Anti-HIV 1/2 cassette

RUO

CONTENTS		
REF	4235240 Anti-HIV 1/2	40 Tests
For professional use only		

HIV 1/2 Ab

A rapid one step test for the simultaneous detection and differentiation of anti-HIV-1 and anti-HIV-2 antibodies (IgG, IgM, IgA) in human serum, plasma, or whole blood

ONE STEP

PRINCIPLE

The LINEAR Anti-HIV 1/2 cassette is a lateral flow immunoassay for the simultaneous detection and differentiation of HIV-1 and HIV-2 antibodies (IgG, IgM, IgA) in human serum, plasma or whole blood. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant HIV-1 antigen conjugated with colloidal gold (HIV-1 conjugates), recombinant HIV-2 antigen conjugated with colloidal gold (HIV-2 conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (1 and 2) and a control line (C). Test line 1 is pre-coated with HIV-1 antigen for the detection of antibodies to HIV-1, test line 2 is pre-coated with HIV-2 antigen for the detection of antibodies to HIV-2, and the C line is pre-coated with a control line antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the strip. HIV-1 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-1 conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1 antigen forming a burgundy colored line at test line 1, indicating a HIV-1 antibody positive or reactive test result. Lack of color development on test line 1 suggests an HIV-1 antibody negative or non-reactive result. HIV-2 antibodies, if present in the specimen, migrate through the conjugate pad where they bind to the HIV-2 conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-2 antigen forming a burgundy colored line at test line 2, indicating a HIV-2 antibody positive or reactive test result. Lack of color development on test line 2 suggests a HIV-2 antibody negative or non-reactive result.
The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of the control antibodies regardless of color development on the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

PACKAGING CONTENTS

REF 4235240 40 HIV 1/2 AB Plus combo rapid test device
40 Capillary tubes (20uL)
1 Sample diluent (5 mL)

STORAGE AND STABILITY

Store at 2-30ºC. 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. **Do not freeze the kit or expose the kit over 30°C**. Do not uses beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Serum, (EDTA, citrate or heparin) or plasma unhemolyzed.
Test specimens as soon as possible. Store at 2-8°C if not tested immediately. Stable up to 5 days at 2-8°C or frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole blood
Drops of whole blood can be obtained by finger tip puncture or veinpuncture. Do not use any hemolized blood for testing. Store at 2-8°C if not tested immediately. The specimens must be tested within 24 hours of collection.

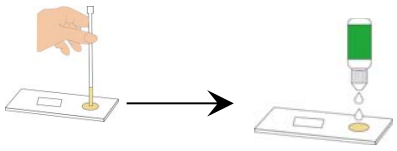
MATERIAL REQUIRED

- Timer
- Lancing device for whole blood test

PROCEDURE

Allow test device, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed pouch and use it as soon as possible. Place the test device on a clean, flat surface.
2. Be sure to label the device with specimen's ID number.
3. Fill the Capillary tubes with specimen (about 20 µL) not to exceed the specimen line. For better precision, transfer specimen using a pipette capable of delivering a 20 µL.
   Holding the Capillary tubes vertically, dispense the entire specimen into the center of the sample well making sure that there are no air bubbles.
   Immediately add 2 drops (60-80 µL) of sample diluent to the sample well with the bottle positioned vertically.



20 µL of specimen **2 drops of sample diluent** **Result** → **15 minutes**

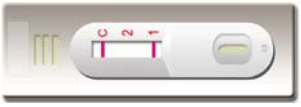
4. Set up timer.
5. Result should be read in 15 minutes. Positive results may be visible in as soon as 1 minute.

Do not read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT

NEGATIVE
If only the C band is present, the absence of any burgundy color in the both test bands (1 and 2) indicates that no HIV antibodies are detected in the specimen. The result is non-reactive.

POSITIVE
1. In addition to the presence of C band, if 1 band is developed, the test indicated presence of antibodies to HIV-1 in the specimen. The result is HIV-1 reactive.



2. In addition to the presence of C band, if 2 band is developed, the test indicated presence of antibodies to HIV-2 in the specimen. The result is HIV-2 reactive.

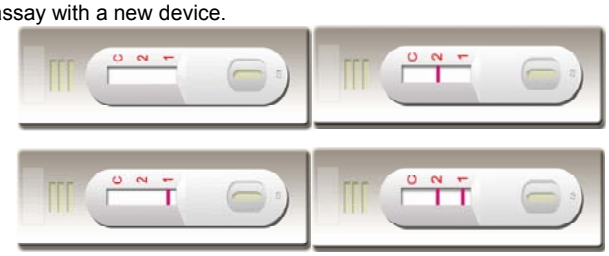
LINEAR CHEMICALS S.L. Joaquim Costa 18 2ª planta. 08390 Montgat, Barcelona, SPAIN
Telf. (+34) 934 694 990 Fax. (+34) 934 693 435. website www.linear.es

3. If the C line and both test lines (1 and 2) are developed, the test indicates that the specimen contains anti-HIV-1 and anti-HIV-2. The result is HIV-1 and HIV-2 positive or reactive. To differentiate and to resolve antibody cross-reactivity, dilute the test specimen with sample diluent 1:50 or 1:100, then re-test the diluted specimen with a new test device. Only test line 1 and the C line will appear if the specimen contains antibodies to HIV-1. If test line 1, test line 2 and the C line all appear, the test indicates presence of antibodies to both HIV-1 and HIV-2.

