

Module 9

Performing HIV Rapid Tests

Purpose	To provide you with necessary knowledge and skills to accurately perform 3 HIV rapid tests and to determine HIV status.		
Pre-requisite Modules	 Module 3: Overview of HIV Testing Technologies Module 4: HIV Testing Strategies & Algorithms Module 6: Safety at the HIV Rapid Testing Site Module 7: Preparation for Testing – Supplies & Kits Module 8: Blood Collection – Fingerprick 		
Learning Objectives	 At the end of this module, you will be able to: Perform 3 HIV rapid tests according to Standard Operating Procedure (SOP) Perform multiple tests simultaneously Accurately interpret individual test results Accurately determine HIV status 		
Content Outline	This module requires live demonstration and hands-on practice.		
Handouts	Job Aids for the tests in your country's testing algorithm Video script for HIV rapid tests Practical exercise recording worksheet		
	Video demonstrating procedures of the tests approved for use in your country		
Notes on Customization	Provide country-specific information regarding test kits and testing algorithm. Delete tests not applicable to your country.		

To achieve the learning objectives of this module, it is important that you attend a live training session where an instructor can demonstrate the procedures and supervise your hands-on practices. The information provided here is for your reference only.



A video accompanies this module. Watch it if it is available to you. If you don't have the video, a copy of the video script is available for your review at the end of the module.

Each video segment explains the important steps you need to take for performing the test. You are expected to be able to answer these questions after you have watched the video:

- What preparation is required for the test kit before testing?
- What are the components in the test kit?
- What information needs to be recorded, and where?
- How do you collect samples? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?

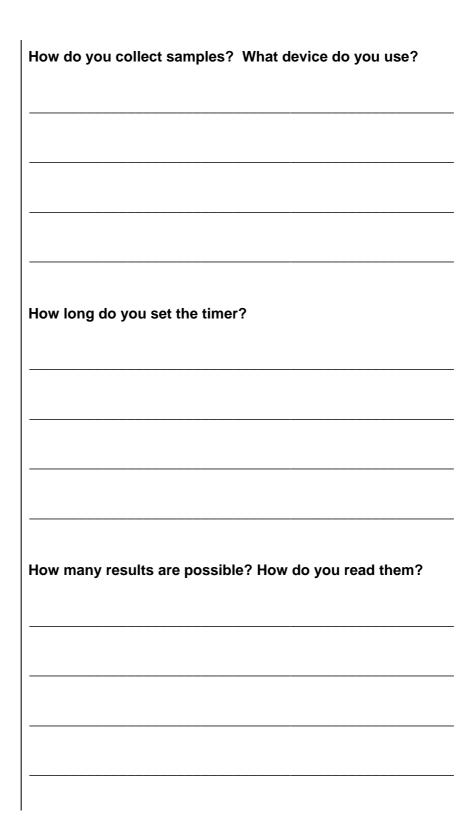
Space is provided in the module for you to take notes during or after the video.



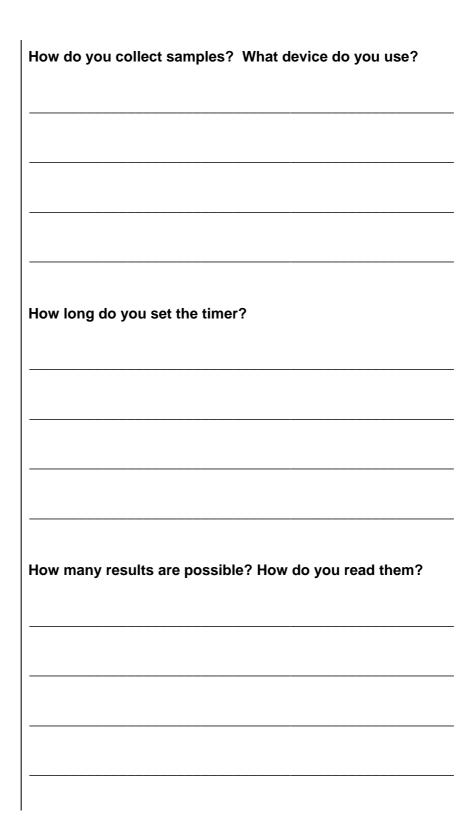
Job Aid

Refer to the color job aids for procedures of the tests used in your country. These job aids are laminated so you may post them in your test site.

