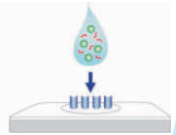
RAPITEST™ HIV 1&2

INTRODUCTION:

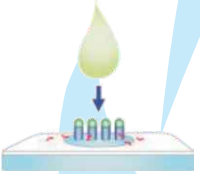
Rapitest™ HIV 1 / 2 is a direct binding flow through immunoassay for the detection of of antibodies to HIV 1 and HIV 2 viruses in human serum and plasma. Highly purified recombinant HIV 1 [gp41 & gp120] and HIV 2 [gp 36] antigens are used for the simultaneous detection and differentiation of antibodies to HIV 1 and HIV 2 . This test is very sensitive and rapid. Results are interpreted in less than 5 minutes. Test results are read visually without any instruments.

HOW IT WORKS:

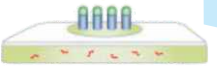


Serum sample is dropped on the surface of the membrane.

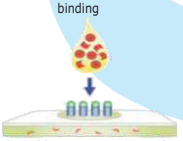
While sample flow through the membrane the analyte is captured on the analyte capture molecule



The membrane is washed to get rid of non specific background binding



Wash buffer flow through the membrane washing away the material that not bound by the analyte capture molecule.



The gold conjugate is dropped on the membrane and it flows through the membrane, the detection molecule binds to the captured molecule and gives visual detection

Wash buffer is added to remove the unbound conjugate and gives the clear visual reaction

PRINCIPLE:

Rapitest™ HIV 1 / 2 Serum (Flow - Through) Test is a membrane based test, which is coated with recombinant antigens specific to HIV 1 antibodies at test region "1" and HIV 2 antibody specific antigens at test region "2". The control Region "C" is a performance control. The reaction well is initially washed with a wash buffer in order to make the membrane ready for testing, then the serum / plasma specimen is added. The respective antigens coated in the membrane captures respective antibodies to HIV 1 / 2 in the serum / plasma, if the specimen has antibodies to HIV 1 / 2. The membrane is again washed to remove excess and un reacted antibodies in the membrane. Prior washing, Protein A conjugated gold sol reagent is added to visualize the presence of bound antigen & antibody complex. A final wash is done to clear the back ground left with pink dots. dots at test region "1" & "2" and control region "C" is a positive result and absence of dot at test region "1" & "2" is a negative result. No dot at region "C" indicates the test is "INVALID".

KIT CONTENTS:

Rapitest™ HIV 1 / 2 Flow – Through Test is supplied with

1. Rapitest™ HIV 1 / 2 Flow - Through Test cassettes - pouched with a sample dropper and a silica gel
2. Wash buffer
3. Protein A conjugate
4. Instruction Manual

STORAGE AND STABILITY:

The test kit can be stored at temperatures between 2°C to 8°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. Do not freeze.

PRECAUTION:

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not intermix reagents from different lot.
5. Do not change the sequence of addition of reagents.
6. Follow standard guidelines for personal safety, handling and disposal of potentially infectious materials.
7. Do not use Whole blood / turbid serum sample.
8. Do not use the kit if the pouch is damaged or the seal is broken.
9. The instructions should be followed exactly to get accurate results.
10. Do not eat or smoke while handling samples.

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SPECIMEN COLLECTION & PREPARATION:

Rapitest™ HIV 1 / 2 Flow - Through Test can be run on serum and plasma samples. The test works best on fresh samples. For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing. For plasma samples, separate the plasma from centrifugation. If the specimen cannot be tested on the day of collection, store the specimen in a refrigerator (at 2 to 4°C) for up to 3 days. If testing cannot be done within 3 days, specimens should be stored in a freezer (at -20°C or colder). Make sure to stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE:

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch and use it as soon as possible.
2. Add **5** drops of the wash buffer to the reaction well, allow it to be absorbed.
3. Using the disposable dropper provided, add **one drop (50 µL)** of serum/plasma to the reaction well of the test device, and let it to be absorbed.
4. Add **5** drops of the wash buffer to the reaction well, allow it to be absorbed.
5. Use the Protein-A conjugate dropper bottle provided, add **5** drops into the sample well.
6. Add **5** drops of the wash buffer to the reaction well, allow it to be absorbed.

READ RESULTS IMMEDIATELY
READING TOO LATE CAN GIVE FALSE RESULTS.

INTERPRETATION OF RESULTS:

NEGATIVE :

Only one colored dot appears on the control (C) region. No dot on the test (T) region.

HIV 1 POSITIVE:

In addition to a pink colored control(C) dot, a distinct pink colored dot will also appear in the test region 1.

HIV 2 POSITIVE:

In addition to a pink control (C) dot, a distinct pink colored dot will also appear in the test region 2.

HIV 1 & 2 POSITIVE:

In addition to a pink control (C) dot, a distinct pink colored dot will also appear in the test region (1) & (2).

INVALID:

A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

1. Test dots HIV-1 and HIV-2 either dark or light in pink color should be considered reactive.
2. All initially reacted samples should be subjected to centrifugation at 10000 rpm for 10 min. The test should be repeated with supernatant collected after centrifugation. If no dot appears on repetition it indicates a falsely reactive sample. A truly reactive sample will not show much change in its color intensity after centrifugation.
3. The false reactivity of the sample is generally due to the presence of suspended particulate matter in the serum which may or may not be visible to the naked eye.
4. If the sample does not soak- in 60 seconds, the sample should be observed for any suspended particulate matter. If it present, centrifuge the sample at 10000 rpm for 15 min. Use a fresh device to re-run the test.
5. Sample found to be reactive by the above screening test must be confirmed by standard supplemental assay, like Western Blot.
6. This test is not an confirmatory test, a positive or negative result at any time does not preclude the possibility of HIV -1 and /or -2 infections.

PERFORMANCE AND CHARACTERISTICS:

In an in-house trial, one thousand and five hundred samples were tested in parallel with a licensed commercially available CE Marked Device and Rapitest HIV 1/ 2. The results obtained as follows.

Sample	No. of Samples	CE Marked Device	Rapitest HIV 1 / 2
Negative for HIV antibodies	1225	1225	1225
Positive for Ab. to HIV-1	245	245	245
Positive for Ab. to HIV-2	18	18	18
Positive for Ab. to HIV-1 & 2	12	12	12

Based on this evaluation the sensitivity and specificity of RAPITEST HIV 1 /2 is 100 % each.

BIBLIOGRAPHY

1.Retroviruses (HTLV-III) in the serum of patients with AIDS, M.G Sarangadharan, et al., Science, Vol.224, 506-508, 4 May 1984.

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3. Principle and Practice of Infectious Diseases, Mandell, Bennett and Dolin, 5th Ed., Vol 1-Part II, 1332-1528, 2000, Churchill Livingstone Publications.

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