NEW LAV BLOT II

18 REF 72252

A qualitative assay for the confirmation of human antibodies to HIV-2 in serum or plasma specimens

IVD CE 0459

0001355 - 2024/11

IFU compliant with Regulation (EU) 2017/746.

Major changes to the previous version are shaded gray. A gray title indicates significant changes in the content of the chapter, please read carefully.

For the European Union (Regulation 2017/746/EU), the Summary of Safety and Performances of this device is available via EUDAMED public access https://ec.europa.eu/tools/eudamed

BIO-RAD

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1. INTENDED USE

The NEW LAV BLOT II is a qualitative assay intended for the confirmation of human anti-HIV-2 antibodies in serum or plasma specimens by immunoblotting for patients from the general population with reactive screening results, within the scope of AIDS diagnosis.

2. SUMMARY AND EXPLANATION OF THE TEST

Discovered in 1983, the human immunodeficiency virus (HIV) is a retrovirus identified as the etiologic agent for acquired immunodeficiency syndrome (AIDS) [1, 2]. AIDS is characterized by changes in the population of T-cell lymphocytes that play a key role in the immune defense system. In the infected individual, the virus causes a depletion of a subpopulation of T-cells, called T-helper cells, which leaves these patients susceptible to opportunistic infections and certain malignancies. The major routes of transmission are sexual contact, contamination by blood or blood products and mother-to-newborn transmission [3, 4].

As of June 2021, 79.3 million people have been infected with the HIV virus, and about 36.3 million people have died of HIV/AIDS since the beginning of the epidemic. Globally, 37.7 million people worldwide were living with HIV at the end of 2020. However, the burden of the epidemic continues to vary considerably between countries and regions [11].

Two types of viruses have been isolated. The first one, named HIV-1, was isolated in France and then in the United States [1, 2]. The second one named HIV-2 was isolated from two patients living in Africa and has proved to be responsible for a new AIDS focus in West Africa [5, 6].

Knowledge of the genetic variability of the HIV virus strains was acquired by sequencing the genes of the representative strains of each subtype. HIV-2 is classified into nine groups: A, B, C, D, E, F, G, H, and I. A and B represent the two largest groups [7]. Overall, HIV-2 group A predominates and HIV-2 group B is less prevalent and co-circulates with HIV-2 A mainly in Ivory Coast and Ghana [8]. Recombinants between HIV-2 groups A and B have also been reported, and the first circulating recombinant form of HIV-2 (CRF01_AB) has been identified in three patients living in Japan [9]. The other HIV-2 groups have been documented in one or two individuals and represent most likely dead-end infections or infections associated with very low spread.

Screening is based on the detection of HIV antibodies and/or antigen in serum or plasma using the enzyme immunoassay technique. The quality of the biologicals used in these tests does not allow some non-specific responses to be eliminated. Considering the severity of the stated diagnosis, it is necessary to confirm or invalidate the screening test results by another technique. Immunoblotting (Western Blot) is a technique that allows the characterization of the antibodies directed against each virus protein, thus confirming seropositivity or identifying possible non-specific reactions [10].

The NEW LAV BLOT II assay includes all the reagents required to perform confirmatory tests by immunoblotting.

3. PRINCIPLES OF THE PROCEDURE

The test is based on the indirect ELISA technique on a nitrocellulose strip containing all the HIV-2 constituent proteins and an internal anti-IgG control. The band corresponding to the internal control is localized on the strip end without any number before the p16 reaction and is used to validate the addition of the specimen and reagents as well as the correct progress of the procedure.

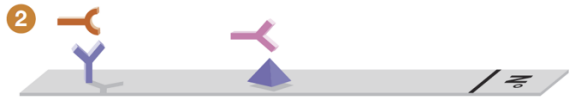
Inactivated HIV-2 proteins are separated according to their molecular weights by polyacrylamide gel electrophoresis in dissociating and reducing medium and subsequently electrically transferred onto a nitrocellulose membrane sheet.