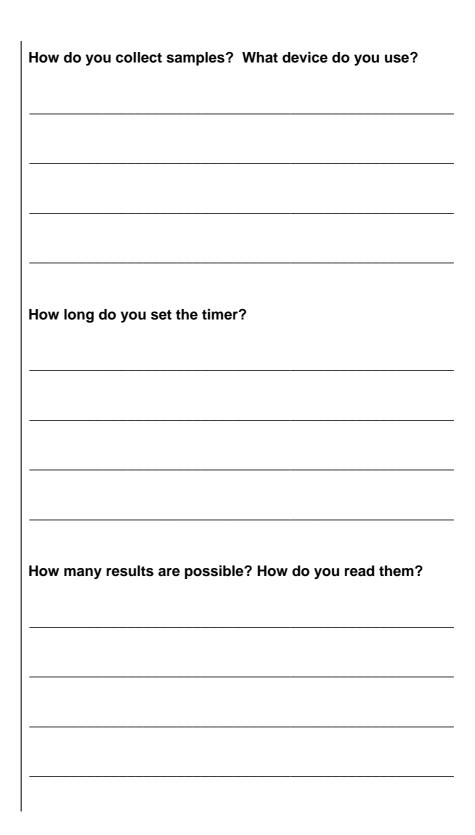
Video: Test 1	What preparation is required for the test kit before testing?
	What are the components in the test kit?
	What information needs to be recorded, and where?



Video: Test 2	What preparation is required for the test kit before testing?
	What are the components in the test kit?
	What information needs to be recorded, and where?



Video: Test 3	What preparation is required for the test kit before testing?
	What are the components in the test kit?
	What information needs to be recorded, and where?





Video: Multiple HIV Tests What are the advantages of performing more than one test at a time?

Why must you keep two test kits separate when performing both at the same time?

Do you collect blood at the same time or separately when performing multiple tests?

	How do you set the timer when two tests require different wait time?
	When is a tie-breaker used? How does it determine HIV status?
Key message	 Always follow universal safety precautions when performing any laboratory procedure Always follow your country testing algorithm Always follow your test site standard operating procedure



Capillus HIV 1 and 2 is a rapid test that detects antibodies to HIV Type 1 or Type 2. You need these standard supplies since they aren't included in the test kit as well as supplies required for a finger prick. You also need the Capillus test kit that should be refrigerated from 2 - 8 degrees Celsius.

Bring the kit to room temperature before performing the test. Only use a test kit that hasn't expired or been damaged. The Capillus kit includes the latex reagent with a dropper, fixed volume pipette for the blood specimen, pipette tips, slides, black interpretation card, and a positive control and a negative control.

Capillus can be used with whole blood from either a finger prick, or drawn from a vein, or with serum or plasma.

At the beginning of your workday always perform the positive and negative test kit controls to make sure that the reagents is working properly. If its working properly, the positive control has white clumps, also called latex aggregation, while the negative control is smooth and milky with out white clumps.

Record the test date, client identification, the name of the person performing the test, the type of test, the expiration date, and both the test lot number and the control lot numbers on appropriate forms.

After educating the client you're ready to perform the Capillus rapid HIV test. As always use universal safety precautions. Make sure the slide is right side up and place it on the black interpretation card. This card helps you to see the reaction better. Record the client identification on the test slide. Then attach a new pipette tip to the 10 microlitre fixed volume pipette from the Capillus kit.

Mix the latex reagent by gently shaking the bottle to ensure that the latex is wellmixed. Avoid air bubbles in the latex reagent. Draw the latex up and down several times with the dropper to continue mixing it. Draw the latex reagent to the calibration mark which is approximately 120 microliters. Avoid drawing up air bubbles. Dispense the latex reagent onto the slide at the edge of the mixing well. Do not allow the dropper to touch the slide.

In this videotape the test is demonstrated by using whole blood from a finger prick. Use the pre-calibrated pipette to collect 10 microliters of the blood specimen. Dispense the specimen directly into the latex solution. Using the pipette, mix the specimen and the latex by pumping the mixture in and out of the tip 3 times then stir in a circular motion at least 5 times. Use the pipette to move the well-mixed specimen and latex solution to the opening of the channel until the capillary flow begins. Allow the latex mixture to flow through the entire capillary channel and into the viewing window.

