Anti-HCV cassette

CONTENTS			
REF	4230240	Anti-HCV	40 tests
For professional *in vitro* diagnostic use only			

Anti-HCV

Rapid test for qualitative detection of Hepatitis C Virus (HCV) Antibodies (IgG+IgM)

ONE STEP

PRINCIPLE

The LINEAR Anti-HCV is an indirect lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant protein A conjugated with colloid gold (Protein A conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test result line (T line) and a control line (C line). The T line is pre-coated with recombinant HCV antigens, and the C line is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. The IgM or IgG antibody to HCV if present in the specimen will bind to the HCV conjugates. The immunocomplex is then captured on the membrane by the pre-coated non-conjugated HCV antigens, forming a burgundy colored T line, indicating a HCV Ab positive test result.

Absence of the T line suggests a negative result. The test contains an internal control which should exhibit a burgundy colored line (control line) of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENT COMPOSITION

HCV test devices, contains protein A coated particles and HCV antigen coated on the membrane.

PACKAGING CONTENTS

REF	4230240	40 HCV test device 40 Disposable specimen droppers HCV Buffer

Do not mix components from different lots

Warning: The HCV Buffer contain sodium azide. Do not allow to contact with skin or mucous membranes.

STORAGE AND STABILITY

Store at 2-30ºC.

The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date or devices with damaged pouch..

SPECIMEN COLLECTION AND PREPARATION

LINEAR Anti-HCV can be performed using either serum or plasma.

Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.

Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

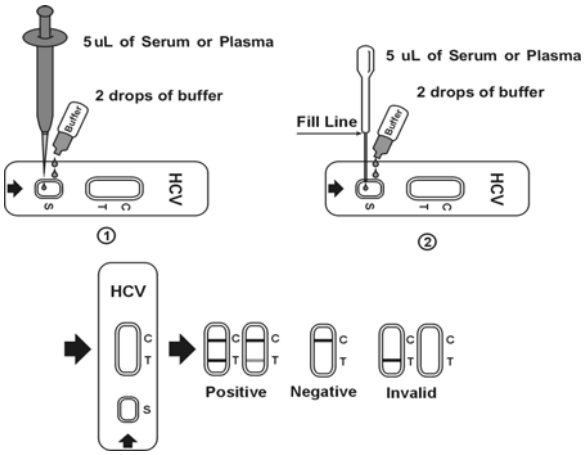
MATERIALS REQUIRED

1. Clock or Timer
2. Equipment for taking blood samples by vein puncture.
3. Centrifuge, pipettes, and tubes for the preparation of serum or plasma samples.

PROCEDURE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
3. Fill only the narrow tip of the dropper and transfer approximately 5 -10 µl of the specimen into the sample well of the device.
4. Add 2 drops of the Sample Diluent buffer into the sample well making sure that there are no air bubbles. Set up the timer.
5. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



Don't read the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF ASSAY RESULT

POSITIVE: * **Two distinct red lines appear**. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:** The intensity of the red color in the test line region (T) may vary depending on the concentration of HCV antibodies present in the specimen. The intensity of the test result line does not correlate with antibody titer of the specimen. Therefore, any shade of red in the test region should be considered positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

LINEAR CHEMICALS S.L. Joaquim Costa 18 2ª planta. 08390 Montgat, Barcelona, SPAIN
Telf. (+34) 934 694 990 Fax. (+34) 934 693 435. website www.linear.es

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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.

CLINICAL SIGNIFICANCE

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.
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 [1, 2]. 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 (3, 4).
LINEAR Anti-HCV test utilizes a combination of protein A coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

ANALYTICAL PERFORMANCE

1. Clinical Performance

A total of 300 samples from susceptible subjects were tested with the LINEAR HCV Ab Rapid Test and by a commercial HCV IgG ELISA kit. Comparison for all subjects is shown in the following table.

