GB QUIK – HIV 1/2 AB RAPID TEST KIT (SERUM/PLASMA)

KIT NAME	KIT SIZE	CAT. NO
GB QUIK – **HIV 1/2** AB RAPID TEST KIT	25T	GBQHIV0025T
GB QUIK – **HIV 1/2** AB RAPID TEST KIT	50T	GBQHIV0050T

GENUINE BIOSYSTEM

INTENDED TO USE

The HIV 1/2 Ab Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay with a double antigen system for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HIV. Any reactive specimen with the HIV 1/2 Ab Rapid Test Cassette must be confirmed with alternative testing method(s).

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from the host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with a high potential risk for developing AIDS.1 HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.2 Both HIV-1 and HIV-2 elicit an immune response.3 Detection of HIV antibodies in serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.4 Despite the differences in their biological characters, serological activities and genome sequences, HIV-1 and HIV-2 show strong antigenic cross-reactivity.5 Most HIV-2 positive sera can be identified by using HIV-1 based serological tests. The HIV 1/2 Ab Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1 and/or HIV-2 in serum or plasma specimens. The test utilizes gold conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1/2 in serum or plasma.

PRICIPLE

The HIV 1/2 Ab Rapid Test Cassette (Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HIV recombinant antigens on the test line region of the device. When a specimen is applied at one end of the membrane, it reacts with HIV recombinant antigen coated gold conjugate in the test. The mixture then migrates chromatographically by capillary action and reacts with the recombinant HIV recombinant antigens on the membrane in the test line region. If the serum or plasma contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line region, showing a positive result. The absence of the colored test line indicates that the serum or plasma does not contain the anti-HIV antibodies, showing a negative result. A colored line will always appear at the control line region to serve as a procedural control. This indicates if the proper volume of specimen has been added and that membrane wicking has occurred.

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KIT CONTENTS:

S. No	Component	QTY
1	Test Casette	25 nos
2	Prefilled Buffer Solution tube	25 nos
3	Sample Dropper	25 nos

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date

SPECIMEN

1. HIV 1/2 Ab Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. specimens may be stored at 2-8 C for up to 3 days. For long term storage, specimens should be kept below -20C
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped , they should be packed in compliance with usual regulations for transportation of aetiological agents.

WARNING AND PRECAUTION

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air conditioning.

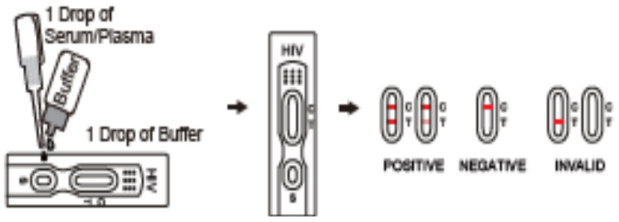
TEST METHODS

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

1.Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (approx. 30µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer approx.40µL and start the timer. Avoid trapping air bubbles in the specimen well (S). Please see the illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). *NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of HIV antibodies in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). INVALID: Control line fails to appear. 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

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

LIMITATIONS OF TEST METHODS

1. The HIV 1/2 Ab Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HIV-1 and/or HIV-2 in serum or plasma.
2. The HIV 1/2 Ab Rapid Test Cassette is limited to the qualitative detection of antibodies to HIV-1 or HIV-2 in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable HIV-

1 or HIV-2 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.

4. A negative 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. Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers fir Disease Control. For samples repeatedly tested as positive, more specific supplemental tests must be performed.

6. Immunochomatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 and/or HIV-2 are present in a patient specimen.

7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERSTICS

Sensitivity: The test has been compared with a leading commercial HIV EIA test using clinical specimens. Results showed the HIV 1/2 Ab Rapid Test Cassette is very sensitive to HIV-1 and/or HIV-2 antibodies. Specificity: The specificity is comparable to a leading commercial HIV EIA test. The test is highly specific for anti-HIV-1 and/or HIV-2 when compared to a leading commercial HIV EIA test. The HIV 1/2 Ab Rapid Test Cassette vs. EIA test.

Method		EIA		Total Results
HIV 1/2 Rapid Test	Results	Positive	Negative	
	Positive	210	2	212
	Negative	1	1050	1051
Total Results		211	1052	1263

Relative sensitivity:99.5%

Relative specificity: 99.8%

Accuracy: 99.8%

REFERENCE

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IVD CE

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