revealHIV

rapid HIV antibody test

A Quick Reference Guide

This guide provides basic information about the testing procedure, interpretation of test results and the limitations of the test. However, it does not replace the Package Insert, which must be read carefully and completely prior to use of the test.

- ***Perform the test on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.***
- ***Once the assay has been started, all subsequent steps should be completed without interruption.***
- ***All solutions must be completely absorbed into the test membrane before proceeding to the next step in the testing procedure.***
- ***Read the test results immediately. Failure to do so may result in inaccurate test results.***

1. Holding the Universal Buffer bottle with the drop dispenser on a slight angle from vertical, apply **3** drops of the buffer to the centre of the test membrane. Allow the buffer to absorb completely.

2. Uncap the specimen tube(s). With the disposable pipette provided in the Test Cartridge Mylar pouch, draw the specimen into the channel of the pipette. Apply 1 drop of specimen to the centre of the test membrane. If the specimen does not completely absorb into the test membrane within 30 seconds, centrifuge an aliquot of the specimen at room temperature (15 - 27°C) at 6000 rpm for at least 5 minutes. Retest the clear supernatant using a new test before proceeding to the next step.

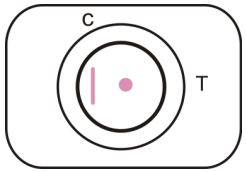
3. Holding the Universal Buffer bottle with the drop dispenser on a slight angle from vertical apply 3 drops of the buffer to the centre of the test membrane. Allow the buffer to absorb completely. **Do not touch the membrane with the drop dispenser tip.**

4. Apply **4** drops of the reconstituted Colorimetric Detection Agent to the centre of the test membrane using a small disposable pipette provided in the poly zipper bag. Allow the solution to absorb completely. **Do not touch the test membrane with the pipette tip.**

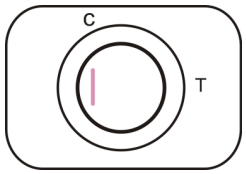
5. Holding the Universal Buffer bottle with the drop dispenser on a slight angle from vertical apply **3** drops of the buffer to the centre of the test membrane. Allow the buffer to absorb completely. **Do not touch the test membrane with the drop dispenser tip.**

Read results immediately as indicated in the Test Results and Interpretation of Results section on the reverse side.

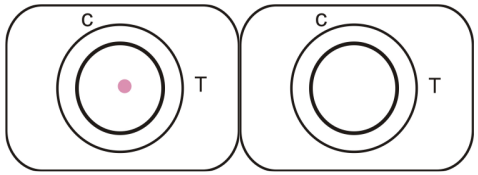
TEST RESULTS AND INTERPRETATION OF RESULTS



Reactive Result
The diagram is an example of a *Reactive Result*. The presence of a red dot, regardless of intensity, on the test membrane across from the letter **T** indicates that HIV-1 and/or HIV-2 antibodies have been detected. The presence of the red vertical control line under the letter **C** validates the test. Accordingly, the test result is interpreted as *Preliminary Positive* for HIV-1/HIV-2 antibodies.



Non-Reactive Result
The diagram is an example of a *Non-Reactive* result. The absence of a red dot on the test membrane across from the letter **T** indicates that HIV-1 and HIV-2 antibodies were not detected. The presence of the red vertical control line under the letter **C** validates the test. Accordingly, the test result is interpreted as *Negative* for HIV-1/HIV-2 antibodies. (A uniform, faint pinkish background may be visible on the test membrane).



Invalid Result
The diagrams are examples of an *Invalid* result. The absence of the red vertical control line under the letter **C** or the presence of a broken control line indicates that there has been a problem with the test reagents or the testing procedure. Also, a problem with the test specimen will occasionally result in a high background colour on the test membrane, which will not permit reading of the test result. Accordingly, in all of these instances (as shown in the diagrams to the left), the test result is deemed *Invalid* regardless of the specimen test result.

- Any specimen with a Reactive result should be retested in duplicate to confirm the initial result, and all repeatedly Reactive results confirmed by appropriate supplemental tests such as the Western blot test, or by suitable tests of multi-test algorithms.
- If an Invalid test result is obtained, testing should be repeated using a new test cartridge.
- Specimens yielding a high background colour should be tested using an alternate method.

Limitations:

The test results should not be used in isolation but in conjunction with clinical status, history, and risk factors, etc., of the individual being tested. The performance of the Reveal® Rapid HIV Antibody Test has been evaluated through limited studies. Although these studies have shown a high level of sensitivity and specificity of the test, both false positive and false negative results can be expected with a screen test of this nature. Please refer to the Package Insert for additional details.

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