Samples with reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID

If no C band is developed, the assay is invalid regardless of any burgundy color in the T bands as indicated below. Repeat the assay with a new device.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

CLINICAL SIGNIFICANCE

Human immunodeficiency virus type I and type II (HIV-1 and HIV-2) are enveloped single strain RNA positive virus. The causative relationship between HIV-1 and HIV-2 virus and acquired immunodeficiency syndrome (AIDS) has been established over decades. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy individuals with a high risk for developing AIDS1. HIV-2 has been isolated from West African AIDS patients and from sero-positive asymptomatic individuals2.

The two types of HIV have significant variation in sequences. HIV-1 has been divided into three groups: group M (for major), including at least ten subtypes (A through J); group O (for outlier); and group N (for non-M, non-O). Similarly, the HIV-2 has been classified into at least five subtypes (A through E). Some HIV-1 variants share up to 50% homology in their envelope genes with the sequences of more common prototype strains.

Both HIV-1 and HIV-2 virus can elicit strong immune responses3, including the production of anti virus antibodies. Presence of specific anti HIV-1 and/or HIV-2 virus antibody in blood, serum and plasma indicates the exposure of an individual to the HIV-1 and/or HIV-2 virus, being of great value for clinical diagnosis4.

ANALYTICAL PERFORMANCE

Clinical Performance HIV-1 Ab. 1,308 samples from susceptible subjects were tested by LINEAR Anti-HIV 1/2 cassettes and by a Chinese State Drug Administration (SDA) licensed EIA. Comparison for all subjects is shown in the following table:

	LINEAR Anti-HIV 1/2 cassette		
EIA	**Positive**	**Negative**	**Total**
Positive	326	0	326
Negative	0	982	982
Total	326	982	1308

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

Clinical Performance for HIV-2 Ab. 195 samples from susceptible subjects were tested by the LINEAR Anti-HIV 1/2 cassettes and by a Chinese State Drug Administration (SDA) licensed EIA. Comparison for all subjects is shown in the following table.

	LINEAR Anti-HIV 1/2 cassette		
EIA	**Positive**	**Negative**	**Total**
Positive	20	0	20
Negative	0	175	175
Total	20	175	195

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

Interferences. Bilirubin 20 mg/dL, Creatinine 442 µmol/L, Glucose 55 mmol/L, Albumin 60 g/L, Salicylic Acid 4.34 mmol/L, Heparin 3,000 U/L, EDTA 3.4 µmol/L, do not interfere.

Cross-Reactivity. other infectious diseases:

Specimen	Sample Size	HIV-1 Ab Reactivity	HIV-2 Ab Reactivity
HBsAg Positive Serum	10	Negative	Negative
HAV Positive Serum	10	Negative	Negative
HCV Positive Serum	10	Negative	Negative
Dengue Positive Serum	10	Negative	Negative
Syphilis Positive Serum	10	Negative	Negative
TB Positive Serum	10	Negative	Negative
H. pylori Positive Serum	10	Negative	Negative
ANA Positive Serum	8	Negative	Negative
HAMA Positive Serum	19	Negative	Negative
RF Positive Serum	3	Negative	Negative

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely. Failure to follow the procedure may give inaccurate results.
2. The intensity of the test band does not correlate with antibody titer of the specimen.
3. A non-reactive result indicates absence of detectable HIV-1 or 2 antibodies. However, a non-reactive result does not preclude the possibility of exposure to or infection.
4. A non-reactive result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. If the symptom persists, while the result is non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PRECAUTIONS

1. The insert must be read completely before performing the test. Failure to follow the insert gives inaccurate results.
2. Do not use the components in any other type of test kit as a substitute for the components in this kit.
3. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
4. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
5. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
6. Dispose of all specimens and materials used to perform the test as bio hazardous waste.
7. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.
8. Handle the negative and positive controls in the same manner as the patient specimens.

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2. Arya, SK, et all. F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987) 328:548-550
3. Caetano JA Immunologic aspects of HIV infection. Acta Med Port (1991) 4 Suppl 1:52S-58S
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LINEAR CHEMICALS S.L. Joaquim Costa 18 2ª planta. 08390 Montgat, Barcelona, SPAIN
Telf. (+34) 934 694 990 Fax. (+34) 934 693 435. website www.linear.es