Lab Rapid HIV Tri Line 1/2

Instructions for use

Ref.: **721**

Intended use . System for rapid qualitative detection of antibodies (IgG, IgA and IgM) specific to HIV with differentiation for anti-HIV-1, including groups M and O, and anti-HIV-2 in human samples of serum, plasma, venous whole blood or capillary.

Professional use.

[For *in vitro* diagnostic use only].

Principle . The system consists of a membrane on which HIV-1 and HIV-2 antigens have been immobilized in test region 1 and test region 2, respectively. When performing the test, the sample is placed to react with the conjugate, which contains colloidal gold particles linked to recombinant antigens. The conjugate complexes with the anti-HIV present in the sample. After adding the buffer, the antibody-conjugate complex migrates through the membrane and finds the test regions, in which the HIV-1 and HIV-2 antigens are immobilized. Then, purple/red line(s) are formed indicating the presence of anti-HIV antibodies in the sample. The control blue line is present even without sample addition and there is a color change from blue to red after sample addition. If the control region line (C) remains blue, it indicates that the test is invalid. The absence of test lines indicates a negative result, as long as the control line, which before the start of the test was blue, changes color and becomes purple/red.

System characteristics . The Lab Rapid HIV Tri Line 1/2 system is an immunochromatographic method that allows the differentiated detection of anti-HIV-1 and anti-HIV-2 antibodies through a simple, fast and easy to interpret procedure in serum, plasma or whole blood samples. The use of the recombinant antigens gp41 and gp36 of the vírus ensure high sensitivity and specificity of the product.

This rapid combination test detects IgG, IgM and IgA antibodies to HIV-1 (including groups M and O) and HIV-2, providing early detection of infection. IgM and IgA antibodies are usually detectable 2 to 4 weeks after exposure to HIV, while IgG antibodies may take 4 to 12 weeks to become detectable. In some cases, it may take up to 6 months for all antibodies to reach detectable levels. The test can identify infection as early as 2 to 6 weeks after exposure, but to ensure diagnostic accuracy, additional testing is recommended after 3 to 6 months, especially if the first test was performed before the end of the immunological window.

Methodology . Immunochromatography.

Reagents

1. Reaction plates - Store between 2 - 30°C. Do not freeze.
Ilt contains colloidal gold-recombinant antigens conjugate, colloidal gold-IgY conjugate, HIV-1/2 recombinant antigens and protein A, applied or immobilized on a membrane.

2. Buffer - Store between 2 - 30°C. Do not freeze.
It contains Tris, EDTA, surfactant and 0.1% sodium azide Buffer.

3. Auxiliary material

- Disposable micropipettes of 10 μL or 20 μL*
- Disposable lancet *
- Wet wipe *

*depending on the commercial presentation. The number of accessories is proportional to the number of reaction plates.

Unopened reagents, when stored under the indicated conditions, are stable until the expiration date printed on the label. The buffer (No. 2), once opened, is stable for 2 months. While handling, reagents are subject to chemical and microbial contamination that can cause reduced stability.

Precaution and special care

The product should never be frozen or exposed to a temperature above 30 °C.

Avoid exposure of reagent plates to ambient humidity.

The usual safety precautions should be used when handling reagents and samples.

Since no known test can guarantee that blood samples do not transmit infections, they should all be considered as potentially infectious. Thus, when handling them, biosafety rules must be followed.

The use of Personal Protective Equipment is essential.

Check the product's expiration date before performing the test.

The buffer (No. 2) contains sodium azide which is toxic. Special care must be taken to avoid ingestion and, in case of eye contact, wash your eyes immediately with abundant water and seek medical assistance. Azide can form highly explosive compounds with lead and copper pipes. Therefore, use large volumes of water to discard the reagent.

The buffer (No. 2) is sealed. Unscrew the cap to break the seal, completely remove the seal ring that remained in the bottle and replace the cap to open the dropper hole.

