


# Anti-HCV dipstick



Store at 4-30 °C

## Configuration

REF	172-050/S
	2 x 25 tests
desiccated containers, containing 25 dipsticks.	2
Instruction leaflet.	1

## Intended use

The Cypress Anti-HCV dipstick is a rapid chromatographic immunoassay for the qualitative detection of antibodies to hepatitis C virus in human serum or plasma. It can be used for clinical diagnosis of HCV infection and for screening of blood donors at the scene. For *in vitro* diagnostic use only. For professional use only.

## Clinical significance

Hepatitis C Virus is a small, enveloped, positive-sense, single-stranded RNA Virus. 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.

## Principle

The Cypress Anti-HCV dipstick is a qualitative, sandwich solid phase gold conjugate immunoassay for the detection of antibody to HCV in serum or plasma through visual interpretation of color development in the test dipstick. The dipstick contains membrane strip that is pre-coated with HCV recombinant antigen on the test band region and goat-anti-rabbit polyclonal antibody on the control band region. The recombinant antigens used for the Cypress Anti-HCV dipstick are encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV antigens-colloid gold conjugate pad is placed at the end of the membrane. During testing, the antibodies of serum or plasma sample react with the colloidal gold conjugate. This mixture then migrates along the membrane chromatographically by capillary action to the test band region and forms a visible line as the antigen-antibody-antigen complex forms. Therefore, the formation of a visible precipitation in the test band region occurs when the sample is positive for the HCV specific antibodies. When the HCV specific antibodies are absent in the sample, no visible color band will form on the test line region. Therefore, the absence of the color band on the test line region indicates a negative result. A colored band will always appear at the control region. This control band serves as a procedural indicator for the proper performance of the test and the strip.

## Reagent composition

- strip
  - Gold conjugate: HCV recombinant antigen-1
  - Test line: HCV recombinant antigen-2
  - Control line: goat anti-rabbit polyclonal antibodies

## Precautions

- The instructions must be followed exactly to get accurate results. Anyone performing an assay with this product must be experienced in laboratory procedures.
- Do not eat, drink or smoke in the area where the samples and kit reagents are handled.
- Use appropriate precautions in the collection, handling, storage and disposal of samples and used kit contents. Wear protective clothing (disposable gloves, laboratory coat, eye protection) when handling samples. Avoid any contact between hands and eyes or mouth during sample collection and testing. All samples, reagents and controls should be handled as if they contain infectious agents.
- Decontaminate and dispose of all samples, reaction kits and potentially contaminated materials in a biohazard container in compliance with local regulations, as if they were infectious waste.
- Use a fresh test strip for every sample. The test strip is not reusable.
- Humidity can adversely affect the results. Bring the dipsticks to room temperature (15-30 °C) before opening the container to avoid

condensation of moisture on the membrane. Remove the dipstick from the container when ready to perform the test.

- The dipstick should remain in the desiccated container until use. Replace cap immediately and tightly after removing the dipstick that is going to be used. Unused dipsticks should remain in the original capped container.

## Preparation

All components are ready for use.

## Storage and stability

The Anti-HCV dipstick test strips should be stored at room temperature between 4-30 °C. Do not use tests beyond expiration date printed on the label. The test is sensitive to humidity as well as heat. Perform the test immediately after removing it from the container.

## Additional material required but not provided

- Timer
- Sample collection container

## Samples

The Cypress Diagnostics kit Anti-HCV dipstick is performed on human serum or plasma.

**Serum:** Serum is used from whole blood collected aseptically by venipuncture into a clean tube without anticoagulant. Allow the blood to clot at room temperature about 30 minutes and separate the serum by centrifugation. Carefully withdraw the serum.

**Plasma:** Plasma is used from whole blood collected aseptically by venipuncture into a clean tube containing anticoagulants (EDTA, heparin or sodium citrate). Centrifuge the blood to collect the plasma from the supernatant.

Separate the serum (from clot) or plasma (from red cells) as soon as possible to avoid hemolysis.

Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. If immediate testing is not possible, they may be stored at 2-8 °C for up to 2 weeks. For long-term storage, serum and plasma should be kept below -20 °C (up to 1 year). Frozen samples should be allowed to thaw completely, and be mixed well before testing. Avoid repeated freezing and thawing of test samples. Lipemic, icteric or hemolyzed samples may give inconsistent test results.

Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.

If specimens are to be shipped, they should be packed in compliance with national regulations covering transportation of etiologic agents.

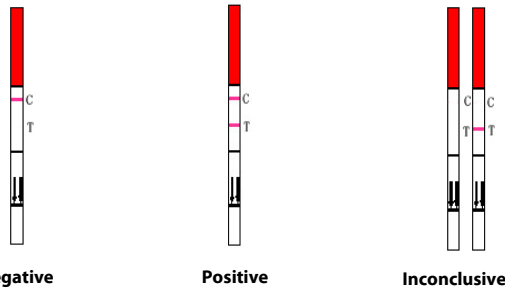
## Procedure

1. Bring the dipsticks to room temperature (15 - 30 °C) before opening the container to avoid condensation of moisture on the membrane. Remove the dipstick from the container when ready to perform the test.
2. Label the strips with patient name or identification number.
3. Immerse the dipstick into the sample with the arrow end pointing towards the sample solution. Do not immerse past the MAX (maximum) line. You may leave the dipstick in the sample solution or you may take the dipstick out after a minimum of 15 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g. mouth of the sample container)..
4. Wait for (a) colored line(s) to appear. The test results should be read at 15 minutes.

Notice: the determination above is carried out at room temperature 15-30 °C. If the room temperature is below 15 °C, the length of time for determination shall be extended correspondingly. Do not read results after 20 minutes.



## Interpretation of the results



Negative

Positive

Inconclusive

### Negative

Only one colored line in the Control area (C), with no line in the Test area (T) indicates a negative result.

### Positive

Two colored lines, one in the Test (T) area and one in the Control area (C) indicate a positive result.

NOTE: The color intensity of the test line may be weaker or stronger than that of the control line.

### Inconclusive

A colored line should always appear in the Control area (no matter if the Test line appears or not). If there is no distinct colored line visible in the Control area, the test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new test strip.

## Quality control

The Cypress Diagnostics kit Anti-HCV dipstick includes a procedural control. Regardless of the presence of antibodies against hepatitis C virus, a colored line should always appear in the Control area. The presence of the control line serves as a verification that the test has been performed successfully, sufficient volume has been added, that proper flow is obtained and that the active ingredients of the main components on the strip are still functional.

## Limitations of the test

- The Cypress Diagnostics Anti-HCV dipstick test will only indicate the presence of antibodies against hepatitis C virus in the sample and should not be used as the sole criterium for the diagnosis of infection. Neither the quantitative value nor the rate of increase or decrease in antibodies against hepatitis C virus can be determined by this qualitative test.
- This test can provide a fast and easy way to obtain a result, but does not completely exclude the possibility of a false positive or a false negative result caused by various factors.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative serological result does not preclude the possibility of an infection.
- If the patient has been infected before, the antibodies will be present in the body for a long time, so the positive result does not mean that the patient is infected.
- Negative result does not rule out infection by HCV because the antibodies to HCV may be absent or may not be present in sufficient quality to be detected at early stage of infection.
- The assay is designed for human serum or plasma only.
- A definitive clinical diagnosis should not be based on the results of a single test but should rather be made by a physician after all the clinical findings have been evaluated.

## Performance characteristics

### Clinical study

The Cypress Anti-HCV dipstick was evaluated in comparison to EIA results of human plasma/serum samples.

	EIA		Total	
	+	-		
Cypress Diagnostics Anti-HCV dipstick	+	538	22	560
	-	9	545	554
Total		547	567	1114

Relative sensitivity: 98,4%

Relative specificity : 96,1%

Relative Accuracy: 97,2%

Positive Predictive Value: 96,1%

Negative Predictive Value: 98,4%

### Specificity

#### Interferences

Common drugs such as acetaminophen, aspirin and penicillin have no significant interference to the Cypress Anti-HCV dipstick.

Endogenous chemicals, such as triglycerides, uric acid and bilirubin has no significant interference to the Cypress Anti-HCV dipstick.

## Bibliography

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