Start the timer and read the test result in three to seven minutes. Discard the used gauze before the client leaves the testing area.

Next, interpret the test results. There are two possible results. A positive result shows any latex aggregation. This means little white clumps form similar to those that

appear in the positive control. A negative result is smooth and milky without any white clumps, as in the negative control.

Next, record the test results on appropriate forms. Finally, discard the tests and materials in the appropriate waste containers.

In review, get the Capillus kit from the refrigerator. Only use a test kit that has not expired or been damaged. Collect all of the supplies and be sure the kit is at room temperature before using it. At the beginning of the workday always perform a positive and negative control.

Record the appropriate information including the lot numbers of the controls on the forms, as well as the client identification on the test slide. Next perform the test. Make sure the slide is right side up and place it on the black interpretation card.

Mix the latex reagent well and avoid creating air bubbles. Continue mixing the reagent by drawing the latex up and down with the dropper. Draw the reagent to the calibration mark which is approximately 120 microliters. Dispense the reagent on to the slide at the edge of the mixing well. And do not allow the dropper to touch the slide.

Perform a finger prick and use the pre-calibrated pipette to collect 10 microliters of the blood specimen. Dispense the specimen into the latex solution and use the pipette to mix it by pumping 3 times and stirring it 5 times. Move the mixture to the opening of the channel and allow it to flow into the viewing window. If the latex does not move up use the pipette to push it up to the window.

Start the timer and read the test result in 3-7 minutes. Next interpret the test results. There are two possible results. The test is positive if there are white clumps or negative if it's smooth and milky. Finally, record the test results on the appropriate forms and discard the used test and other materials in the appropriate waste containers.



Determine HIV 1 and 2 is a rapid test to detect antibodies to HIV type 1 and type 2. You need these standard supplies which are not included in the test kit as well as supplies required for a finger prick. You also need the Determine test kit that should be stored from 2-30 degrees Celsius. If the kit is refrigerated bring it to room temperature before performing the test. Only use a kit that hasn't expired or been damaged.

The kit includes a packet of test strips, as well as a vial of chase buffer which is used if you're testing from whole blood. The Determine rapid HIV test can be used with whole blood from either a finger prick, or drawn from a vein, or with serum or plasma.

Record the test date, client identification, the name of the person performing the test, the type of test, the test lot numbers, and the expiration date on appropriate forms. Use one strip per test. When you pull a test strip from a packet preserve the lot number by cutting it on the right side away from the lot number that appears on the left side. This way the lot number will still be there the next time you need a new test strip. Next pull the foil from the top of the test strip. Set the test strip facing up and record the client identification on the test strip.

After educating the client, you're ready to perform the Determine rapid HIV test. As always use universal safety precautions. For whole blood specimens either from a finger prick or drawn from a vein use a micropipette to collect 50 microliters of blood. Apply the specimen to the absorbent pad on the test strip. Wait 1 minute until the blood is absorbed on the pad. Then apply 1 drop of the chase buffer to the blood specimen pad. Start the timer and read the result in 15 minutes. Discard the used gauze before the client leaves the testing area.

If you're testing serum or plasma specimens apply 50 microliters of serum or plasma to the white absorbent pad. You don't need to use the buffer with serum or plasma.

Next interpret the test results. There are three possible results.

- For a positive result, two red lines of any intensity appear in both the control window labeled "control" and the client window labeled "patient". The intensity is not as important as the presence or absence of the lines. It's ok if either the control line or the client line is weak.
- For a negative, result one red line appears in the control window of the strip but no line appears in the patient window.
- For an invalid result no red line appears in the control window of the strip. If this happens do not report invalid results. Repeat the test with a new test strip even if a red line appears in the patient window.

Record the test results on appropriate forms and discard the tests and materials in the appropriate waste containers.