To dispose reagents and biological material, we suggest applying local, state or federal protection standards.

Required material and not provided

1. Timer.

Labtest

Sample

Serum, plasma (EDTA, citrate, heparin) or whole blood (EDTA, citrate, heparin).

The analyte is stable for 3 days at 2-8 ºC. Store the serum or plasma sample at minus 20 ºC or below for up to 6 months in an airtight container to prevent evaporation[12]. The whole blood sample must not be frozen. Ensure that the samples are thawed and homogenized before use. Suspended particles must be removed by centrifugation. Samples must not be inactivated by heat as they may produce incorrect results. Do not use samples with signs of contamination or frozen and thawed samples repeatedly. Do not use hemolyzed and/or lipemic samples.

Additionally, whole capillary blood samples can be obtained by finger stick (See procedure below). Whole blood obtained by fingerstick should be used for immediate testing.

A Standard Operating Procedure (SOP) should be created to establish adequate procedures for sample collection, preparation and storage. We emphasize that pre-analytical errors can be much larger than the errors that occurred during the analytical procedure.

Interferences

No false positive results were observed in samples positive for anti-HAV, anti-HBs, anti-HBc, anti-HCV, anti-HEV, HBsAg, Syphilis, anti-EBV VGA, anti-VZG, anti-HSV, anti-CMV , anti-chromatin, rheumatoid factor and anti-TPO.

The presence of heterophile antibodies in samples from patients with autoimmune and rheumatic diseases can lead to false results.

No interference was observed for samples containing hemoglobin up to 1000 mg/dL, bilirubin up to 10 mg/dL, lipids up to 1200 mg/dL.

The presence of heterophile antibodies in samples from patients with autoimmune and rheumatic diseases can lead to false results.[15]

Limitations

1. As with all diagnostic tests, all results must be considered with other clinical information.

2. The presence of heterophile antibodies in a sample from a patient with autoimmune or rheumatic diseases can lead to false results.

3. Negative test results may be due to a titer of antibodies against HIV-1/2 in the sample lower than the test's minimum detection limit or the absence of antibodies in the sample, depending on the day it was collected.

4. A negative result at any time does not exclude the possibility of exposure or infection by HIV-1/2.

5. It is suggested to repeat the test if the test line appears very weakly colored.

6. This test should not be used on samples from immunosuppressed individuals.

Procedure

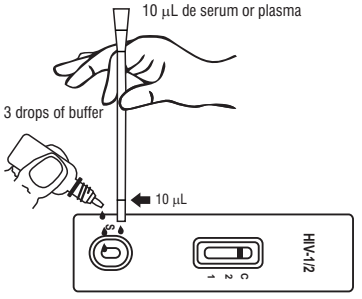
Samples and product must be at ambient temperature at the time of testing.

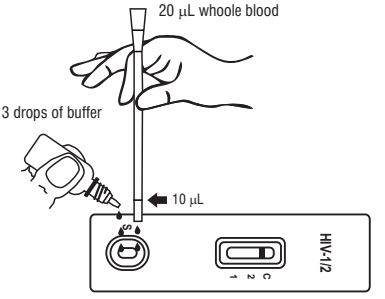
1. Remove the reaction plate from the protective envelope, identify it properly and place it on a horizontal surface.

2. Using a pipette, add 10 μL of serum or plasma (use the pipette once, aspirating the sample to the mark) or 20 μL of whole blood (use the pipette twice, aspirating the sample to the mark) in the sample opening (S).

3. Then add 3 drops of buffer in the sample opening (S).

4. Perform the reading of the results after 20 minutes. Do not do the reading after 30 minutes.





Capillary whole blood samples (collected by finger stick)

1. Remove the reaction plate from the protective envelope, identify it appropriately and place it on a horizontal surface.