	LINEAR HCV Ab 2.0 Rapid Test		
HCV IgG ELISA	**Positive**	**Negative**	**Total**
Positive	24	0	24
Negative	1	275	276
Total	25	275	300

Relative Sensitivity: 100%, Relative Specificity: 99.6%, Overall Agreement: 99.7%

2. Seroconversion Panel

BBI (Boston Biomedica Inc.)'s seroconversion panel (PHV910 –(M)) were tested with the LINEAR HCV Ab Rapid Test. The result is shown in the following table.

Member ID	Days bleeding	Abbott HCV EIA 2.0 s/co*	LINEAR HCV Ab 2.0 Rapid Test
910-01	0	0.2	negative
910-02	4	0.3	negative
910-03	8	1.3	Positive
910-04	11	2.9	Positive
910-05	15	2.4	Positive

* EIA results expressed as specimen absorbance to cut-off ratio(S/CO). Ratios> 1.0 are considered reactive.

3. Correlation

The LINEAR Anti-HCV has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 98%.

4. Worldwide Performance Panel

BBI (Boston Biomedica Inc.)'s worldwide performance panel (WWHV301) were tested with the LINEAR HCV Ab Rapid Test.
The result is showed in the following table.

Member ID	Origin	Genotype	Abbott EIA	LINEAR
301-01	Argentina	1b	Positive	Positive
301-02	Argentina	1b	Positive	Positive
301-03	Argentina	3a/b	Positive	Positive
301-04	Argentina	2a/c	Positive	Positive
301-05	Argentina	Not tested	Negative	Negative
301-06	Uganda	4c/d	Positive	Positive
301-07	Uganda	Not tested	Positive	Positive
301-08	Ghana	Not tested	Negative	Negative
301-09	China	1b, 2a/c	Positive	Positive
301-10	China	2	Positive	Positive
301-11	China	1b	Positive	Positive
301-12	China	2	Positive	Positive
301-13	China	1a/b,2a/c	Positive	Positive
301-14	Egypt	3a	Positive	Positive
301-15	Egypt	4	Positive	Positive
301-16	Egypt	4h	Positive	Positive
301-17	Egypt	Not tested	Positive	Positive
301-18	USA	1b	Positive	Positive
301-19	USA	1a	Positive	Positive
301-20	USA	1a	Positive	Positive

NOTES

1. LINEAR Anti-HCV is for screening use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen. Any reactive specimen must be confirmed with alternative testing method(s) and clinical findings.
2. LINEAR Anti-HCV will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.

   As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

   If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
3. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of antibodies to HCV from individual subjects. Failure to follow the procedure may give inaccurate results.
4. A negative result indicates absence of detectable antibodies to HCV. However, a negative test result does not preclude the possibility of exposure to or infection with HCV.

   A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Do not perform the test in a room with strong air flow, e.g. an electric fan or strong air-conditioning.

REFERENCES

1. Kuo,G, Choo Q-L, Alter, HJ, et al. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. Science 1989. 244:362-4.
2. Esteban JI, Gonzalez A, Hernandez JM, et al. Evaluation of antibodies to hepatitis C virus in a study of transfusion-associated hepatitis. N Engl J Med 1990. 323:1107-12.
3. Miyamura T, Saito I, Katayama T, et al. Detection of antibody against antigen expressed by molecularly cloned hepatitis C virus cDNA: application to diagnosis and blood screening for posttransfusion hepatitis. Proc Natl Acad Sci USA 1990. 87:983-7.
4. Estaban JI, Esteban R, Viladomiu L, et al. Hepatitis C virus antibodies among risk groups in Spain. Lancet 1989. 2:294-7.
5. Houghton M, Weiner A, Han J, Kuo G, Choo Q-L. Molecular Biology of the Hepatitis C viruses: Implications for diagnosis, Development, and Control of Viral Disease. Hepatology 1991. 14:381-8.
6. Alter HJ, Purcell RH, Shih JW, Melpolder JC, Houghton M, Choo Q-L, Kuo G. Detection of antibody to hepatitis C virus in prospectivity followed transfusion recipients with acute and chronic non-A,non-B hepatitis. N Engl J Med 1989. 321:1494-1500.

O4230-3/0903
R1.ing