

## One Step Hepatitis C Virus Antibody Test Cassete

Specimen : serum and Plasma

### Introduction

*Assayplus* one step anti-HCV test is a lateral flow immunoassay device for the visual detection of hepatitis C antibodies (anti-HCV) in serum or plasma. It is used as an aid in the diagnosis of hepatitis C infection. The assay is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum or plasma. Purified recombinant antigens are employed to identify anti-HCV specifically. This one step test is very sensitive and only takes 20 minutes for the result to be read. Test results are read visually without any instrument.

### Assay principle

Serum or plasma sample is used for the test. After a specimen is loaded to the device, the specific antibodies, HCV IgG in the specimen sample react to the gold-conjugated HCV antigen. As HCV antibody - HCV antigen-gold conjugated complex migrates along nitrocellulose membrane, anti-HCV antibody in the complex is captured by the test line coated with recombinant HCV antigen causing a pink to deep pink band. The intensity of the band is variable depending on the amount of antibody present in the blood sample. A red control line should always develop on the test strip to indicate the proper performance.

### Kit Components

Each test kit contains:

- 1: A foil pouch contains one test cassette
- 2: 100ul Pipette tip

### Stability and Storage Conditions

*Assayplus* HCV one step test kit is stable at room temperature between 8-30°C for one and half year when in the unopened pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

### General Precautions

- The test is for In Vitro Diagnostic Use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5°C for 1 hour or treat with Sodium hypochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

### Sample Collection

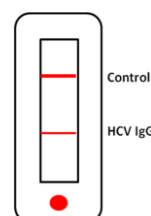
*Assayplus* HCV one step test kit can be run on serum or plasma. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at – 20°C or colder.

### Test Procedure

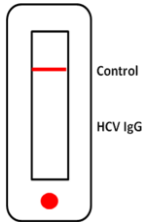
1. Remove test cards from the pouches as needed. Lay on a clean flat surface
2. Add 40-50 ul of serum or plasma into well
3. Let it run for 25 minutes to read result

### Reading the Test Results

#### 1. HCV IgG positive:



## 2. HCV negative:



## 3. Indeterminate

Control line should appear always If test line is positive or negative. If control line is negative, It is recommended that a fresh device be used and the test repeated carefully following the directions in this insert.

### Quality Control

A known positive and negative control should be run to insure proper performance. All controls should be handled in the same manner as patient samples.

### Limitations of the Test

The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly.

*Assayplus* HCV one step test is designed to detect antibodies against HCV virus in serum or plasma. Testing of any other body fluids has not been validated and may not yield appropriate results.

For samples that test positive by *Assayplus* HCV one step test, more specific confirmatory testing should be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established. The use of a rapid test alone is not sufficient to diagnose HCV even if antibodies are present. Also, a negative result does not preclude the possibility of infection with hepatitis C virus.