HIV 1+2 Triline Ab Rapid Test (WB,S,P)

Labgene biotech

INTENDED USE

Labgene HIV 1+2 Triline Ab rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection of antibodies against Human Immunodeficiency Virus (HIV)-1 and/or HIV-2 in human whole blood, serum or plasma samples.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG001-10T	10	1 X 2 mL	01 in an individual pouch	-
LG001-25T	25	1 X 3 mL		
LG001-30T	30	1 X 3 mL		
LG001-40T	40	2 X 2 mL		
LG001-50T	50	2 X 3 mL		
LG001-100T	100	4 X 3 mL		
LG001LS-10T	10	1 X 2 mL		10
LG001LS-25T	25	1 X 3 mL		25
LG001LS-30T	30	1 X 3 mL		30
LG001LS-40T	40	2 X 2 mL		40
LG001LS-50T	50	2 X 3 mL		50
LG001LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

The human immunodeficiency virus (HIV) is a lentivirus that causes acquired immunodeficiency syndrome (AIDS). HIV attacks the immune system, resulting in a chronic, progressive illness that leads to life threatening opportunistic infections. There are two types of HIV: HIV-1 and HIV-2. HIV-1 has been isolated from patients with AIDS and AIDS related complexes, and from healthy persons with high potential risks of developing AIDS. Patients with HIV-2 are found primarily in parts of West Africa. Both types are transmitted by sexual contact, through blood, or from mother to child and appear to cause clinically indistinguishable AIDS. HIV infections are staged by CD4 cell counts and clinical symptoms. Not all people progress through all "stages" and the time frames may also vary greatly from person to person. Treatment with anti-retrovirals increases the life expectancy of people infected with HIV. HIV-1 and HIV-2 are similar in their morphology, cell tropism, host interaction and generic structure. Serological studies have determined that HIV-1 and HIV-2 have multiple common epitopes in core antigens but much less so in the envelope antigens. The clinical diagnosis related to HIV can be done by the detection of antibodies to HIV 1/2 in human whole blood/serum/plasma samples on an immunoassay.

PRINCIPLE

Labgene HIV 1+2 Triline Ab Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection and differentiation of antibodies against HIV 1 & 2 in human whole blood samples/serum/plasma samples. When a whole blood/serum/plasma specimen sample is dispensed into the sample well, the sample flows through the filter efficiently after adding buffer solution. If the antibodies against gp41 & gp120 antigen (for HIV-1), is present in the sample, it will bind with gold-gp41+120 antigen conjugate and antibodies against gp36 antigen (for HIV-2) if present in the sample specimen will bind with gold-gp36 antigen conjugate. This complex moves forward in the membrane, binds with gp41+gp120 and gp36 recombinant antigens coated on the membrane as two separate lines respectively, causing magenta red coloured bands to form at the HIV-1 or HIV-2 respective regions of the test membrane. The intensity of the lines will vary depending upon the amount of antibodies present in the sample. The appearance of the colored line in a specific test region (1 or 2) should be considered as positive for that particular HIV type (HIV-1 or HIV-2). If no band is present in the Control area, the test is invalid and another test must be run using a fresh device, regardless of the presence or absence of band in the Test area.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

The HIV 1+2 Triline Ab Rapid Test can be performed using either serum, plasma or whole blood.

Plasma :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum :

- Collect blood specimen into a collection tube containing no anticoagulants.
- Allow the blood to clot.
- Separate the serum by centrifugation,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2°C-8°C for up to three days if the tests cannot be performed immediately. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature and mix gently. Do not use haemolysed sample.

Whole Blood :

Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

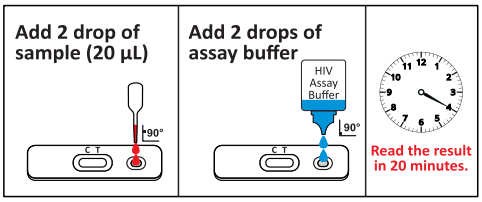
Collection using a lancet:

- Clean the area to be lanced with the alcohol swab
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

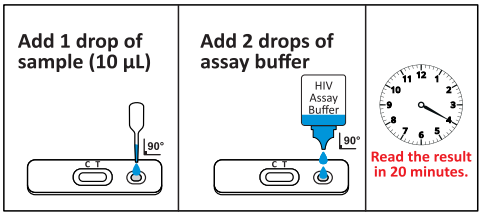
PROCEDURE

1. Allow test device, specimen, to reach room temperature (15°C- 30°C) prior to testing.
2. Place the test device on a clean and level surface.
3. **For Serum or Plasma sample:** Hold the dropper vertically and **transfer 1 drop of sample (10 µL)** to the sample well of the test device, then **add 2 drops of assay buffer** and start the timer.
4. **For Whole blood sample:** Hold the dropper vertically and **transfer 2 drops of sample (20 µL)** to the sample well of the test device, then **add 2 drops of assay buffer** and start the timer.
5. Read the result in 20 minutes. Read results as shown under interpretation of Results.