2. Clean the finger that will be punctured by rubbing the area with a moistened tissue. Let it dry naturally.

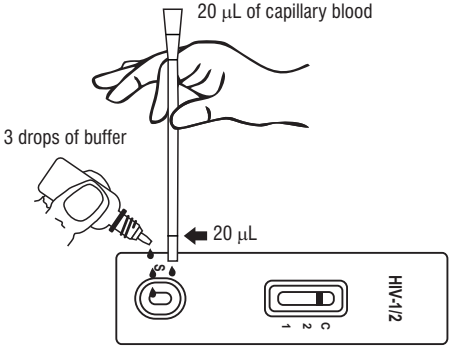
3. Carefully twist and pull the protective cap off the sterile lancet to remove it. Puncture the selected finger using the lancet, positioning it ov

4. Collect 20 µL of the total capillary blood sample using the 20 µL micropipette once. To do this, position it vertically and squeeze the middle of the micropipette, and insert its open end into the drop of blood. Gradually release the micropipette to collect blood up to the mark line.

5. Press the micropipette to release the blood sample into the sample hole (S) of the reaction plate.

6. Then add 3 drops of buffer into the sample well (S).

7. Read the results after 20 minutes. Do not read after 30 minutes.



Interpretation of results

Negative. Change in color of the control line (C) from blue to purple/red and absence of lines in test regions 1 and 2.

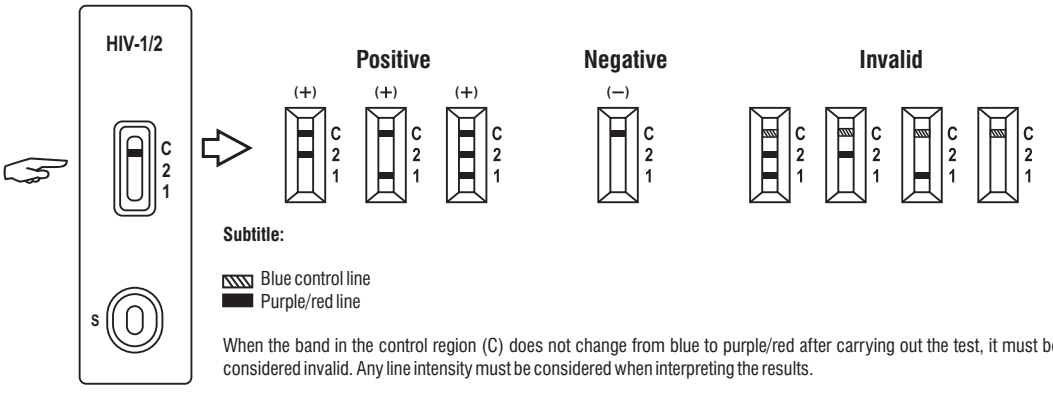
Positive HIV-1. Change in color of the control line (C) from blue to purple/red and formation of a line in test region 1.

Positive HIV-2. Change in color of the control line (C) from blue to purple/red and formation of a line in test region 2.

Mixed infection HIV-1 and HIV-2. Change in color of the control line (C) from blue to purple/red and formation of both lines, in test region 1 and in test region 2.

Invalid. If the line in the control region (C) does not change color from blue to purple/red, the test must be considered invalid. The absence of a line in the control region (C) indicates a procedural error or system deterioration. Review the procedure and repeat the test with a new reagent plate.

Reagent Plaque



When the band in the control region (C) does not change from blue to purple/red after carrying out the test, it must be considered invalid. Any line intensity must be considered when interpreting the results.

Note: A blue line in the control area region (C) will always be present before the test is performed; if it remains blue after the test and is not replaced by a red line, the test must be considered invalid.

Any test line intensity should be considered when interpreting the results.

Any sample that presents a positive result in a rapid test, as this is a screening test, must be analyzed by complementary tests, such as Western Blot, Immunoblot or qualitative or quantitative molecular tests for HIV. Rapid tests can be used as the only methodology for diagnosing HIV infection only in special situations, according to SVS/MS nº29, December 17, 2013.[8]

This product is a screening test, so a negative result does not rule out the possibility of HIV infection. When interpreting the test result, other clinical information must be taken into account.