The procedure comprises the following steps:

1. Strip rehydration.
2. Incubation of the specimens to be confirmed or the control serums.
   If anti-HIV-2 antibodies are present, they bind to the identified viral proteins present on the strip.
3. After washing, the alkaline phosphatase-labeled anti-human IgG antibodies are incubated. The conjugate binds to anti-HIV-2 antibodies captured on the solid phase.
4. After washing and removing the excess conjugate, the color development solution demonstrates the enzymatic activity of the complexes bound to the nitrocellulose.
5. The appearance of specific colored bands demonstrates the presence of anti-HIV-2 antibodies in the specimen.

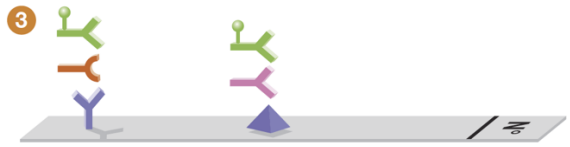
Test Format

- NEW LAV BLOT nitrocellulose strip
- 2 ml of working buffer solution/diluent
- Incubate for 5 minutes at room temperature with slow shaking



- 20 µl of sample or controls
- Incubate for 2 hours at room temperature with slow shaking

Wash



- 2 ml of conjugate solution
- Incubate for 1 hour at room temperature with slow shaking

Wash

- 2 ml of color development solution
- Incubate for 5 minutes at room temperature with slow shaking

Wash, Dry and Read

Internal anti-IgG antibodies control	HIV native proteins	Alkaline phosphatase anti-human IgG antibodies conjugate	Human IgG antibodies from samples	Anti-HIV antibodies from positive samples

4. REAGENTS

Each kit contains reagents sufficient for 18 determinations. The determinations may be performed in multiple independent runs.

4.1 Description

Identification on label		Description	Presentation/Preparation
R1	**HIV-2 Nitrocellulose Strip**	HIV-2 nitrocellulose strip Activated by transfer of HIV-2 viral proteins and internal anti-IgG control Strips are placed in disposable trays	18 strips in 3 trays (6 cells each) Ready for use
R2	**Buffer Solution/Diluent (5X)**	Buffer solution/diluent (concentrated 5X) Contains 0.5% chloroform	1 vial 100 ml To be diluted
R3	**Negative Control**	Negative control Human serum negative for HBsAg, anti-HIV-1, anti-HIV-2 and anti-HCV antibodies Preservative: < 0.1% sodium azide	1 vial 0.2 ml Ready for use
R4	**Anti-HIV-2 Positive Control**	Anti-HIV-2 positive control Human serum positive for anti-HIV-2 and anti-HIV-1 antibodies, negative for anti-HCV antibodies and HBsAg, heat-inactivated Preservative: < 0.1% sodium azide	1 vial 0.2 ml Ready for use
R5	**Conjugate**	Conjugate Goat alkaline phosphatase-labeled anti-human IgG antibodies Preservative: < 0.1% sodium azide	1 vial 40 ml Ready for use
R6	**Color Development Solution (BCIP/NBT)**	Color development solution (BCIP/NBT) 5 bromo-4 chloro-3 indolyl phosphate (BCIP) and nitro blue tetrazolium (NBT) as developing buffer	1 vial 40 ml Ready for use

4.2 Storage and handling requirements

This kit must be stored at +2-8 °C.
Reagents can be used until the expiry date shown on the package even after being opened.
The diluted buffer solution/diluent (R2) is stable for 1 month at +2-8 °C.
Avoid any microbial contamination of the reagents.

5. WARNING AND PRECAUTIONS

For *in vitro* diagnostic use.
Device for professional user in a laboratory environment only.

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident occurs, please report it to the manufacturer and to your national Competent Authority.

5.1 Health and Safety precautions:

- This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with the potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately in accordance with the Good Laboratory Practices.

- The test kit contains human blood components. No known test method can offer complete assurance that infectious agents are absent. Therefore, all human blood derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for blood borne pathogens as defined by local, regional and national regulations.

- Biological spills: Human source material spills should be treated as potentially infectious.

- Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment, with an appropriate chemical disinfectant that is effective for the potential biohazards (commonly a 1:10 dilution of household bleach, 70-80% Ethanol or Isopropanol, an iodophor [such as 0.5% Wescodyne Plus, etc.), and wiped dry.

- Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry. Materials used to absorb the spill may require biohazardous waste disposal. The area should be decontaminated with a chemical disinfectant.

NOTE: Do not place solutions containing bleach into the autoclave!

- Dispose of all specimens and materials used to perform the test as though they contain an infectious agent. Laboratory, chemical, or biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations.

- For hazard and precautionary statements in this test kit, please refer to the H and P codes on the labels and the information provided at the end of this instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

- This product contains in trace amounts a component which is identified as carcinogenic but does not require labelling as hazardous.

5.2 Precautions related to the procedure

5.2.1 Preparing

The reliability of the results depends on the correct implementation of the following Good Laboratory Practices:

- Do not use the kit if the packaging of any component is damaged.
- Do not use expired reagents.
- Before use, wait for 30 minutes for the reagents to stabilize at room temperature (+18-30°C).
- Do not mix or use reagents from different lots within a test run.
  Note: It is possible to use other buffer solution (label identification: R2 in blue) and color development solution (R6) lots with the restriction that the same lot is used within a given test run.
- Carefully reconstitute reagents, avoiding any contamination.
- The use of disposable equipment is preferred. If using glassware, wash thoroughly and rinse with deionized water.
- Use a new dispensing tip for each specimen.
- Never use the same container to dispense conjugate and color development solution
- The NEW LAV BLOT II Assay must ONLY be used with serum or plasma. Using other types of specimens or testing of venipuncture whole blood specimens collected using a tube containing an anticoagulant other than citrate, heparin or EDTA may not yield accurate results.

5.2.2 Processing

Adherence to the instructions for use is necessary to ensure proper performance of this product.

- Do not change the assay procedure.
- Check the pipettes and other equipment for accuracy and correct operation.
- This test should be performed at +18-30°C.
- Make sure that the strip side with the reference mark and the number is visible so that the viral proteins on this side are covered by the various reaction media throughout the test.
- The controls supplied should be tested in parallel with patient specimens for each test run. The positive control is required to validate the test and correctly interpret the bands.

- If suspended particles are present in the development solution, allow to settle in the vial before pipetting. These particles do not interfere with the test.
- The color change of the solution from colorless to grey - dark grey does not interfere with the test.
- Do not allow strips to dry more than 10 minutes during the test.
- Adequate lighting is required to read the test results.

6. SPECIMENS

Collect a blood specimen according to current practices.
The tests should be performed using undiluted serum or plasma specimens (EDTA, heparin, citrate).
Separate the serum or plasma from the clot or red cells as soon as possible to avoid any hemolysis. Extensive hemolysis may affect test performance. Specimens with aggregates should be clarified by centrifugation prior to testing. Suspended fibrin particles or aggregates may yield falsely positive results.
The specimens can be stored at +2-8°C if the test is performed within 7 days, or they may be deep-frozen at -20°C. Plasma specimens should be quickly thawed by heating for a few minutes at 40°C (to limit fibrin precipitation).
Specimens that have been frozen and thawed more than 3 times should not be used.
If the specimens are shipped, pack them in accordance with regulations for the transportation of etiological agents.
DO NOT USE CONTAMINATED, HYPERLIPEMIC OR HYPERHEMOLYZED SERUM OR PLASMA SPECIMENS.
Note: Specimens containing up to 90 g/l albumin, 100 mg/l bilirubin, lipemic specimens containing up to the equivalent of 36 g/l triolein, and hemolyzed specimens containing up to 10 g/l hemoglobin do not affect the test results.

7. PROCEDURE

7.1 Materials required

7.1.1 Materials provided

Each kit contains reagents sufficient for 18 determinations. The determinations may be performed in multiple independent runs.

Ready-to-use reagents:
HIV-2 nitrocellulose strips (18), negative control (0.2 ml), anti-HIV-2 positive control (0.2 ml), conjugate (40 ml) and color development solution (BCIP/NBT) (40 ml).
Refer to § 4.1 Description.