In review, collect all of the supplies including the Determine test kit. Only use tests and buffer that haven't expired or been damaged. Record the appropriate information on the forms as well as the client identification on the test strip. Use one strip per test and be sure to preserve the lot number on the remaining packet of strips. Next, perform the test. For whole blood specimens either from a finger prick or blood drawn from a vein use a micropipette to collect 50 microliters of blood. Apply the specimen to the absorbent pad on the strip. Wait 1 minute until the blood is absorbed on the pad and then apply 1 drop of the chase buffer to the blood specimen pad.

For serum or plasma specimens apply 50 microliters of serum or plasma to the white absorbent pad. You do not need to use the buffer with serum or plasma.

Start the timer and read the result in 15 minutes. Next interpret the test results. There are three possible results. A positive result has two red lines of any intensity that appear in both the control and patient windows. A negative result has one red line in the control window but no line in the patient window. An invalid result has no red line in the control window of the strip. If this happens do not report invalid results. Repeat the test with a new test strip even if a red line appears in the patient window.

Finally, record the test results on the appropriate forms and discard the used tests and other materials in the appropriate waste containers.



Hema-Strip 1 and 2 is a rapid test that detects antibodies to HIV Type 1 and Type 2. You need these standard supplies which aren't included in the test kit as well as supplies required for a finger prick. You also need a Hema-Strip test kit that should be stored from 20-30 degrees Celsius. Only use a test kit that has not expired, been opened or damaged.

The test kit should include items necessary to perform one test. These include:

- A test device with a test strip inside,
- The buffer vial attached to the test device,
- Other items in the packaging or in the kit include
- A lancet,
- A bandage, and
- A rack for holding the test device upright.

Hema-Strip can be used with whole blood from either a finger prick, or drawn from a vein.

After educating the client, record the test date, client identification, name of the person performing the test, type of test, test lot number, and expiration date on appropriate forms. Open the packet and make sure that there's liquid in the buffer chamber because sometimes the chambers can leak. Record the client identification on the test device. Now you're ready to perform the Hema-Strip rapid HIV test. As always use universal safety precautions.

For whole blood from a finger prick let the tip of the device fill with blood until the tip is full. For whole blood drawn from a vein put the device into the tube of blood and let the tip of the device fill with blood until the tip is full.

Remove the buffer vial from the top of the blood specimen and place it on a flat surface. Hold the buffer vial and firmly press the blood specimen tip through the foil cover. Continue pushing the device, usually 2 more times, to the bottom of the vial until the test device and buffer vial snap together tightly with the device at the bottom of the vial. Place the test device upright in the rack.

Next, start the timer and read the test at 15 minutes. Discard the used gauze before the client leaves the testing area.

Next interpret the test results. There are three possible results.

- For a positive result two pink or purple lines of any intensity appear in both the control line on the top and the client, or test line, below. The intensity isn't as important as the presence or absence of the lines. It's ok if either of control line or test line is weak.
- For a negative result one pink or purple line appears only in the control area of the strip and no line appears in the client area.
- For an invalid result no line appears in the control area. If this happens do not report invalid results. Repeat the test with a new test device even if a line appears in the client area.

Record test results on appropriate forms and discard the tests and materials in the appropriate waste containers.

In review, collect all of the supplies and the Hema-Strip test kit. Only use a test kit that has not expired, been opened or damaged. Record the appropriate information on the forms as well as the client identification on the test device.

For whole blood from a finger prick, or drawn from a vein, let the tip of the device fill with blood until the tip is full of blood.

Remove the buffer vial from the top of the blood specimen and place it on a flat surface. Hold the buffer vial and firmly press the blood specimen tip through the foil cover. Continue pushing the device, usually 2 more times, to the bottom of the vial until the test device and buffer vial snap together tightly with the device at the bottom of the vial. Place the test device upright in the rack.

Start the timer and read the test results at 15 minutes. Next, interpret the test results. There are three possible results. A positive result has two pink or purple lines in both the control and test areas. A negative result has one pink or purple line in the control area of the strip but nothing in the test area. For an invalid result no line in the control area of the strip. If this happens do not report invalid results. Repeat the test with a new test device even if a line appears in the test area.

Finally, record the test results on the appropriate forms and discard the used tests and other materials in the appropriate waste containers.