Internal quality control[13] . The laboratory must maintain an internal quality control program that clearly defines applicable regulations, objectives, procedures, criteria for quality specifications and tolerance limits, corrective actions, and activity log.

The change of the line in the control region from blue to purple/red is indicative of adequate performance of the procedure. To ensure that the system has not been adversely affected and that it maintains established levels of performance, we suggest associating a quality system using known samples on a daily basis, one negative and the other positive.

Performance characteristics

Comparative Studies . Serum/plasma samples: The comparison studies were carried out using 2456 positive and negative samples tested with the Lab Rapid HIV Tri Line 1/2 - Labtest system and a product with similar methodology commercially available as a comparative method, obtaining the results presented in the table below.

	Lab Rapid HIV Tri Line 1/2 - Labtest	
Comparative Method	Positive	Negative
Positive	555	0
Negative	0	1901

Relative sensitivity: > 99.5%
Relative Specificity: > 99.0%
Efficiency: 100%
Kappa Index: 1.0

Comparative Studies . Capillary whole blood samples: For capillary whole blood samples, comparison studies were performed using 203 HIV-positive and -negative samples tested with the Lab Rapid HIV Tri Line 1/2 - Labtest system and a product with a similar methodology available commercially as a comparative method, obtaining the results shown in the following table:

	Lab Rapid HIV Tri Line 1/2 - Labtest	
Comparative Method	Positive	Negative
Positive	103	0
Negative	0	100

Sensitivity: 100.00% (CI* = 95% : 96.48% to 100.00%)
Specificity: 100.00% (CI* = 95% : 96.38% to 100.00%)
Efficiency: 100%
Kappa Index: 1.0

*CI = Confidence Interval

The Kappa index greater than 0.80 indicates an excellent agreement[14] between the two methods, demonstrating that the Lab Rapid HIV Tri Line 1/2 - Labtest system is substantially equivalent to the comparative method. In addition, comparative studies were carried out using a comercial panel containing 6 positive samples for anti-HIV-1 and anti-HIV-2 antibodies. The Lab Rapid HIV Tri Line 1/2 - Labtest system correctly identified all panel samples, with 100 % agreement.

Repeatability - Intra-assay inaccuracy . Intra-assay inaccuracy was verified by evaluating three replicates of eight samples, six positive with varied titers and two negative. The tests were performed by the same operator on a batch of the product. The negative and positive results found showed a perfect agreement with the expected results.

Reproducibility - Total Inaccuracy . Total inaccuracy was verified by evaluating three replicates of eight samples, six positive with varied titers and two negative. The tests were performed by three operators in three batches of the product. The negative and positive results found showed a perfect agreement with the expected results.

Pro-zone Effect . The product has no pro-zone effect in samples with high titers that remain positive until dilution 1:200 for anti-HIV-1 and 1:10 for anti- HIV-2.

Clinical significance . Acquired immunodeficiency syndrome (AIDS) is caused by two types of human immunodeficiency virus, HIV-1 and HIV-2. This virus belongs to the genus Lentivirus of the Family *Retroviridae* and was discovered in 1983[9]. Infection with the HIV-1 virus is reported worldwide, it is more virulent and is divided into groups: M, N, O and P[10,11]. Infection with the HIV-2 virus occurs mainly in West Africa and, in some European countries, is divided into groups: A, B, C, D, E, F, G and H8,10. Both viruses have significant antigenic cross-reactivity in their core proteins, however the envelope glycoproteins have less cross-reactivity. Detection of antibodies by envelope proteins ensures adequate determination of both types after infection.
Transmission of infection occurs through three main routes: unprotected sexual contact, contact with contaminated blood (including blood transfusions and use of contaminated syringes) and transmission from mother to child during pregnancy, childbirth or breastfeeding.