Reagent to be diluted:
Buffer solution/diluent (5X)

7.1.2 Materials required but not provided

- Distilled or demineralized water
- 100 ml, 250 ml and 500 ml graduated cylinders
- 2 ml graduated pipettes
- Automatic or semi-automatic adjustable or fixed pipettes allowing the measurement or dispensing of 20 µl
- Disposable gloves
- Liquid jet vacuum pump with safety bottle
- Sodium hypochlorite (bleach)
- Absorbent paper
- Tweezers
- 1, 2 or 3 dimensional shaker (shaking to ensure a homogeneous environment and total immersion of the strips during the shaking steps)
- Container for biohazardous waste
- Protective glasses

7.2 Reagent preparation

All reagents are ready to use except the buffer solution/diluent (R2).
Preparation: shake the buffer solution/diluent vial before collection. Dilute the buffer solution/diluent to 1:5 in distilled water (e.g. for a complete tray: 30 ml buffer solution + 120 ml distilled water). Homogenize.
Carefully reconstitute the reagent, avoiding any contamination.

7.3 Assay Procedure

1. Before use, wait 30 minutes to allow reagents to stabilize at room temperature (+18-30°C).
   Remove the transparent cover of the tray being used.
   Make sure that the strip side with the reference mark and the number is visible so that the viral proteins on this side are covered by the various reaction media throughout the test.
   Strips should be carefully handled with plastic tweezers.
   Remove the transparent cover of the tray being used.
   Do not allow the strips to dry more than 10 minutes during the test.
   The controls supplied should be tested in parallel with patient specimens for each test run. The positive control is required to validate the test and correctly interpret the bands.
2. Add 2 ml of the reconstituted buffer solution/diluent into each cell.
   Incubate for 5 ± 1 minutes at room temperature (+18-30°C) under shaking.
3. Add 20 µl of each specimen or control serum into the corresponding cell.
   Incubate for 2 hours ±5 minutes at room temperature (+18-30°C) under shaking.
4. Completely drain the contents of each cell using a vacuum pump with a trap containing a disinfectant (25% bleach).
   Make sure that the strip does not move during aspiration; use the aspiration well designed for this use.
   Rinse the aspiration tip which is in contact with the specimens under the tap between each aspiration to avoid specimen cross-contamination.
   Wash each strip with 2 ml of the reconstituted buffer solution/diluent and immediately remove it by aspiration, using the same precautions.
   Wash each strip twice. Allow contact for 5 minutes under shaking with 2 ml of the reconstituted buffer solution/diluent (i.e. a total of 3 wash steps).
   Remove the solution used for the last washing.
5. Dispense 2 ml of conjugate into each cell. The conjugate solution should be previously stabilized at room temperature.
   Incubate for 1 hour ± 5 minutes at room temperature (18-30°C) under shaking.
6. Washing: proceed as described in step 4.
7. Dispense 2 ml of color development solution into each cell. If suspended particles are present in the development solution, allow them to settle in the vial before pipetting. These particles do not interfere with the test.) The color change of the solution from colorless to grey-dark grey does not interfere with the test.
   Incubate under shaking and monitor the appearance of the coloration. All the bands corresponding to the viral proteins should be observed with the positive control serum. (Development time: between 5 and 15 minutes maximum).
8. Stop the reaction by removing the development solution and rinsing the strips 3 times with distilled water.
9. Dry the strips between 2 sheets of absorbent paper at room temperature (18-30°C).
   Sort the strips and position them perfectly using the reference mark. Validate then interpret.
   CAUTION: do not stick adhesive tape on the strip side corresponding to the viral proteins.

7.4 Quality Control

All manufactured reagents are prepared according to our Quality System, from reception of the raw material to commercialization of the final product. Each lot undergoes quality control assessments and is released to the market only after conforming to pre-defined acceptance criteria. The records related to production and controls of each single lot are kept within Bio-Rad.

7.5 Test validation criteria

The internal anti-IgG control band should be present with a strong color. It is used to validate the addition of the specimen and reagents as well as the correct progress of the test procedure. The absence or weak intensity of the coloration of the internal anti-IgG control band indicates either that the sample or reagents were not dispensed or that the test procedure was not followed.
Positive control: presence of all bands corresponding to the viral proteins and the control band
Negative control: none of the viral protein should be present, the control band is present.

