GB QUIK – HCV AB RAPID TEST KIT (SERUM/PLASMA)

GENUINE BIOSYSTEM

KIT NAME	KIT SIZE	CAT. NO
GB QUIK – **HCV** AB RAPID TEST KIT	25T	GBQHCV025T
GB QUIK – **HCV** AB RAPID TEST KIT	50T	GBQHCV050T

INTENDED TO USE

The HCV Ab Rapid Test Cassette (Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Hepatitis C virus (HCV) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Ab Rapid Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens (1, 2). Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests (3, 4). HCV Ab Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elveated levels of HCV antibodies in serum or plasma.

PRICIPLE

The HCV Ab Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another device.

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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 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. Do not use beyond the expiry date .

SPECIMEN

1. HCV 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 -20 **C**.
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.

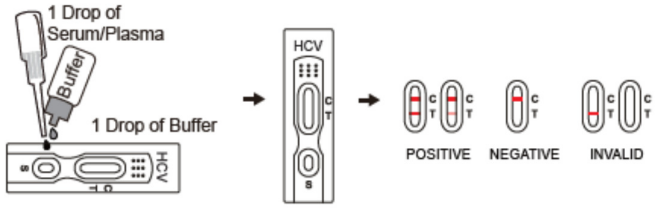
WARNING AND PRECAUTION

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.

TEST METHODS

Allow the test cassette, specimen, buffer, and/or controls to reach 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 one drop of serum or plasma (about 30µl) to the sample well (S) then add one drop (about 40µl) of sample buffer immediately. Avoid air bubbles. See illustration below.
3. Set up timer.
4. Wait for the colored line(s) to appear. Read results in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(please refer to the illustration above)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line 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 device. 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 test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS OF TEST METHODS

1. The HCV Ab Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. The HCV Ab Rapid Test Cassette (Serum/Plasma) will only indicate the presence of antibodies to HCV in specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. A negative result can occur if the quantity of the antibodies to HCV 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.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERSTICS

Sensitivity: HCV Ab Rapid Test Cassette (Serum/Plasma) has passed a sero conversion panel and compared with leading commercial HCV EIA test using clinical specimens.

Specificity: The recombinant antigens used for HCV Ab Rapid Test Cassette (Serum/Plasma) are encoded by genes for both structural (nucleocapsid) and non-structural proteins. HCV Ab Rapid Test (Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.

The HCV Ab Rapid Test Cassette vs.EIA test.

Method		EIA		Total Results
HCV Ab Rapid Test	Results	Positive	Negative	
	Positive	105	19	124
	Negative	2	1760	1762
Total Results		107	1779	1886

Relative sensitivity: 98.1%
Relative specificity: 98.9%
Accuracy: 98.9%

REFERENCE

1.Choo, Q.L., G.Kuo,A.J. Weiner, L.R. Overby,D.W. Bradley, andM. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome Science 189;244:359

2.Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362.

3.Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie .Confirmation of hepatitis C Virus infection by new four- antigen recombinant immunoblot assay. Lancet 1991;337:317

4.Wilber, J.C.Development and use of laboratory tests for hepatitis Cinfection: a review.J. Clin. Immunoassy 1993;16:204.

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Genuine Biosystem Private Limited
Plot 97 & 98, Kattabomman street,
Parvathy nagar Extn,
Old Perungalatur, Chennai-600063.TN.India
Ph:044-48681845
Email:info@gb-group.co.in
Web: www.genuinebiosystem.com