OraQuick HIV 1 and 2 is a rapid test that detects antibodies to HIV Type 1 and Type 2. You need these standard supplies which are not included in the test kit as well as supplies required for a finger prick. You also need an OraQuick test kit which should be stored from 2-30 degrees Celsius. If the kit is refrigerated bring it to room temperature before performing the test. Only use a test that has not expired, been opened or damaged.

The kit should include:

- One loop per test which is used with whole blood or serum, but not used with oral fluids,
- A test device,
- A developer vial, and
- A stand that's supplied with every 500 tests

OraQuick can be used with oral fluids, or with whole blood from either a finger prick, or drawn from a vein, or with serum or plasma.

Record the test date, client identification, name of the person performing the test, type of test, test lot number, and expiration date on appropriate forms. Now you're ready to perform the OraQuick rapid HIV test. As always use universal safety precautions.

After educating the client, open the packet and record the client identification on the developer vial. Uncap the vial by gently rocking the cap back and forth and place the uncapped vial into the stand. Open the other side of the packet and label the test device.

In this videotape both whole blood from a finger prick and oral fluids are used to demonstrate the test.

For blood specimens, collect 5 microliters by filling the loop with the specimen. Or if the loop is not available, collect 5 microliters of blood using a micropipette. Put the loop into the developer all the way to the bottom of the vial and stir. Then discard the loop into the appropriate waste container. Next, put the test device all the way down into the developer vial. Make sure the results window faces towards you so it can be read. Start the timer and read the test result between 20 and 60 minutes. Keep the device in the developer vial until the results are read. Discard the used gauze before the client leaves the testing area.

If you use an oral fluids specimen, label the developer vial with client information, then open it and place it in the stand. Also, open the device side of the pouch and without touching the collection pad, label the test device with the client information. Tell the client how to swab completely around the outer gums with the device, by gently wiping the porous flat pad completely across the upper and lower gums, one time around. Then the client uses the device to swab his mouth. Watch carefully as he gently swabs across his upper and lower gums one time around. Doing so will allow for an adequate specimen to be collected. Take the test device from the client and put it all the way down into the developer vial. Make sure the results window

faces towards you so it can be read. Start the timer and read the test result in 20 to 60 minutes. Do not remove the device until the after the results are read.

Next you interpret the test results. There are three possible results.

- For a positive result two lines of any intensity appear in both the control area labeled "C" and the test, or client, area labeled "T". The intensity is not as important as the presence or absence of the lines.
- And for a negative result one line appears only in the control area and not in the test area.
- For an invalid result no line appears in the control area. If this happens do not report invalid results. Repeat the test with a new test device even if a line appears in the test area.

Record test results on appropriate forms. Discard the test and materials in the appropriate waste containers.

In review, collect all of the supplies and the Ora-Quick test kit. Only use a test kit that has not expired, been opened or been damaged. Record the appropriate information on the forms. Open the test packet and label the developer vial with the client information, and set it in the stand. Also, label the test device with the client information.

For a whole blood specimen from a finger prick fill the loop with the specimen. Put the loop into the developer vial all the way to the bottom and stir. Place the test device into the developer vial. Make sure the window faces towards you so it can be read. Start the timer and read the test results in 20 to 60 minutes.

For an oral fluids specimen, demonstrate how the client should swab their mouth. The client should gently swab around the outer gums with the test device, by gently wiping the porous flat pad completely across the upper and lower gums, one time around. Take the test device from the client and put it all the way down into the developer vial. Make sure the results window faces toward you so it can be read. Start the timer and read the test result in 20 to 60 minutes.

Next interpret the results. There are three possible results. A positive result has two lines of any intensity, one in the control area and one in the test area. A negative result has one line only in the control area and no line in the test area. For an invalid result no line appears in the control area. If this happens do not report invalid results. Repeat the test with a new test device even if a line appears in the test area.

And finally, record the test results on the appropriate forms and discard the used test and other materials in the appropriate waste containers.



Uni-Gold HIV is a rapid HIV test that detects antibodies to HIV Type 1 and Type 2. You need these standard supplies that are not included in the test kit as well as supplies required for a finger prick. You also need a Uni-Gold test that should be stored from 2-30 degrees Celsius. If the kit is refrigerated bring it to room temperature before performing the test. Only use a test that has not expired, been opened or damaged.