7.6 Calculation / interpretation of results

Reading:
The presence of anti-HIV-2 constituent protein antibodies in controlled specimens is shown by the appearance of specific colored bands (blue-purple). Their position corresponds to the molecular masses of the viral proteins listed in the following table.
IMPORTANT:
Use the positive control **(see figure at the end of the document)** to locate and identify the revealed antibodies and check that the internal control band is present on each test strip.
Each specific and readable band must be interpreted.

Denomination	Genome	Nature	Aspect in Western Blot
GP 140	ENV	Precursor of GP 105 and GP 36	± Diffuse band
GP 105/GP125	ENV	Envelope glycoprotein	Diffuse band
P 68	POL	Reverse transcriptase	Clear band
P 56	GAG	Precursor of core proteins	Clear band
GP 36	ENV	Transmembrane glycoprotein	Diffuse band
P 34	POL	Integrase	Clear band
P 26	GAG	Core protein	Clear band
P 16	GAG	Core protein	Clear band

*The P 34 band is a well-defined band in the same position as the diffuse GP 36 Band.

Interpretation

Interpretation	Profile
Positive	ENV + GAG + POL
Indeterminate	ENV + GAG ENV + POL GAG + POL GAG POL ENV
Negative	Non-classified bands No band

Note
In the event of indeterminate results, new specimen should be tested later. Contamination with a positive serum may cause a positive or indeterminate profile.

8. TEST LIMITATION

- Visual reading can introduce some variability in the final conclusion between two different technicians or two different tests. This difference may be linked to the subjectivity of the visual interpretation.
- The variability of HIV-1 (group M and group O) and HIV-2 viruses can lead in very rare cases to false negative reactions. No known test method can offer complete assurance that the HIV virus is absent.
- A positive screening test associated with a negative confirmatory test may occur during the first stage of infection; hence, a negative result indicates that the tested sample does not contain anti-HIV antibodies detectable with NEW LAV BLOT II. Such a result does not, however, exclude the possibility of a recent HIV-1/HIV-2 infection. A new specimen should be tested later.

- Using less restrictive interpretation criteria may induce a different classification of the specimens. Actually some specimens classified as indeterminate according to the pack insert interpretation criteria should be reported as reactive according to other criteria.
- An "indeterminate" profile does not exclude one of the following situations: seroconversion, HIV-1 infection, or a cross-reaction with other retroviruses. A new specimen should be tested later.
- A positive profile does not exclude an HIV-1 infection. Additional testing with an NAT assay or a differentiation assay is recommended.

9. PERFORMANCE CHARACTERISTICS

9.1 Analytical performance characteristics

9.1.1 Precision measurement

9.1.1.1 Repeatability

Four (4) samples, 1 HIV-2 negative sample, 2 HIV-2 low positive samples and 1 HIV-2 medium positive sample were tested 6 times during the same run. For each sample, the same results were obtained for the 6 replicates.

9.1.1.2 Intermediate precision

Ten (10) samples, 1 HIV-2 negative sample, 3 HIV-2 low positive samples, 3 HIV-2 medium positive samples and 3 HIV-2 high positive samples were tested in one replicate over 5 days. For each sample, the same results were obtained for the 5 replicates.

9.1.2 Analytical specificity (cross reactivity)

Interferences due to different diseases/states potentially associated with HIV infection were investigated by testing 74 specimens collected from patients suffering from infectious diseases (EBV, CMV, HSV, HAV, HBV, HCV, HTLV, toxoplasmosis, rubella), chronic renal failure, liver cirrhosis or auto-immune disorders (rheumatoid factors, HAMA) as well as pregnant women. Additionally, 16 specimens from patients with systemic lupus (SLE) were tested.

Among the 90 specimens, 51 were negative and 39 (10 SLE, 3 HTLV, 5 HCV, 2 rheumatoid factor, 5 HAMA, 3 rubella IgG, 2 HBs Ab, 4 liver cirrhosis, 1 Toxoplasma IgG, 1 Toxoplasma IgM, 1 HAV IgG, 1 EBV IgG positive specimens and 1 specimen from pregnant woman) were indeterminate. No false positive result was obtained.

