MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

Rapid HIV Testing

- This type of HIV testing makes it possible for the patient to get pre-test and post-test counseling, their test results, and any medical referrals they may need all in one visit and in a very short amount of time.

BENDING THE CURVES

Determine HIV Rapid Test

(For use with whole blood, serum, or plasma)

Store kit: 2 - 30° C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

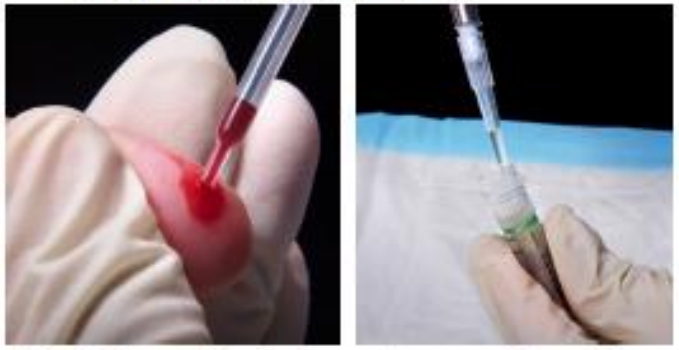
This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.

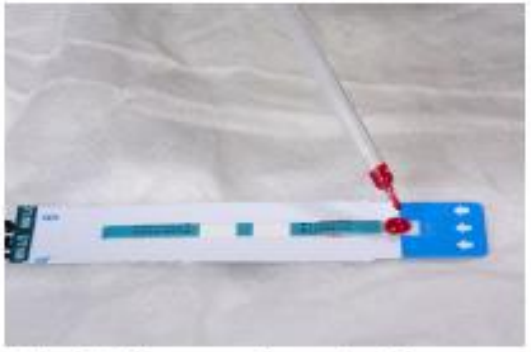
2. Use 1 strip per test and be sure to preserve the lot number on the remaining packet of strips.

3. Label the test strip with client identification number.

4. Pull off the protective foil cover.



5. Collect 50 µl of specimen using either a pasteur or precision pipette.



6. Apply the specimen to the absorbent pad on the strip.

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7. For whole blood only add 1 drop of chase buffer to the specimen pad.

8. Wait 15 minutes (no longer than 60 minutes) before reading the results.

9. Read and record the results and other pertinent info on the worksheet.

Determine HIV Rapid Test Results

Reactive

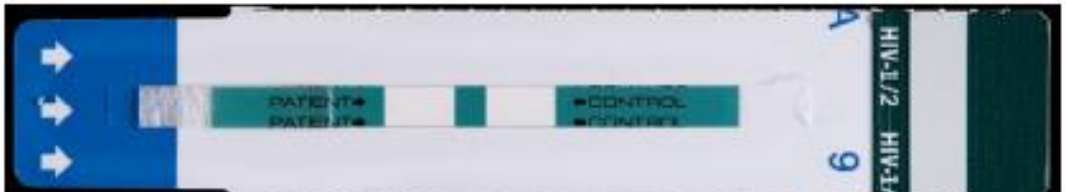
2 lines of any intensity appear in both the control and patient areas.

Non-reactive

1 line appears in the control area and no line in the patient area.

Invalid

No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the patient area.



Uni-Gold HIV Rapid Test

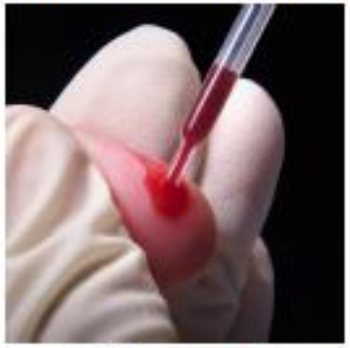
For use with whole blood, serum, or plasma
Store Kits: 2 - 30° C

- Check kit before use. Use only items that have not expired or been damaged.
- Bring kit and previously stored specimens to room temperature prior to use.
- Always use universal safety precautions when handling specimens. Keep work areas clean and organized.

This outline is not intended to replace the product insert or your standard operating procedure (SOP).

1. Collect test items and other necessary lab supplies.

2. Remove device from package and label device with client identification number.



3. Collect specimen using the disposable pipette.

4. Add 2 drops (approx. 60µl) of specimen to the sample port in the device.

5. Add 2 drops (approx. 60µl) of the appropriate wash reagent to sample port.

6. Wait for 10 minutes (no longer than 20 min.) before reading the results.

7. Read and record the results and other pertinent info on the worksheet.

Uni-Gold HIV Rapid Test Results

Reactive

2 lines of any intensity appear in both the control and test areas.

Non-reactive

1 line appears in the control area and no line in the test area.

Invalid

No line appears in the control area. Do not report invalid results. Repeat test with a new test device even if a line appears in the test area.

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What's Are the Advantages of A Rapid HIV Testing?

- There are distinct advantages of rapid testing over conventional testing. They include:
  - they are less costly for HIV testing agencies whose budgets are limited
  - almost all people tested will get post-test counseling and their results because only one visit is necessary
  - because results are delivered quicker, positive people get into medical care quicker
  - by learning of infections earlier, potential exposures that would have occurred between traditional testing and receiving results is reduced
  - rapid tests are easier to use
  - their results that are as accurate as a traditional Elisa test

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False Positive Tests Do Occur

- One problem with rapid HIV testing is the occurrence of false positive tests. I
- Experts urge that all positive rapid tests be confirmed with a conventional ELISA and Western Blot.

