GBLISA Human Anti-Hepatitis C Virus (HCV)

GENUINE BIOSYSTEM

Kit contents	Contents	Cat no.
GBLISA HCV	96T	GBLHCV096T

[Intended Use]

This reagent is used for qualitative detection of hepatitis C virus antibodies in human serum or plasma, and is suitable for screening of blood donors and auxiliary diagnosis of clinical hepatitis C virus infection.

[Principle]

This kit adopts the principle of indirect method enzyme-linked immunosorbent assay. The sample to be tested is incubated in the antigen-coated microtiter strip, and if the sample contains antibodies against hepatitis C virus, an antigen-antibody complex is formed, and then enzyme-labeled anti-IgG is added to form an "enzyme-labeled antibody-antibody to be tested-coated antigen" complex. A color development reaction is generated with the participation of TMB
substrate.

[Reagents Composition]

Pre-coated microtiter plates 8*12 stripes (96 wells)	1 piece
Enzyme working liquid	1 bottle
Positive control	1 vial
Negative control	1 vial
Assay Diluent	1 bottle
Wash buffer concentrate	1 bottle
TMB substrate	1 bottle
Stopping solution	1 bottle

[Storage and Stability]

The kit should be dry and stored at 2°C~8°C, avoid heavy pressure and pay attention to moisture, light, and heat. It is valid for 12 months. After opening the microporous reaction plate, it should be sealed and dried in aluminum foil bag, and stored at 2°C~8°C, and the validity period is 14 days.

[Instruments]

The enzyme label instrument with 450nm/630nm wavelength.

[Specimen]

The specimens shall be blood, serum in type and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. Samples may be refrigerated at 2~8° C for a maximum period of five (5) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20° C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing.

[Test Procedure]

Specimen Pre-treatment requirement: No need.
Bring all reagents, specimen and controls to room temperature before use. Patient specimen and controls should be assayed in duplicate.
Test procedure should be performed by a skilled individual or trained professional
1. Prepare wash buffer 1:20 in distilled or deionized water before use.
2. Remove the required number of well strips. Restore the resealed bag to the refrigerator.
3. Pipette 100 μL of the Assay Diluent to each well.
4. Pipette 10 μL of the sample to the corresponding wells in order, pipette 10 μL of the negative and positive controls into correspondingly labelled wells in duplicate.
5. Swirl the microplate gently for 20-30 seconds and cover, then incubate at 37℃ for 1 hour.
6. Discard the contents and wash the wells 5 times with 300 μL of diluted wash buffer per well and tap the plate firmly against absorbent paper to ensure that it is dry.
7. Pipette 100 μL of the enzyme working solution into each well, then incubate at 37℃for 30 minutes.
8. Repeat the step 6 for washing.
9. Pipette 100 μL of TMB substrate into each well immediately, then incubate at 37℃ for 15 minutes.
10. Pipette 50 μL of stopping solution into each well immediately.
11. Reading value: read OD value at 450nm (using a reference wavelength of 620-630nm) within 10 minutes after addition of the stopping solution.

[Expected Values]

Calculation of the critical value (C.O.).
Critical value = negative control OD mean + 0.12
The mean value of negative control OD was calculated as 0.02 if it was less than 0.02.

[Interpretation of Test Results]

1. Samples with OD value S/C.O. ≥1 is considered positive for HCV antibody reactions; samples with OD value S/C.O. <1 is considered negative for HCV antibody reactions.
2. If the mean OD value of negative control >0.08 or the mean OD value of positive control ≤0.5, the experiment is invalid and should be retested.

[Limitations of the Procedure]

1. Due to the limitations of the methodology, a negative result of this reagent does not exclude the possibility of hepatitis C virus infection; a positive result must be judged in conjunction with other indicators.
2. This reagent is only for human serum or plasma samples, and is not suitable for other body fluid samples.
3. This reagent is a qualitative reagent and cannot be used as a quantitative reagent

[Performance Characteristics]

1. Negative reference compliance rate 20/20
2. Positive reference compliance rate 20/20
3. Minimum detection limit compliance rate ≥ 3/5
4. Precision (CV) ≤ 15%

[WARNINGS AND PRECAUTIONS】

1. This product is only used for in vitro diagnosis, not for other purposes, the operation should be strictly in accordance with the instructions.
2. Do not use expired kits; Different batches of kits should not be mixed; Do not mix with reagents from other manufacturers.
3. All human derived materials used in the preparation of this reagent were tested negative for HBsAg, HBsAb, HAV-IgM, HCV, TP, and CMV (using an experimental method approved by the CDSCO).

Because there is no clear test methods can ensure no HBsAg detection of negative samples completely, HAV and other infectious virus, so all material derived from the human body, especially the clinical samples should be treat by infectious samples, and according to the ministry of health, Ministry of Science and Technology, the state food and drug administration issued by the relevant laboratory specifications and requirements.

4. During the operation, special attention should be paid to all samples and waste liquid and other materials such as test tubes, buffer solution and suction head, which may contain infectious substances. During the operation, work clothes and gloves should be worn. It is strictly prohibited to suck samples by mouth. In case of contact with any wound, consult a doctor in time. If any liquid spills during the experiment, it should be immediately disinfected with disinfectant. At the end of the experiment, all used samples and laboratory items should be disposed of as medical waste.

5. Some of the ingredients contained in this reagent, such as Proclin ®300, may cause allergic reactions in a very small number of people. Long-term contact with skin should be avoided and hands should be washed thoroughly after contact.

6. When conducting laboratory operations according to the product specifications, the manufacturer only warrants that the assay kit functions as an in vitro diagnostic function within the specified range described in the specifications. The manufacturer assumes no responsibility for any other warranty or implication, including commercial value, or other use within the scope of application. The responsibility of the manufacturer is limited to the replacement or return of the product.

7. A negative test result does not guarantee the absence of low levels of antibodies in the sample and does not completely exclude the possibility of HCV infection.

8. This immunoassay cannot absolutely exclude the presence of non-specific reactions. If you are in doubt about the test results, please confirm the results of the test sample with the appropriate confirmation reagent or method.

IVD CE

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