9.2 Clinical performance characteristics

9.2.1 Diagnostic specificity

The specificity studies were conducted on specimens from 235 blood donors and from 200 hospitalized patients. Additionally, 88 EIA false-positive specimens and 3 specimens giving indeterminate result with reference Western-Blot assay were tested.

Population	Nbr	Results with NEW LAV BLOT II		
		Negative	Indeterminate	Positive
Blood donor specimens	235	191	44	0
Hospitalized patient specimens	200	87	113	0
EIA false-positive specimens	88	73	15	0
Indeterminate specimens	3	0	3	0
Total	**526**	**351**	**175**	**0**

Among the 526 specimens, no positive results were observed: 66.7% (351/526) of specimens were found to be negative and 33.3% (175/526) were found to be indeterminate.

9.2.2 Diagnostic sensitivity

9.2.2.1 Sensitivity on HIV-2 positive specimens

A total of 249 specimens reactive for HIV antibodies using EIA and characterized as HIV-2 with HIV-1/2 differentiation tests (EIA, Immunoblot) were tested. 247 were confirmed to be positive and 2 were found to be indeterminate.

9.2.2.2 Sensitivity on HIV-1/HIV-2 double positive specimens

A total of 51 specimens reactive for both HIV-1 and HIV-2 antibodies with reference confirmation assays were tested. All were found to be positive.

9.2.2.3 Sensitivity on HIV-1 positive specimens

A total of 135 specimens characterized as HIV-1 positive with reference confirmation assays were tested. 3 were found to be negative, 111 were found to be indeterminate and 21 were found to be positive.

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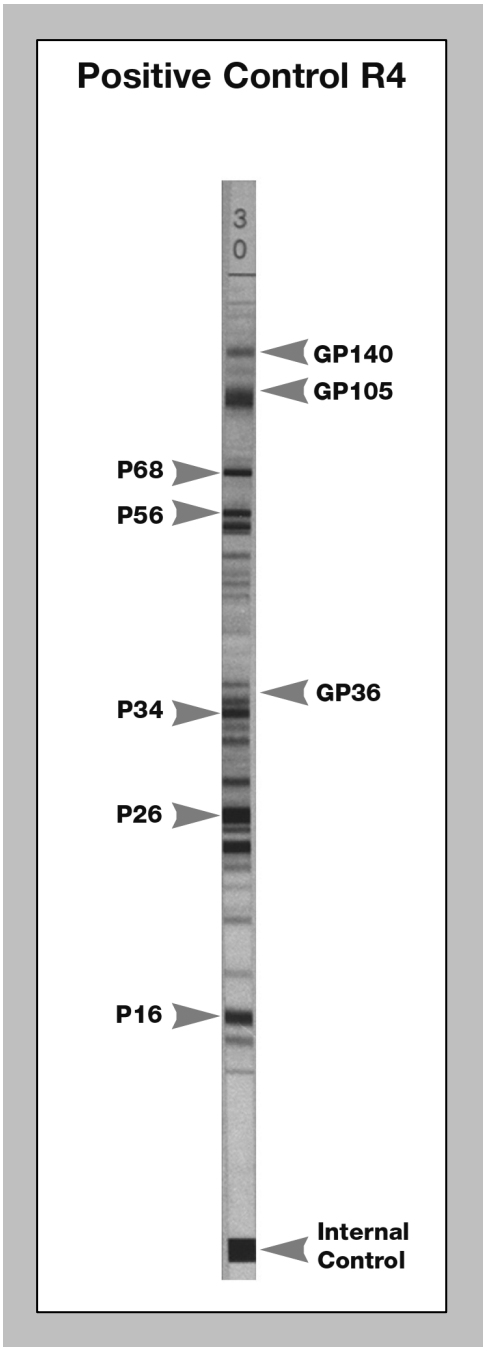
Positive control R4 example profile

Caution: precise bands may differ in reality.
Do not use this picture for final interpretation. Use the positive control strip to identify the patient antibodies and check that the internal control (Internal Control) band is present on each strip.



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