IVD

Asan Easy Test® HCV

Diagnostic Kit for Hepatitis C Virus Antibody Detection

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test® HCV is a chromatographic immunoassay for the rapid qualitative determination of HCV antibodies in human serum or plasma. For diagnosis of HCV infection, HCV recombinant antigens (core, NS3, NS4, NS5) were used as a capture materials of the immunochromatographic test. The Asan Easy Test® HCV contains the membrane, which is pre-coated with properly mixed recombinant HCV antigens (core, NS3, NS4, NS5) on the test band region. During the test, the sample is allowed to react with the colloidal gold-rHCV conjugate, which has been pre-dried on the conjugate pad between membrane and sample pad. The mixture then moves upward on the membrane by capillary action. For positive result, a visible line with high sensitivity and specificity as forming antibody-rHCV-gold complex appears in the test band region of the membrane. Regardless of the presence of HCV antibodies, the mixture continuously moves across the membrane to pre-dried control line. Therefore, the control line will always appear and verify proper performance of the test. The Asan Easy Test® HCV minimizes the possibility for the false positive and places high confidence in the test result using high quality of HCV recombinant antigens.

MATERIALS PROVIDED

The Asan Easy Test® HCV contains following items to perform the assay.

1. Test device in aluminium pouch with a desiccant.
2. Assay solution.
3. Instruction manual for use.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1. The test should be performed using human serum or plasma.
2. If specimens are not immediately tested, they should be refrigerated at 2~8℃ . For storage periods more than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing test.
2. Remove the device from its protective pouch.
3. Add 10㎕ of serum or plasma into the sample well(S).
4. Dispense 3~4 drops(about 100㎕) of assay solution into the sample well(S).
5. Interpret test results within 20 minutes. Do not interpret after 20 minutes.

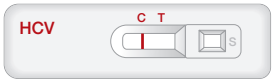
(**CAUTION** : The above interpretation time is based on reading the test results at room temperature of 15~30℃ . If your room temperature is significantly lower than 15℃ , then the interpretation time should be properly increased.)

INTERPRETATION OF THE TEST

1. A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is a control band.
2. The down section ("T" zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is a test band.

A. NEGATIVE RESULTS:

The presence of only one purple color band("C" band) within the result window indicates a negative result .



B. POSITIVE RESULTS:

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result .

C. INVALID RESULTS:

If no band is visible within the window after performing the test, the result is considered invalid . Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

LIMITATIONS OF THE TEST

Other clinically available tests are required if questionable results are obtained. As all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE & EXPIRATION

1. Asan Easy Test HCV® should be stored at 1 ~ 30℃ (35.6 ~ 86 ℉)
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

Multi-site studies were performed using a total of 200 specimens. Each specimen was tested with Asan Easy Test® HCV and Commercial HCV. The results are summarized in the following tables.

n= 200		RIA method		Total
		Positive	Negative	
Asan Easy Test® HCV	Positive	100	1	101
	Negative	0	99	99
Total		100	100	200

※ Relative Sensitivity : 100%, Relative Specificity : 99%
※ Detection limit : 2.0 s/CO

REFERENCE

1. Choo QL, Kuo G, Weiner AJ, et al, Isolation of a cDNA clone derived from a blood-borne non-A, non-B hepatitis. Science, 244:359-362, 1989.
2. Alter HJ, Purcell RH, Shih JW, et al, Detection of Antibody to hepatitis C virus in prospetively followed transfusion recipients with acute and chronic non-A, non-B hepatitis. N. Engl. J. Med. 321: 1494-1500, 1989.
3. Kuo G, Choo QL, Alter HJ, et al, An assay for circulating antibodies to major etiologic virus of human non-A, non-B hepatitis. Science, 244:362-364, 1989.

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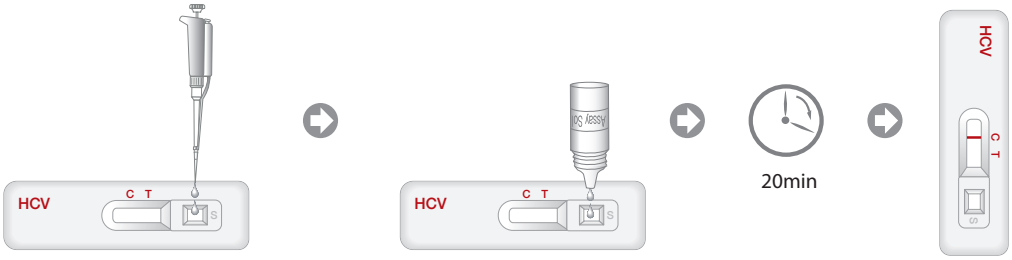

Add 10㎕ of serum or plasma

3drops of assay solution

Reading