE should be paged** anytime there is a rapid positive result in the clinic.
- **Linkage to Care staff** should be called anytime there is a rapid positive result in the clinic.
- All clients having preliminary positive results should be offered **Viral Load and CD4 testing** in addition to the confirmation test.

Instructions for Viral Load and CD4 Testing

Clients with a positive Rapid test should be offered CD4 and VL testing the same day. To perform these tests:

- **The client must agree to give his or her ACTUAL name and date of birth.**
- Ensure that the ID Clinic can process the specimens prior to collection. Shipping samples can be a problem late in the afternoon, especially on Fridays. The extension to the ID Clinic is: x7240.
- Draw **three small purple-top** tubes and **one large yellow-top** tube. Each tube should be labeled with the following information:
  - Patient’s Last Name, First Name
  - Date of Collection
  - Patient’s Date of Birth
- All tubes must be hand-delivered to the ID Clinic within **20 minutes** of collection.
- The results take up to 10 days to return. An appointment should be scheduled for the patient to return at a time when Dr. Thrun or Dr. Rietmeijer is attending in the clinic. (In most instances, the Linkage to Care staff will schedule follow-up appointments.)
- Test results will be available on the Sunquest program. Instead of typing in the patient’s name, use the patient’s date of birth in the Hospital Number field: GILEAD-DDMMYY.
Follow up Testing for Negative Confirmatory Result

Occasionally, confirmatory test results are indeterminate. If the Western blot is indeterminate, it is recommended that:

- For blood specimens, the person should be advised to return for repeat testing in one month.
- For oral fluid specimens, the Western blot test should be repeated using a blood specimen.

Clarification of Results

1) Meaning of “indeterminate” on the HIV Rapid Test Form

On the “HIV Rapid Test Form,” in the box labeled “RAPID TESTING RESULTS” there is a field for “indeterminate.” This field should be used whenever the test produces an invalid result. A test result is considered invalid if any of the following occurs: no reddish-purple line appears in the area adjacent to the “C” triangle; a reddish background in the results window makes it difficult to read the results after 20 minutes; or any of the lines appear outside the areas adjacent to the “C” or “T” triangle areas. See the OraQuick manufacturer’s instructions for further clarification.

2) What to do if the OraQuick results are invalid

As described in the CDC Quality assurance guidelines (page 13), if the OraQuick test produces invalid results, you should do the following:

a. Offer the client a repeat test using OraQuick.

b. If a second invalid result occurs:
   i. Offer the client a standard Elisa via blood draw or an Orasure oral specimen test.
   ii. Run positive and negative controls on the lot used for this testing. Remember to make the appropriate log entries.

c. If the same test kit lot yields repeated invalid results, the test kits may have gone bad, or there may be a larger problem with an entire lot, affecting multiple sites. Please notify Andrei Kisselev at CDPHE immediately, 303/692-2722.

d. Each invalid rapid test result should be documented with a separate, fully completed HIV Rapid Test Form submitted to CDPHE.

3) What to do if the Western Blot results are indeterminate

If you receive confirmatory Western Blot results on a test that was preliminary positive and these confirmatory results are indeterminate, you should offer to retest the client using a standard blood draw. DO NOT retest the individual with a second OraQuick test or an Orasure oral specimen test.

If the second Western Blot result is also indeterminate, advise the client to wait four to six weeks before seeking a retest.

4) Additional steps if the Western Blot results are negative

If you receive confirmatory Western Blot results on a test that was preliminary positive and these confirmatory results are negative, you should offer to retest the client using a standard blood draw. DO NOT retest the individual with a second OraQuick test or an Orasure oral specimen test.