

## OnSite™ HCV Ab Plus Rapid Test

REF R0023S (5 mm strip)

## INTENDED USE

The OnSite HCV Ab Plus Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus (HCV) antibodies (IgG, IgM, IgA) in human serum or plasma. It is intended to be used by healthcare professionals to aid in the diagnosis of infection with HCV.

Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

## SUMMARY AND EXPLANATION OF THE TEST

HCV, which was formerly described as the parentally transmitted form of non-A, non-B hepatitis (NANBH)<sup>1</sup>, causes chronic disease in 50% of cases<sup>2</sup>. HCV can also be transmitted through intravenous drug abuse and sexual contact<sup>3</sup>.

Hepatitis C virus is a single-stranded RNA virus with structural similarities to the flavivirus family. Nucleic acid sequences of HCV cDNA clones provide the basis for the construction of recombinant peptides representing putative hepatitis C virus proteins<sup>4,5</sup>. Anti-hepatitis C virus antibody screening of blood using synthetic or recombinant proteins helped to identify apparently healthy blood donors with anti-HCV antibodies who otherwise might have transmitted the virus<sup>6</sup>. Therefore, the OnSite HCV Ab Plus Rapid Test is a useful tool for detection of HCV infection.

The OnSite HCV Ab Plus Rapid Test was developed to detect anti-HCV antibodies (IgG, IgM, IgA) in human serum or plasma. The test can be performed by minimally skilled personnel and without the use of laboratory equipment.

## TEST PRINCIPLE

The OnSite HCV Ab Plus Rapid Test is a double antigen lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3, NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugate) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample pad of the test device, the specimen migrates by capillary action across the strip. The antibodies to HCV, if present in the specimen, will bind to the HCV Ag conjugate. The immunocomplex is then captured on the membrane by the pre-coated, non-conjugated HCV fusion antigen forming a burgundy colored T line, indicating an HCV Ab positive or reactive test result. Absence of the T line suggests a negative result.

The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of control antibodies regardless of the color development on T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

## REAGENTS AND MATERIALS PROVIDED

- Individually sealed foil pouch containing:
  - One strip device
  - One desiccant
- Plastic droppers
- Sample diluent (REF SB-R0023, 5 mL/bottle)
- One package insert (instruction for use)

## MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

## WARNINGS AND PRECAUTIONS

## For In Vitro Diagnostic Use

- This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Bring all test materials to room temperature (15-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Do not use hemolyzed blood specimens for testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
- Handle the negative and positive controls in the same manner as patient specimens.
- The test results should be read 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 15-20 minute window should be considered invalid and must be repeated.
- Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

## REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°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 to temperatures above 30°C.

## SPECIMEN COLLECTION AND HANDLING

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

## Plasma/Serum

- Step 1: Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.
- Step 2: To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.
- Step 3: To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

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

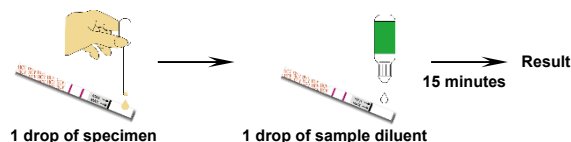
Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

## ASSAY PROCEDURE

- Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to performing the assay.
- Step 2: When ready to test, open the pouch at the notch and remove the test strip. Place the test strip on a clean, flat surface.
- Step 3: Fill the plastic dropper with the specimen.

Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the center of the sample making sure that there are no air bubbles.

Immediately add 1 drop (about 35-50 µL) of sample diluent to the sample pad with the bottle positioned vertically.



- Step 5: Set up a timer.
- Step 6: Results should be read at 15 minutes. Positive results may be visible in as short as 1 minute. Negative results must be confirmed at the end of the 20 minutes only. **Any results interpreted outside of the 15-20 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.**

## QUALITY CONTROL

- 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.
- 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 testing of specimens.
  - A new lot of test kits is used.
  - A new shipment of test kits is used.
  - The temperature during storage of the kits falls outside of 2-30°C.
  - The temperature of the test area falls outside of 15-30°C.
  - To verify a higher than expected frequency of positive or negative results.
  - To investigate the cause of repeated invalid results.

## INTERPRETATION OF ASSAY RESULT

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



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



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

- INVALID:** If no C line develops, 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 were collected from susceptible subjects and tested with the OnSite 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.

HCV ELISA	OnSite HCV Ab Plus Rapid Test		
	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. Worldwid Performance Panel

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

Member ID	Origin	Genotype	Abbott EIA	OnSite 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)) were tested with the OnSite HCV Ab Plus Rapid Test. The result is shown in the following table.

Member ID	Days bleeding	Abbott HCV EIA 2.0 s/co*	OnSite 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  $\geq 1.0$  are considered reactive.

## LIMITATIONS OF TEST

- 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.
- The OnSite HCV Ab Plus Rapid Test is limited to the qualitative detection of antibodies to HCV in human serum or plasma. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.
- A negative or non-reactive result for an individual subject indicates absence of detectable antibodies to HCV. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
- A negative or 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 if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- Infection may progress rapidly. If the symptoms persist and the result from OnSite HCV Ab Plus Rapid Test is negative or non-reactive, it is recommended to test with an alternative test.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## REFERENCES

- 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.
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- 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.
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- 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.
- Alter HJ, Purcell RH, Shih JW, Melpolder JC, Houghton M, Choo Q-L, Kuo G. Detection of antibody to hepatitis C virus in prospectively followed transfusion recipients with acute and chronic non-A, non-B hepatitis. N Engl J Med 1989. 321:1494-1500.

## Index of Symbols

	Consult instructions for use		For <i>in vitro</i> diagnostic use only		Use by
	Catalog #		Lot Number		Tests per kit
	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		



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