

HEALTH-CHEM DIAGNOSTICS LLC

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RAPIDTEST HIV® SCREEN – LATERAL FLOW

NAME AND INTENDED USE

The **RAPIDTEST HIV Lateral Flow** test is for the rapid detection of HIV-1 and HIV-2 antibodies in saliva, whole blood, plasma or serum. Both the testing and the results of the testing are intended to be used by medical and legal professionals only, unless otherwise authorized by regulation in the country of use. Not intended for sale in the USA or its Protectorates. The test should not be used without appropriate supervision. The **RAPIDTEST HIV® Lateral flow** test is intended only as an initial screening test and reactive samples should be confirmed by a supplemental assay such as the Western Blot test.

<i>Simple:</i>	Requires no expensive equipment No incubations
<i>Rapid:</i>	Takes only 3-5 minutes to complete
<i>Convenient:</i>	All reagents are ready to use
<i>Safe:</i>	Contains no infectious materials
<i>Easy:</i>	Two Lines indicate a POSITIVE One Line indicates a NEGATIVE
<i>Complete:</i>	Contains all materials to collect the specimen and run the test

EXPLANATION OF THE TEST

The Human Immunodeficiency Virus (HIV) is the causative agent of Acquired Immune Deficiency Syndrome (AIDS). The normal method of detecting infection with HIV is by observing the presence of antibodies to the virus by the ELISA method, followed by confirmation with the Western Blot Test.

Most manufacturers have produced the ELISA test in a micro-titer plate format which requires sophisticated and expensive equipment to obtain a result. Also, it requires highly skilled personnel to perform the test. In many developing world countries the equipment and staff to run these sophisticated tests are limited, and as a result infected blood is still being used for transfusions and many people remain undiagnosed. Therefore, there is a great need for a simple, manual, visual and robust test that can be used to quickly test blood or saliva for HIV antibodies. The **RAPIDTEST HIV® Lateral flow** test is a membrane-based solid phase assay* which uses only one reagent and can provide a definitive result in as little as 3-5 minutes. The assay contains antigens which capture the antibodies from a plasma, serum or saliva sample on a membrane. The antigen/antibody complex is visualized by the reaction of a secondary antibody gold complex which produces a pink to red color. A positive sample produces two distinct red lines on the membrane while a negative sample

produces only one line. The antigens used consist of the specific reactive components of both HIV-1 and HIV-2.

The capture antigens used in this new generation test are recombinant peptides which correspond to highly immunoreactive regions of HIV-1 and HIV-2. Five (5) surface and three (3) core binding sites have been identified. The antigens are absorbed on a nitrocellulose membrane and can capture any HIV antibody present in the sample.

The assay starts with the application of a saliva sample followed by the accompanied diluent applied to the sample well. A HIV antibody-binding colloidal gold-antigen conjugate embedded in the sample pad reacts with the HIV antibody present in the saliva, serum or plasma sample forming conjugate/HIV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HIV antibody complex is captured by an antibody-binding protein A immobilized on a membrane forming a pink test band in the test region. A negative sample does not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. The antigens used in the conjugate test are recombinant proteins which correspond to highly immunoreactive regions of HIV-1 and HIV-2. A pink control band in the control region appears at the end of test procedure regardless of test result. This control band is the result of colloidal gold conjugate binding to an anti-HIV antibody immobilized on the membrane. The control band indicates that the colloidal gold conjugate is functional.

MATERIALS PROVIDED

1. Test slide
2. Sample diluents
3. Saliva collection device(s) (Sani-Sal®)
4. Instruction for use.

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and Negative Controls

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic and laboratory investigational use only.
- Keep out of reach of children.
- For professional medical and legal use only, unless otherwise authorized by regulation in the country of use.
- All positive results may be confirmed by an alternate method.

- Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
- Devices used for testing should be autoclaved before disposal.
- Do not use kit materials beyond their expiration dates.
- Do not interchange reagents from one kit lot to another.

SAMPLE COLLECTION AND HANDLING

While saliva is recommended as the sample, plasma and serum will also work. Only use fresh saliva collected with a SaniSal® Saliva Collection Device. If the test is not performed immediately, saliva samples should be kept refrigerated. Do Not Freeze.

