SPECTRUM

The Creative Approach To Bioscience

HCV Ab Plus Rapid Test - Cassette
(Serum / Plasma)

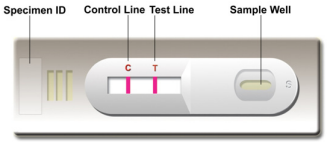
REF: 1165 001 25 test
REF: 1165 002 50 test

INTENDED USE
The Spectrum HCV Ab Plus Rapid Test is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-Hepatitis C virus antibodies (IgG, IgM, IgA) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the Spectrum HCV Ab Plus Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Hepatitis C virus (HCV), which was formerly described as the parentally transmitted form of non-A, non-B hepatitis (NANBH)1, becomes a chronic disease in 50% of the cases2. HCV can also be transmitted through intravenous drug abuse, sexual, and household contact3. Hepatitis C virus is a single stranded RNA virus with some structural relations to the flavivirus family. Nucleic acid sequences of HCV cDNA clones provided the basis for the construction of recombinant peptides representing putative Hepatitis C virus proteins4,5.

Anti-hepatitis C virus antibody screening of blood using synthetic or recombinant proteins, helped to identify apparent healthy blood donors with anti-HCV antibodies who otherwise might have transmitted the virus6. Therefore, the Spectrum HCV Ab Plus Rapid Test is a useful tool for blood bank screening safety.

TEST PRINCIPLE
The Spectrum HCV Ab Plus Rapid Test is a double antigen lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant HCV antigens conjugated with colloidal gold (HCV Ag conjugates), and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with recombinant HCV antigens, and C band 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 antibodies to HCV, if present in the specimen, will bind to the HCV Ag 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 or reactive test result.

Absence of the T line suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored line of the immunocomplex of goat-anti rabbit IgG/rabbit IgG-gold conjugates regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED
1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Sample Diluent (1 vial, 5 mL)
4. One package insert (instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDED
1. Clock or Timer

WARNINGS AND PRECAUTIONS
For in Vitro Diagnostic Use
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.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

4. Bring all test materials to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimen 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. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The testing 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.
13. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS
All reagents are ready to use as supplied. Store unused test device unopened at 2°C-8°C. The positive and negative controls should be kept at 2°C-8°C or the temperature indicated. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma
1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

Serum
1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately. Store specimens at 2°C to 8°C for up to 5 days. The specimens should be frozen at -20°Cfor longer storage.

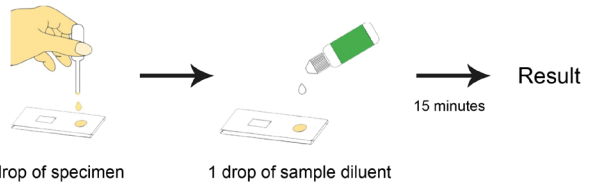
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well, prior to assay, once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

Step 4: Fill the plastic dropper with the specimen.
Holding the dropper vertically, dispense 1 drop (about 30-40 µL) of specimen into the sample well making sure that there are no air bubbles. Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.



Step 5: Set up timer.

Step 6: Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

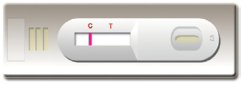
Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. ***Internal Control:*** This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. ***External Control:*** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kits fall outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. ***NEGATIVE RESULT:*** If only the C line is developed, the test indicates that no detectable antibodies to HCV are present in the specimen.The result is negative or non-reactive.



2. ***POSITIVE RESULT:*** If both the C and the T lines are developed, the test indicates the presence of antibodies to HCV in the specimen. The result is positive or reactive.

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

3. ***INVALID:*** If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. *Clinical Performance*

A total of 1050 samples from susceptible subjects were tested with the Spectrum HCV Ab Plus Rapid Test and by a commercial HCV ELISA kit. Comparison of the results for all subjects is shown in the following table.

	Spectrum HCV Ab Plus Rapid Test		
HCV ELISA	Positive	Negative	Total
Positive	312	4	316
Negative	3	731	734
Total	315	735	1050

Relative Sensitivity: 98.7%, Relative Specificity: 99.6%, Overall Agreement: 99.3%

2. *Worldwide Performance Panel*

BBI's (Boston Biomedica Inc.) worldwide performance panel (WWHV301) was tested with the Spectrum HCV Ab Plus Rapid Test. The results are shown in the following table.

Member ID	Origin	Genotype	Abbott EIA	Spectrum HCV Ab Plus Rapid Test
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

3. *Seroconversion Panel*

BBI's (Boston Biomedica Inc.) seroconversion panel (PHV910 –(M)) was tested with the Spectrum HCV Ab Plus Rapid Test. The results are shown in the following table

Member ID	Days bleeding	Abbott HCV EIA 2.0 s/co*	Spectrum HCV Ab Plus 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.

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HCV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Spectrum HCV Ab Plus Rapid Test is limited to the qualitative detection of antibodies anti-HCV in human serum or plasma. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
3. A non-reactive result for an individual subject indicates absence of detectable antibodies to HCV. However, a non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
4. A non-reactive 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.
6. If the symptoms persist when the result from Spectrum HCV Ab Plus Rapid Test is non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. 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.
2. Estaban JI, Esteban R, Viladomiu L, et al. Hepatitis C virus antibodies among risk groups in Spain. Lancet 1989. 2:294-7.

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