

Rapid Immunochromatography Test For HIV 1 / 2 - WB

INTENDED PURPOSE

Retrocheck® HIV - WB is an *in vitro*, rapid, qualitative two site sandwich immunoassay used for the detection of antibodies to HIV 1 / 2 virus in human serum, plasma and whole blood. For Professional use.

SUMMARY

Retrocheck® HIV - WB is using an immunochromatography method for the detection of antibodies to HIV 1 / 2 virus in human serum, plasma and whole blood. Highly purified antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide representing HIV-1 and gp 36 representing HIV-2 are used in this test to detect antibodies to HIV 1&2.

PRINCIPLE

Retrocheck® HIV - WB utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane. A mixture of highly purified recombinant antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide, representing HIV-1 and recombinant gp36 representing HIV-2 are coated on the membrane in the test region and anti-rabbit antiserum in the control region.

As the test sample flows through the membrane assembly within the test device, the colored HIV 1 / 2 specific recombinant antigen-colloidal gold conjugate complexes with HIV antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the HIV 1 / 2 specific recombinant antigens coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Retrocheck® HIV - WB kit has the following components.

A. Individually pouched devices comprising of:

1. Test Device : Comprising of HIV 1 / 2 specific recombinant antigen-colloidal gold conjugate, Rabbit IgG- colloidal gold conjugate, membrane assembly predisposed with HIV 1 / 2 specific recombinant antigen and goat anti-rabbit antiserum coated at the test region and the control region respectively.
2. Disposable Plastic Dropper.
3. Desiccant Pouch.

B. Sample Running Buffer: 0.1 M Tris buffer with 1.5% Tween 20 and 0.1% Sodium azide.

REF	Cat. No./Component	402010001	402010010	402010025	402010050	402010100
	Test Device	1	10	25	50	100
	Sample Running Buffer	1ml X 1 bottle	5ml X 1 bottle	10ml X 1 bottle	10ml X 2 bottles	10ml X 4 bottles

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the bottle.

After first opening of the sample running buffer bottle, the buffer is stable until the expiration date, if kept at 4°C to 30°C.

Do not freeze the kit or components.

NOTES

1. For *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.
7. If the color of the desiccant has turned from blue to white at the time of opening the pouch, another test device must be run.
8. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. No prior preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Anticoagulated whole blood can also be used as specimen. Whole blood or plasma specimens containing anticoagulants other than EDTA, Trisodium - citrate or Heparin may give incorrect results. Serum/Plasma may be stored at 2-8°C upto 24 hours in case of delay in testing. For long-term storage, freeze the specimen at -20°C. Whole blood should be used immediately and should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided. Maximum of 2 freeze/thaw cycles are allowed.
4. Do not use haemolysed, clotted, contaminated, viscous / turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not heat inactivate the sample before use.
7. Frozen samples for retrospective studies must be centrifuged at 3000 rpm for 15 minutes and the clear supernatant must be used for tests.

Precautions under the HIV regulations:

1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HIV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Let the sealed pouches attain room temperature (20-30°C).
2. Tighten the cap of sample running buffer bottle clockwise to pierce the dropper bottle nozzle. The pin situated inside the buffer bottle cap will break through the plastic membrane which seals the opening of the dropper bottle.
3. Tear open the sealed pouches and retrieve the appropriate number of test device as required. Label the test device appropriately. Once opened, the devices must be used immediately.
4. The addition of the specimen and buffer must be done at the center of the sample/reagent addition ports holding the sample dropper / dropper bottle in a vertical position. Ensure the drops are free falling. Use a new sample dropper for each specimen to avoid cross contamination.
5. Dispense two drops (50 µl) of serum / plasma OR whole blood using the sample dropper provided into the sample port "A".
6. Dispense five drops of sample running buffer into reagent port "B".
7. Between 15-30 minutes after addition of buffer, read the results as follows:

**Positive**

If HIV-1 and/or HIV-2 antibodies are present, two colored bands appear at Test (T), and Control (C) region.