For saliva collection, Use the following procedure:

1. Hold the saliva collection device **by the cap only**. Twist and pull the device from the flexible test tube. Place the device between the cheek and gum for about 4 minutes or until the foam sponge has expanded and thoroughly wetted.
2. Remove the saliva collection device from the mouth (again handling only by the plastic cap), and re-insert the wet device into its flexible test tube by twisting gently.
3. Pull the cylinder from the tube. Finger squeeze (or centrifuge, if necessary) the flexible plastic test tube to extract the saliva sample to the bottom of the test tube.
4. Re-assemble the saliva collection device and discard it along with the attached cap. Use appropriate precautions and procedures for waste disposal. The saliva sample may be transferred from the bottom of the test tube using the dropper pipette.

INSTRUCTIONS - SAMPLE PREPARATION & ASSAY PROCEDURE

1. Bring diluent and specimens to room temperature.
2. Remove slide from sealed pouch (Serum/Whole Blood pouches contain a micro-pipette, to aid in transferring samples to the respective wells).
3. FOR SALIVA, add 50µL (1 drop from a Sani-Sal® Saliva Collector) of saliva sample to the front of the sample well (closest to the test area). When using a Serum/Whole Blood Test Device, sample should be placed in the front well marked "Patient S" using the enclosed pipette.
4. Dispense drop wise 100µL (2 drops) of SAMPLE DILUENT to the rear of the sample well immediately. If using a Serum/Whole Blood Test Device, dispense in the diluent hole, marked "D".
5. **REACTION TIME:** The Health-Chem Diagnostics RAPID HIV® SCREEN – LATERAL FLOW is a membrane-based solid phase assay, which uses only one reagent and can provide a definitive result in 3-5 minutes. Read the test results within 10 minutes for

easiest interpretation. A very weak positive could react in as long as 30 minutes. Do Not interpret the results after ONE HOUR.

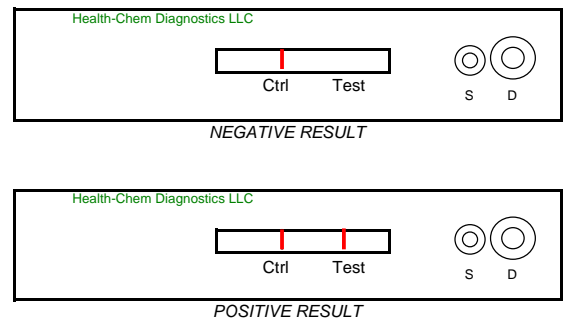
Note: Positive result could appear as soon as 1 minute for a sample with high levels of HIV antibodies.

PRECAUTIONS

- If at all possible, use fresh samples with the test.
- Saliva specimens may be infectious, although the risk of infection from saliva is lower than the risk from plasma or serum. Properly handle and dispose of all used reaction devices in an approved biohazard container.

READING THE TEST RESULTS

1. Positive: A pink test band appearing in the test region indicates a positive result. The lower the antibody concentration, the weaker the test band may be.
2. Negative: The absence of a pink test band in the test region indicates a negative result,
3. Invalid: There should always be a pink control band in the control region regardless of test result. If control band is not seen, the test is considered invalid; some test should be repeated using a new test device.



STORAGE

It is recommended that all components provided should be stored REFRIGERATED at 4 to 8 degrees C. or in the coolest and driest area available. All components are stable, if stored and transported properly, for 12 months. DO NOT FREEZE. Allow solutions to reach room temperature before performing the test,

RECENT STUDY RESULTS

Specificity- 100%*

In an in-house laboratory study, Saliva from 63 confirmed negative with Western Blot whole blood samples were evaluated with RAPIDTEST HIV® SCREEN - Lateral Flow test using both, EIA and Western Blot as reference tests. The study gave 100% specificity for the test.

Sensitivity- 100%*

In the above mentioned study, RAPIDTEST HIV® SCREEN – LATERAL FLOW Test was evaluated with 32 confirmed whole blood positive samples. The sensitivity of RAPIDTEST HIV® SCREEN Lateral Flow test was found to be 100% relative to Western Blot assay.

Sensitivity and Specificity were also confirmed by the following outside studies:

	PATCH*	Ghana	South Africa	Chan, Et Al. Canada Ref#11	R.J. Sherman Ref#12 (Saliva vs Western Blot)
SENSITIVITY	99.5%	100%	98.0%	100%	99.9%
SPECIFICITY	99.3%	100%	100%	98.1%	99.7%
N =	457	100	107	296	1938

PATCH*: The Program for Appropriate Technology in Health (WHO Collaborating Center on AIDS). These studies were conducted in the following geographic regions, over a two year period:

Region: USA=230 / INDIA=84 / SUB-SAHARA-AFRICA=78 / SOUTHEAST ASIA=16 / MEXICO=49.

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Manufactured by:

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