One Step Cassette Style ANTI-HCV Test

INTRODUCTION

One Step Cassette Style ANTI-HCV Test is a rapid, direct binding test for the visual detection of hepatitis C antibodies (anti-HCV) in serum. It is used as an aid in the diagnosis of hepatitis C infection. One Step ANTI-HCV Test is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum. Purified recombinant antigens are employed to identify anti-HCV specifically. This one step test is very sensitive and only takes 10-20 minutes for the result to be read. Test results are read visually without any instrument.

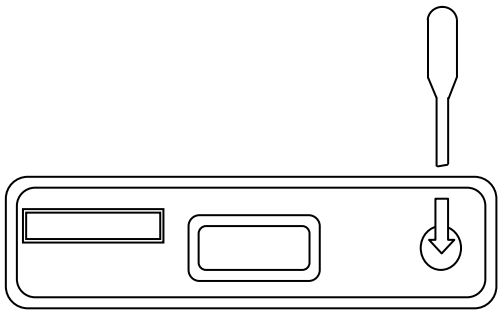
SPECIMEN COLLECTION & PREPARATION

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. Stir and bring the specimens to 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 kit from the pouch and use it as soon as possible.
2. Draw 0.2 mL (about 3 - 4 drops) sample using the pipette, and dispense it into the sample well on the cassette.
3. Wait 10-20 minutes and read result. It is important that the background is clear before the result is read. Do not read results after 30 minutes.



PRECAUTION

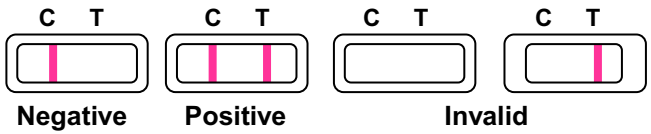
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.

INTERPRETATION OF RESULTS

Negative: Only one color band appears on the control (C) region. No apparent band on the test (T) region.

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

Invalid: A total absence of color in both (C) and (T) regions or no colored band appears on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

1. This test should be used for the detection of antibodies to HCV in serum samples.
2. Only detect the presence of Anti-HCV, it 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. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result any time does not preclude the possibility of Hepatitis C Virus infection.

SENSITIVITY & SPECIFICITY

To establish the sensitivity and specificity of IND Diagnostic One-step Anti-HCV test kit relative to other rates of °ualitative serum Anti-HCV tests, 469 clinic samples were studied. Another commercially available °ualitative test kit was used to compare with IND Diagnostic One-Step Anti-HCV test kit for relative sensitivity and specificity in 469 serum samples. Only 8 samples were discordant, the agreement is 98.3%.

Table 1 - Comparison of One-step Anti-HCV for 469 cases

		Results of IND kits		Subtotal
		+	-	
Results of Commercia lkits	+	94	6	100
	-	2	367	369
Subtotal		96	373	469

References:

Engvall E, Perimann P. Enzyme-Linked Immunosorbent Assay (ELISA) Quantitative Assay of Immunoglobulin G. Immunochem 1971:8:871-4.

Engvall E.Perimann P. Enzyme-Linked Immunosorbent Assay (ELISA). In: Pecters H, editor. Protides of the Biological Fluids. Proceedings of the Nineteenth Collo°uium, Burgge. Wxford: Pergamon Press, 1971:553-6.

Engvall E, lonsson K, Perimann P Enzyme-Linked Immunogolbulin G By Means of Enzyme-Labelled Antigen and Antibody-Coated Tubes. Biochem Biophys Acta 1971, 251:427-34.

BanWeemen BK, Schuurs AHW M. Immunoassay Using Antigen-Enzyme Conjugates. FEBS Letters 1971:15:232-6.

Wisdom GB. Enzyme-Immunoassay.Clin Chem 1976; 22:1243-55.

Wolters G, Kuijpers L, Kacaki 1, Schuurs A. Solid-Phase Enzyme-Immunoassay for Detection of Hepatitis B Surface Antigen. J Clin Pathol 1976:29:873-9.

Buti-M; Cotrina-M; Chan-H; Jardi-R;Rodreguez-F;etc. Rapid method for the detection of anti-HCV antibodies in patients with chronic hepatitis C. Rev-Esp-Enferm-Dig. 2000 Mar; 92(3): 140-6

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