The kit includes 20 test devices, a vial of wash reagent, and 20 disposable pipettes. Use one device and one pipette for each test. Uni-Gold can be used with whole blood from either a finger prick or drawn from a vein, or with serum, or plasma.

Record the test date, client identification, the name of the person performing the test, the type of test, the test lot number, and the expiration date on appropriate forms.

After educating the client, you're ready to perform the Uni-Gold rapid HIV test. Record the client identification on the test device. As always, use universal safety precautions.

In this videotape, the test is demonstrated using whole blood from a finger prick. Fill the disposable pipette with the specimen. Hold the pipette over the specimen or sample port and add two drops, or approximately 60 microliters, to the specimen carefully. Add two drops, or approximately 60 microliters, of the wash reagent to specimen port. Start the timer and read the test results in 10 to 20 minutes. Discard the used gauze before the client leaves the testing area.

Next you interpret and record the results. There are three possible results.

- For a positive result two lines of any intensity appear in the window. One line appears in the control area which is labeled with a "C" and one in the client or test area which is labeled with a "T". The intensity in not as important as the presence or absence of the lines.
- For a negative result one line appears only in the control area and no line appears in the test area.
- For an invalid result no line appears in the control area. If this happens do not report invalid results. Repeat the test with a new test device even if a line appears in the test area.

Record test results on appropriate forms and discard the tests and materials in the appropriate waste containers.

In review, collect all of the supplies and the Uni-Gold test kit. Only use a test kit that has not expired, been opened or damaged. Record the appropriate information on the forms as well as the client identification on the test slide. Fill the disposable pipette with the specimen which can be whole blood from either a finger prick or drawn from a vein, or serum, or plasma. Hold the pipette over the specimen or sample port and add two drops, approximately 60 microliters, of the specimen carefully. Next add two drops, or approximately 60 microliters, of the wash reagent to the specimen port. Start the timer and read the test results in 10 to 20 minutes.

Next interpret and record the results. There are three possible results. For a positive result two lines of any intensity appear in the window. One line appears in the control area and one in the client or test area. For a negative result one line appears in the control area and no line appears in the test area. For an invalid result no line appears in the control area. If this happens do not report invalid results. Repeat the test with a new test device even if a line appears in the test region.

Finally, record the test results on the appropriate forms and discard the used tests and other materials in the appropriate waste containers.



Now that you've seen how to perform each of each of the different rapid HIV tests it's helpful to see how to perform more than one test at a time. Usually 2 rapid HIV tests are performed at the same time. If the tests have different results a 3rd test is used to determine the final decision.

There are advantages and disadvantages to starting the procedure of one test before the other. For example, in a combination of tests such as Capillus and Determine, you can start the Determine test first because it has fewer steps than Capillus, but Capillus has a shorter time to incubate. Practice performing both tests together until you're comfortable with knowing how to time the tests together.

With practice you'll also learn how to organize both test kits so they're easy to use and ready to receive the blood specimen. It's very important to separate the supplies for each test so one test doesn't get mixed up with the other test. That way you use the correct supplies with the correct kit.

It's also important to collect the blood specimen for both tests at the same time. This prevents you from having to prick the client more than once. In some situations you can use the same pipette to collect the blood specimen for both tests. You can also collect the blood specimen or a dried blood spot card for quality assurance or other purposes at this time.

The following demonstration shows a health care worker performing both the Determine and Uni-Gold rapid HIV tests at the same time. After making sure her work area is clean and disinfected, she organizes her supplies so that everything is within reach. As with all laboratory procedures she uses universal safety precautions to protect both herself and the client.

She also follows the quality assurance plan for her testing site to ensure accurate and reliable testing. First she checks the tests to make sure they have not expired, been damaged, or opened. She opens both test kits and organizes the supplies so she has each of the test materials separated to prevent getting the two tests mixed up. On appropriate forms she records all necessary information such as the types of tests, the test lot numbers, the expiration dates, as well as the test date, client identification, and her name since she is performing the test.

Next she's ready to perform the multiple tests. She uses a new pair of gloves with each client. And she has the client sit facing her so she can easily perform the tests. After educating the client, she records the client information on both of the test devices and begins performing the finger prick.