WHOLE BLOOD:



SERUM / PLASMA :



⚠ **Do not read the results after 25 minutes. For each sample, use a separate dropper and test cassette.**

INTERPRETATION OF RESULTS

Positive: Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (HIV-1 & HIV-2)

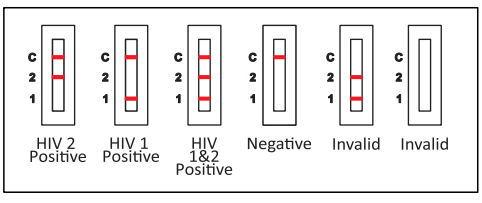
HIV-2 Positive: If both C and HIV-2 line appear, the test indicate positive or reactive for antibodies against HIV-2 Virus in the specimen.

HIV-1 Positive: If both C and HIV-1 line appear, the test indicate positive or reactive for antibodies against HIV-1 Virus in the specimen.

Negative: Only one colored line appear in the control line region ©. No apparent colored line appear in the test line region (HIV-1 & HIV-2).

INVALID: No visible band appears at the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

RESULTS:



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LIMITATIONS

- The HIV 1+ 2 triline rapid test is for in vitro diagnostic use only.
- Humidity and temperature can adversely affect results. This test should be used for the detection of antibodies against HIV virus in human whole blood, serum or plasma specimens only.
- This assay is intended as an aid for the clinical diagnosis. Conduct this assay in conjunction with clinical examination, patient's medical history and other test results.
- If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result. A negative result does not preclude the possibility of HIV infection. This assay is a screening assays and any positive result should be confirmed by Western Blot method or other confirmatory methods.
- As with all diagnostic assays, all results must be interpreted together with other clinical information available to the physician.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

The in house performance evaluation of HIV 1+2 Triline aRapid Test has been done by HIV positive & negative clinical samples confirmed by leading commercial anti HIV 1+2 Elisa & Lateral Flow tests. The co-relation between these two systems was found to be 100%.

Status	Positive	Negative	Total
Positive	50	00	50
Negative	00	610	610
Total	50	610	660

Relative Sensitivity: 100%,
Relative Specificity: 100%,
Overall agreement: 100%

External Evaluation

The external performance evaluation of the HIV 1+2 Triline Ab rapid test has been done by National Institute of Biologicals (NIB), India. The results are shown in following table:

Sensitivity	100%
Specificity	100%

CROSS REACTIVITY WITH OTHER INFECTIOUS DISEASES

Specimen	Sample Size	HIV-1 Ab Reactivity	HIV-2 Ab Reactivity
HBsAg Positive Serum	10	Negative	Negative
HCV Positive Serum	10	Negative	Negative
Syphilis Positive Serum	10	Negative	Negative

REFERENCES

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2. Centers for Disease Control and Prevention (CDC). Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens in health-care settings. MMWR 1988: 37(24):377-388.
3. Chang, SY, Bowman, BH, Weiss, JB, Garcia, RE and White, TJ. The origin of HIV-1 isolate HTLV-IIIB. Nature (1993) 3;363:466-9.
4. Busch, M.P., Lee, L.L., Satten, G.A., Henrard, D.R., Farzadegan, H., Nelson, K.E., Read, S., Dodd, R.Y and Peterson, L.R. Time course of detection of viral and serogic markers preceding human immunodeficiency virus type 1 seroconversion: implications for screening of blood and tissue donors. Transfusion (1995) 35:91-7.
5. Dorn J et. al. Analysis of Genetic Variability within the Immunodominant Epitopes of Envelope gp41 from Human Immunodeficiency Virus Type 1 (HIV-1) Group M and Its Impact on HIV-1 Antibody Detection. Journal of Clinical Microbiology, Feb. 2000, p. 773-780 Vol. 38, No. 2.

INDEX OF SYMBOLS

REF	Product Reference No.	ISO ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-001-04	

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