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HCV Rapid Test Device

Catalog No.: BG201C BG201S

Immunochromatographic test for the detection of HCV antibody in serum or plasma

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. 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. 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.

HCV-Card Rapid Test (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in serum or plasma specimen. HCV-Card Rapid Test is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

Principle of the test

The HCV-Card Rapid Test (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is coated with recombinant HCV antigen on the test line region of the card. During testing, the serum or plasma specimen reacts with the recombinant HCV antigen coated colloidal gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with another recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of a control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory. Use the control in the same manner as a specimen by following the test procedure. The expected results should be obtained when using the control.

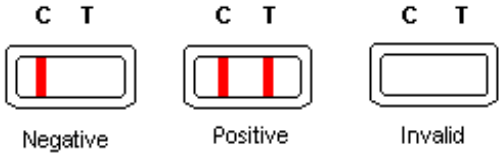
SPECIMEN COLLECTION

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing. If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Bring the specimens to normal room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
2. Draw 0.1ml (about 3 drops) sample into the pipette, and dispense it into the sample well on the cassette.
3. Wait 10-20 minutes and read results. Do not read results after 30 minutes.

INTERPRETATION OF RESULTS



Negative: Only one colored band appears on the control region. No apparent band on the test region.

Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.

STORAGE AND STABILITY

The test kits can be stored at room temperature (18 to 30°C) in the sealed pouch for duration of shelf life. The test kits should be kept away from direct sunlight, moisture and heat.

WARNINGS AND PRECAUTIONS

This kit contains no infectious reagents, however proper precautions should always be taken when handling patient specimens.

1. Preclude any pipetting by mouth.
2. Do not allow smoking or eating where specimen and reagents are being handled.
3. Wear disposable gloves while handling kit reagents or specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate intermediate-to-high level disinfectant.

6. Decontaminate and dispose of all specimens and potentially contaminated materials as if they were infectious.
7. Do not use reagents after the expiration date.
8. For in *vitro* diagnostic use only.

LIMITATIONS OF THE TEST

1. The HCV-Card Rapid Test (Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of antibodies to HCV in serum or plasma specimen. Neither the quantitative value nor the rate of increase in HCV antibodies can be determined by this qualitative test.

2. The HCV-Card Rapid Test (Serum/Plasma) will only indicate the presence of antibodies to HCV in the 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.

PERFORMANCE CHARACTERISTICS

Sensitivity

The analytical sensitivity of the HCV-Card is 2 NCU

BIBLIOGRAPHY

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