ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HCVD

PRATHAM® HCV Antibody Test

A lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis C virus in human serum/plasma/whole blood

INTENDED USE

PRATHAM® HCV Antibody Test Device is an in vitro diagnostic rapid test based on the principle of immunochromatography test for qualitative detection of Hepatitis C virus in human serum / plasma / whole blood. For professional use only.

INTRODUCTION

Hepatitis C virus (HCV) is a leading cause of Hepatitis. The worldwide prevalence of HCV is 0.2% to 2% in blood donors and up to 80% in intravenous drug users. Hepatitis C virus is a single-stranded RNA virus that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids, blood transfusion, and use of contaminated needles or syringes. Chronic Hepatitis may progress to severe outcomes without prompt medical intervention, including cirrhosis and liver cancer (hepatocellular carcinoma). Diagnosis of HCV infections could be based on serological tests.

TEST PRINCIPAL

PRATHAM® HCV Antibody Test is a double antigen lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3, NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold, 2) nitrocellulose membrane strip containing a test line (T Line) and a control line C Line). The T line is pre coated with recombinant HCV antigens (core, NS3, NS4 and NS5), and the C line is pre-coated with a control line antibody. When an adequate volume of the specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Antibodies to HCV, if present in the specimen, will bind to the HCV Antigen conjugates. The immuno complex is then captured on the membrane by the pre-coated, non-conjugated HCV fusion antigen forming a burgundy colored T line suggesting a positive result. The test contains an internal control C line), which should exhibit a burgundy colored line of the immuno complex of control line. If the C line does not develop, the test result is invalid, and the specimen must be retest with another device.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micro Pipette, Tips & Centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -20ºC or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior of use.

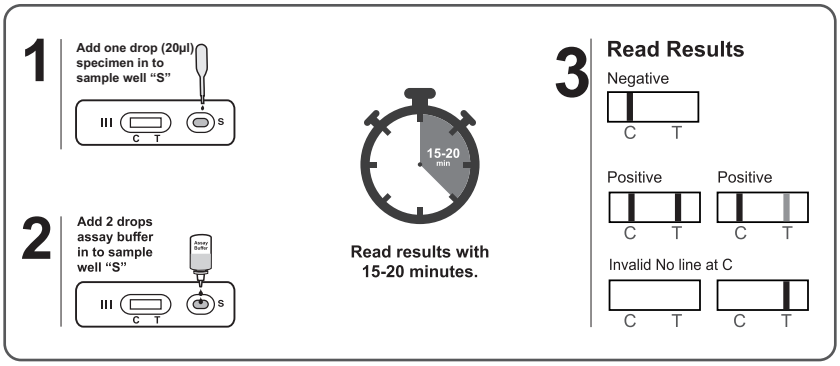
WARNING AND PRECAUTIONS

- Use product insert to perform the assay.
- Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips any where discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add one drop (20µl) of serum / plasma / whole blood into the sample well.
5. Add 2 drops of assay / running buffer into the sample well using provided buffer vial.
6. Interpret test results within 20 minutes. Don't interpret results after 20 minutes.

INTERPRETATION OF RESULTS



Negative:
A pink colored band appears only at the control region 'C', indication a negative result for HCV infections.

Positive:
Appearance of two pink/purple lines, one at the test line region 'T' and other at the control line region 'C', indicates that the specimens has infected with Hepatitis C virus and it should be considered as positive.

Invalid:
No visible band at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number. Contact the distributor with the lot number.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

IN-HOUSE EVALUATION

In an in-house study, the performance of device was evaluated using a panel of thirty known positives (of varying reactivity) and 150 known negative specimens in comparison to licensed Competitor HCV rapid test. The results of the evaluation are as follows:

Results					
Types of specimens	**Numbers**	**Pratham Hepatitis B Surface Antigen Test**		**Competitor HBsAg test**	
		Positive	Negative	Positive	Negative
Positive	30	30	0	30	0
Negative	150	0	150	0	150
Sensitivity		100%			
Specificity		100%			

LIMITATION OF THE TEST

1. A negative result does not preclude the possibility of infection with HCV infection.
2. It is recommended to always use fresh specimen with this test kit, specimen which have been frozen and thawed several times contain particulate which can block the immunochromatographic membrane hence resulting in slower or no movement of specimens which may result into invalid results.
3. This test is standardized to work best when the test procedure mentioned in the package insert is strictly followed. Any deviation from the test procedure may lead to erroneous results.
4. Any faint line for HCV should be considered reactive irrespective of its color intensity.
5. Specimen found to be reactive by the above screening test must be confirmed by standard supplemental assay, like ELISA or PCR.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

BIBLOGRAPHY OF SUGGESTED READING

1. Restricted Isotopic Antibody reactivity to Hepatitis C Virus Synthetic Peptides in Immunocompromised Patients, Marisol Deves Arlette De Saez, Graciela Leon, Firelei Sirit, Clarisa Coson, Henry Bermudez, Ferdinando Liprandi, Oscar Noya, Flor H. Pujol, Clinical and Diagnostic Laboratory Immunology, Vol.6 No.2, 279-281, May 1999.
2. Immunodiagnosis of Viral Hepatitides A to E and Non-A to E, Gang Yang, Girish N.Vyas, Clinical and Diagnostic Laboratory Immunology, Vol.3, 247-256, May 1996.
3. Clinical Significance of Hepatitis C Virus Genotypes, Nizar N.Zein, Clinical Microbiology Reviews, Vol.13 No.2, 223-235, April 2000.
4. Perspectives for the Treatment of Infections with Flaviviridae, Pieter Leyssen, Eric De Clerq, John Neyts, Clinical Micro Reviews, Vol. 13 No.1, 67-82, Jan. 2000.
5. Principle and Practice of Infectious Diseases, Mandell, Burnett and Dolin, 5th Edn., Vol. 1 Part-ll, 1307, 2000, Churchill Livingstone Publications.

SYMBOLS

 Read instructions for use	 Name of Manufacturer	 For single use only
 No. of test	 Expiry Date of Kit.	 Date of manufacturing of IVD Kit
 In-vitro diagnostic use	 Keep away from Sunlight	 Reference Catalogue Number
 Storage Condition		

Manufactured By:

ASTAM DIAGNOSTICS PVT. LTD.

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