Anti-HCV cassette

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REF	4230240	Anti-HCV	40 tests
For professional use only			

Anti-HCV

Rapid test for qualitative detection of antibodies to HCV in human serum, plasma or whole blood

ONE STEP

PRINCIPLE

Linear Anti-HCV cassette detects antibodies (IgG, IgM, IgA) to HCV through visual interpretation of color development in the internal strip. Protein A is immobilized on the test region of the membrane. During testing, the specimen reacts with recombinant HCV antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient HCV antibodies in the specimen, a colored band will form at the test region (T) of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region (C) serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. The (T) line is pre-coated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and the C line is pre-coated with a control line antibody.

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 Plastic specimen droppers
1 Sample diluent (5 mL)

STORAGE AND STABILITY

Store at 2-30ºC. The test cassette is stable through the expiration date printed on the sealed pouch. The cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date or devices with damaged pouch. Do not reuse tests. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

Serum and Plasma. Collect blood aseptically by venipuncture into plain, heparinized or EDTA tubes, and separate the serum or plasma from the cells by centrifugation. Separate serum or plasma from the blood as soon as possible to avoid hemolysis. Test samples as soon as possible after collecting. Store samples at 2-8°C if not tested immediately. Specimens might be stored at 2°- 8°C for up to 5 days. For longer storage the specimens should be frozen at -20°C. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Blood. Drops of whole blood can be obtained by either finger puncture or heel stick. These blood samples must be used immediately before clotting occurs. Whole blood samples containing anticoagulants should be stored in refrigeration (2-8°C) or on ice prior to testing. Whole blood samples must be tested within 24 hours of collection. Do not use any hemolyzed blood for testing.

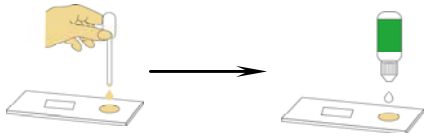
MATERIALS REQUIRED

- Timer.
- Specimen collection container.
- General laboratory equipment.

PROCEDURE

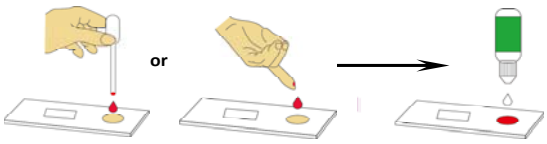
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

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 the plastic dropper with the specimen. Holding the plastic dropper vertically, dispense **1 drop** (about 30-45 µL) of serum/plasma or **1 drop** of whole blood (about 40-50 µL) into the sample well (S).
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   Immediately add **1 drop** (about 35-50 µL) of Buffer into the sample well.



1 drop of specimen 1 drop of sample diluent

Result
15 minutes



1 drop of specimen 1 drop of sample diluent

4. As the test begins to work, color will migrate across the membrane.
5. Wait for the colored band(s) to appear. The result should be read at **15 minutes**.
   Do not read after 20 minutes.

INTERPRETATION OF ASSAY RESULT

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately.

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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. Antibodies to HCV are 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. Compared to first generation HCV EIAs using single recombinant antigens, new serologic tests include multiple antigens using recombinant protein and/or synthetic peptides to avoid nonspecific cross-reactivity and to increase sensitivity.

ANALYTICAL PERFORMANCE

Relative Sensitivity: 99%
Relative Specificity: 99.5%
Overall Agreement: 99.3%

Table: HCV Rapid Test vs. EIA

		HCV Rapid Test		
		+	-	Total
EIA	+	312	3	315
	-	4	731	735
		567	316	734

Worldwide Performance Panel

BBI's (Boston Biomedica Inc.) worldwide performance panel (WWHV301) was tested with the Linear Anti-HCV cassette. The results are shown in the following table.

Member ID	Origin	Genotype	Abbott EIA	Linear Anti-HCV
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

Seroconversion Panel

BBI's (Boston Biomedica Inc.) seroconversion panel (PHV910 –(M)) was tested with the Linear Anti-HCV cassette. The results are shown in the following table.

Member ID	Days bleeding	Abbott HCV EIA 2.0 s/co*	Linear HCV Ab Plus Combo 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

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all test materials to room temperature (15°C-30°C) before use.
5. Do not use components from any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive controls in the same manner as patient specimens.
11. The test results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the results after 15 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

LIMITATIONS OF TEST

1. The intensity of the test line does not have a linear correlation with the antibody titer in the specimen.
2. LINEAR Anti-HCV is for screening use only. This test should be used for the detection of antibodies to HCV in serum, plasma or whole blood specimen. Any reactive specimen must be confirmed with alternative testing method(s) and clinical findings.
3. 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.
4. 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. 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. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.

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