References

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16. Labtest: Dados de Arquivo.

Labtest

Presentation

Product	Reference	Content	
Lab Rapid HIV Tri Line 1/2	721-20	Test Device	20 un
		Buffer	1 X 3,0 mL
		Micropipette of 10 µL	20 un
Lab Rapid HIV Tri Line 1/2	721L-10	Test Device	10 un
		Buffer	1 X 3,0 mL
		Micropipette of 20 µL	10 un
		Lancet	10 un
		Wet Wipe	10 un
Lab Rapid HIV Tri Line 1/2	721L-20	Test Device	20 un
		Buffer	1 X 3,0 mL
		Micropipette of 20 µL	20 un
		Lancet	20 un
		Wet Wipe	20 un
Lab Rapid HIV Tri Line 1/2	721L-25	Test Device	25 un
		Buffer	2 X 3,0 mL
		Micropipette of 20 µL	25 un
		Lancet	25 un
		Wet Wipe	25 un

For information about other commercial presentations, consult the website www.labtest.com.br or contact SAC.

Customer information

[Guarantee Terms and Conditions]

Labtest Diagnóstica guarantees the product performance, within the specifications, until the expiration date indicated on the labels, provided that the care for use and storage indicated on the labels and in these instructions are correctly followed.

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Ref.: 171125(02)

Símbolos utilizados com produtos diagnósticos in vitro

Símbolos usados con productos diagnósticos in vitro . Symbols used with IVD devices

Conteúdo suficiente para < n > ensaios Contenido suficiente para < n > ensayos Sufficient content for < n > trials	**Consultar instruções de uso** Consultar instrucciones de uso Consult instructions for use	**Produto de uso único** Producto de un solo uso Single use product	**Risco biológico** Riesgo biológico Biological risk
Prazo de validade (aaaa-mm-dd ou mm/aaaa) Fecha de expiración (aaaa-mm-dd o mm/aaaa) Expiration date (yyyy-mm-dd or mm/yyyy)	**Período após abertura** Período post-abertura Period after-opening	**Fabricante** Fabricante Manufacturer	**Corrosivo** Corrosivo Corrosive
Limite de temperatura (conservar a) Temperatura límite (conservar a) Temperature limit (store at)	**Número do catálogo** Número de catálogo Catalog Number	**Data de fabricação** Fecha de fabricación Date of manufacture	**Tóxico** Tóxico Poison
Representante Autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Authorized Representative in the European Community	**Identificador único do dispositivo** Identificador único del dispositivo Unique device identifier	**Reagente** Reactivo Reagent	**Marca CE** Marcado CE CE Mark
Carcinogênico/mutagênico e/ou sensibilizante à respiração Carcinogénico/mutagénico y/o sensibilizante respiratorio Carcinogenic/mutagenic and/or respiratory sensitizer	**Número do lote** Denominación de lote Batch code	**Controle** Control Control	**Atenção** Atención Attention
Tóxico para os organismos aquáticos Tóxico para los organismos acuáticos Toxic for aquatic organisms	**Gases/líquidos comburentes** Gases/líquidos oxidantes Oxidizing gases/liquids	**Controle negativo** Control negativo Negative control	**Liofilizado** Liofilizado Lyophilized
Reagente contendo micropartículas Reactivo con micropartículas Reagent with microparticles	**Substância inflamável** Sustancia inflamable Flammable substance	**Controle positivo** Control positivo Positive control	**Instalar até** Instalar hasta Install before
Dispositivo médico de diagnóstico in vitro Dispositivo médico para diagnóstico in vitro In vitro diagnostic medical device	**Material Calibrador/Padrão** Material Calibrador/Estándar Calibrator/Standard Material	**Cartucho contendo reagente** Cartucho que contiene reactivo Cartridge containing reagent	**Pré-Tratamento** Pretratamiento Pre-Treatment