**Negative**

If HIV-1 and/or HIV-2 antibodies are not present, only one colored band at Control (C) would appear.

**Invalid**

The test is invalid if the Control band is not visible at 30 minutes. Verify the test procedure and repeat the test with a new **Retrocheck® HIV - WB** device.

**Invalid**

The test is also invalid if only the Test band and no Control band is visible at 30 minutes. Verify the test procedure and repeat the test with a new **Retrocheck® HIV - WB** device.

8. Negative results must be confirmed only at the end of 30 minutes although, depending on the concentration of antibodies to HIV in the specimen, positive results may start appearing as early as 2 minutes.

REMARK

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. Diagnostic Specificity:

A total of 1040 samples were tested with **Retrocheck® HIV - WB** at French Establishment of Blood, (E.F.S.), Nord de France, C.Q.F.D. Laboratory, 12, Boulevard de Belfort. The diagnostic specificity is determined as 100 %.

Number of samples tested	Retrocheck® HIV - WB	
	Negative	Positive
1040	1040	0

2. Diagnostic Sensitivity:

523 HIV positive samples were tested with **Retrocheck® HIV - WB**, all of them were found positive. The diagnostic sensitivity is determined as 100%.

HIV Type	Number of samples tested	Retrocheck® HIV - WB	
		Negative	Positive
HIV-1	360	0	360
HIV-2	100	0	100
HIV-1 subtype non-B	63	0	40

3. Possible interferences:

The table below shows the results of **Retrocheck® HIV - WB** tested on a variety of samples containing possibly interfering substances.

Sample type	Number of samples tested	Retrocheck® HIV - WB	
		Negative	Positive
Clinical specimens	200	200	0
Pregnant women	201	201	0
Related infection(*)	100	100	0

(*) The results were negative for samples containing CMV Ab Positive (13), HCV Ab Positive (17), VZ IgG Ab Positive (4), EBV Ab Positive (8), HBs Ag Positive (16), HA IgG Ab Positive (10), HTLV Ab Positive (13), Rubella Ab Positive (10) and Parvovirus B19 Ab Positive (9).

4. Seroconversion Panels:

The sensitivity, evaluated on 32 commercially available seroconversion panels (available from Sera Care Diagnostics) were screened with 2 CE marked EIAs: Vironostika HIV Ag/Ab (bioMerieux), Vironostika HIV Uniform II Ag/Ab (bioMerieux), Enzygnost Anti-HIV ½ Plus (Siemens) or Genscreen HIV ½ v2 (BIO-RAD) and the INNOSTEST HIV Antigen mAb (Fujirebio) and further characterized by the CE marked INNO-LIA HIV I/II Score (Fujirebio).

5. Precision:

Repeatability and Reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples. No variations were found in the outcome of the various tests.

LIMITATIONS OF THE TEST
















- The test detects the presence of antibodies to HIV in the specimen and hence should not be used as the sole criterion for the diagnosis of HIV infection.
- As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion still exists, additional follow-up testing using other clinical methods is recommended.
- A negative result at any time does not preclude the possibility of exposure to or infection with HIV.
- A positive test result, even a very faintly positive, must be verified with a confirmation test.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

- Popovic, M., et al., Detection Isolation and continuous production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and pre-AIDS. Science 1984;224:497.
- Carlson, J. R., et al., AIDS serology testing in low and high risk groups. JAMA 1985;253:3405.
- Centers for Disease Control, Update on Acquired Immune Deficiency Syndrome (AIDS) MMWR 1982;31:507.
- Gallo, R. C., et al., Frequent detection and isolation of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and a risk for AIDS. Science. 1984; 224:500.
- Data on file: Qualpro Diagnostics.

 2265			
 Temperature Limit	 Consult Instructions for use	 Date of Manufacture	 Do not re-use
 Manufacturer	 In vitro Diagnostic Medical Device	 Authorised Representative in the European Community	
 Use-by Date	 Catalogue Number	 Device	 Sample Running Buffer
 Contains sufficient for <n> tests	 Batch Code	 Disposable Plastic Sample Dropper	



Manufactured by:

Qualpro Diagnostics

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