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Is a Confirmatory Test Required if the Rapid Test is Positive?

- As is true of conventional ELISA HIV testing, a positive rapid HIV test result should be confirmed with the Western Blot test.

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The ELISA / Western Blot

- The standard screening test for HIV is a blood test known as the *enzyme immunoassay (EIA)* or *ELISA* for short.
- This HIV testing requires a small sample of blood from the person being tested.
- Typically, the test requires two visits; one to receive pretest counseling and have your blood drawn and the second to receive HIV testing results, post-test counseling and medical referrals for HIV care if the results are positive.

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Getting an HIV test is easy; understanding an HIV test is not so easy.

- There is more than one type of HIV test used to determine if a person has been infected with HIV.
- These tests detect different substances in the blood that are present when a person has been infected with HIV.
  - One detects HIV proteins that circulate in the body after a person has been infected.
  - Two others detect HIV antibodies that have been produced by the body after HIV infection has occurred.

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Elisa

- This is the first step of an HIV test.
- This test detects the presence of HIV antibodies in the blood.
  - If the test is negative then the person is determined not to be HIV infected and testing stops there.
  - If the test is positive the second step of the test is run to confirm the positive results of the first step.

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Western Blot

- This test is used to confirm the positive Elisa test results.
- The Western Blot test detects specific protein bands that are present in an HIV infected individual.
- In combination with a positive Elisa, a positive Western Blot is 99.9 percent accurate in detecting that HIV infection has occurred.

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HIV PCR

- The HIV PCR test detects specific Deoxyribonucleic Acid (DNA) and Ribonucleic Acid (RNA) sequences that indicate the presence of HIV in the genetic structure of anyone HIV infected.
- After HIV infection occurs, RNA and DNA from the HIV virus circulates in the blood.
- The presence of these DNA and RNA "pieces" indicates the presence of HIV virus.

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HIV POSITIVE

- If an HIV infection has been confirmed, tests are routinely performed to determine the status of a person's immune system and the level of viral activity in the body.
- These are expressed in the **CD4 count** and **viral load**.

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CD4 Count

- The test measures the level of CD4 helper T-cells in the body—cells that are not only vital to immune function, but are the target of HIV infection.
- As HIV gradually depletes these cells, the body becomes less and less able to defend itself against a widening range of opportunistic infections.
- The test is performed by taking a blood sample, the results of which measure the number of CD4 cells in a microliter (µL) of blood.
  - This is known as the CD4 count.

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CD4 Count

- The baseline CD4 count establishes the status of your immune system, while follow-up testing largely determines:
  - the stage of infection and the rate (or speed) of disease progression
  - the likelihood of certain infections developing as CD4 cells are depleted
  - when antiretroviral therapy is needed to avoid these infections, and
  - how well you respond to therapy, either by maintaining or "reconstituting" your immune function.

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CD4 Count

- Normal CD4 counts are anywhere between 500-1,500 cells/ µL.
- Most treatment guidelines recommend that antiretroviral therapy be started with a CD4 count of under 350 cells/µL, or in the presence of an AIDS-defining illness.
- A CD4 count of 200 cells/ µL or less is technically classified as AIDS.
  - Research has shown that initiating therapy at or below this level correlates to poorer clinical outcomes and the reduction in life expectancy by as much as 15 years.

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Viral Load

- While the CD4 count is an indicator of immune status and treatment efficacy, the viral load is arguably the more important measure when antiretroviral therapy begins.
- The viral load measures the amount of virus in the blood.

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Tests for Viral Load

- Labs typically use two types of test—a PCR (polymerase chain reaction) or a bDNA (branched DNA)—to quantify the number of HIV RNA copies in a milliliter (mL) of blood. HIV viral load can range from "undetectable" (or below the detection levels of testing assays) to the tens of millions.

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Undetectable Viral Load

- An undetectable result does not mean that there is no virus or that a person is "clear" of HIV. In fact, less than 5% of HIV in the body can be found in the blood. It simply means that the virus population has fallen below testing detection levels.

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Goals of Viral Suppression

- The aim of antiretroviral therapy is to fully suppress viral activity to undetectable levels, which, in turn, is associated with:
  - greater drug durability (i.e. the drugs last longer)
  - a lower risk for the development of drug resistant virus
  - better clinical outcomes correlating to increased life expectancy, and
  - the potential reduction of HIV transmission risk to an uninfected sexual partner (a strategy referred to as "treatment as prevention").

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Drug Adherence

- An increase in the viral load can often be an indication of a failing drug regimen, poor drug adherence, or both.
- It's important to note that drug adherence of at least 95% is required to ensure viral suppression to undetectable levels.
- Uneven adherence not only reduces a person's ability to achieve this, it increases the likelihood of treatment failure by allowing drug resistant virus to develop.
- This cause-effect relationship is the reason adherence should always be checked before therapy is changed.

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Blips

- That said, incidental variations in viral load (or "blips") can occur even among those with 100% adherence.
  - These are usually minimal and should not be the cause for alarm.
- Regular monitoring of the CD4 count and viral load is recommended, usually every three to six months as indicated by the doctor until the CD4 is above 300, after which the CD4 should be checked every 6 or 12 months.

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