After performing a finger prick she also collects 50 microliters of blood with a micropipette for the Determine test. She applies the 50 microliters of blood to the absorbent pad on the Determine test strip.

While she waits 1 minute until the blood is absorbed on the pad she collects blood for the Uni-Gold test. She holds the pipette over the Unigold specimen port and adds two drops of blood carefully. She then adds two drops or approximately 60 microliters

of the wash reagent to the Unigold specimen port. Next she applies 1 drop of the chase buffer to the absorbent pad on the Determine test strip.

When she's sure she doesn't need any more blood she gives the client a piece of gauze to place on the finger until the bleeding stops.

She sets the timer for 15 minutes. The Uni-Gold test result is ready in 10 minutes and the Determine test result is ready in 15. Uni-Gold results are only stable for 20 minutes after adding the specimen to the device. Finally, she discards the used gauze before the client leaves the testing area.

Next, she interprets the tests. She checks the control lines to see if each test is valid. If the control line in either test shows an invalid reaction she should repeat the test with a new test device even if a line appears in the test area.

Usually both tests have the same results. If both tests have a positive result then the tests are to be interpreted as HIV positive. If both tests have a negative result then the tests are interpreted as HIV negative. If one test has a positive result and the other has a negative result, she has to collect another specimen and perform a third test to make the final decision. Your regional test plan indicates which test to perform for the tie breaker. If the third test has a positive result then the tests would be interpreted as HIV positive. But if the third test has a negative result then the tests would be interpreted as HIV negative.

Finally, she records the results in the appropriate forms and discards the tests and waste materials in the appropriate containers.

In review, keep the following things in mind when you're performing multiple tests at one time. Before you perform the tests on a client, practice each test separately so you know how to accurately perform each test together. Keep your work area clean and disinfected. Check the tests to make sure they have not expired, been damaged, or opened. Keep the supplies and tests organized so they are easy to use and the supplies for each test are kept separate. Record the appropriate information and client identification on the forms and the test devices.

After educating the client, perform a finger prick and collect the blood specimen for both tests at one time. If you're collecting a dried blood spot, collect the specimen on the card before collecting for the other tests to ensure you have at least one specimen. Now perform the rapid HIV tests following the standard operating procedures. Next, time both tests. Discard the used gauze before the client leaves the testing area. Interpret the test results. Check the control line to see if each test is valid. If no line appears in the control area this indicates an invalid reaction and you should repeat the test with a new test device even if a line appears in the test area.

Usually both tests have the same results. If both tests have a positive result then the tests are interpreted as HIV positive. If both tests have a negative result then the tests are interpreted as HIV negative. But if the tests have different results you need to perform a third test to make a final decision about the test. Your regional test plan indicates which type of test to perform to help determine the test results. If the third test has a positive result then the test results are interpreted as HIV positive. But if the third test has a negative result then the test results are interpreted as HIV positive. But if the third test has a negative result then the tests are interpreted as HIV positive.

Finally, record all of the test results on appropriate forms and discard all used materials in the appropriate containers.

In conclusion, as a health care professional you play an important role in helping clients learn their HIV status. As you saw in this videotape the rapid HIV tests are simple and easy to perform. It just takes a little practice to correctly perform the steps. In addition, you'll produce reliable and accurate results which you can confidently give to your clients if you follow quality assurance procedures, that is following written standard operating procedures, running positive and negative controls before client specimens, periodically rechecking rapid test results with ELISA results, and reporting only valid results.

For more information consult your local health officials or the companion training materials.

Practical Exercise Recording Worksheet

Instructions:

- 1. Place a (✓) in the space provided to indicate the practical session for which you are recording results.
- Record all results, including any tests repeated.
- 3. Fill out completely and accurately.

Name:		Date:_		
Session 1	Ses	sion 2	Final Pra	ctical Examination
	TEST 1	т	EST 2	TEST 3
Kit Name Lot # Expiry Date				
	н	V Rapid Test Res	ults	
SAMPLE ID	TEST 1	TEST 2	TEST 3	HIV Status
SAMPLE ID	Rep	eat Results (If Net	eded) TEST 3	HIV Status

Reason for repeats:

Test 1:	_
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Test 2:

Test 3:	