BIOGENIX
INC. PVT. LTD.

HCV Rapid Test (Serum/Plasma)

INTENDED USE

BIPL HCV Ab Rapid Test is a 4th generation double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA) in human serum, 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 BIPL HCV Ab 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), causes chronic disease in 50% of patients. HCV can also be transmitted through intravenous drug abuse and sexual contact. Hepatitis C virus is a s ingle-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. 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. Therefore, BIPL HCV Ab Rapid Test is a useful tool for blood bank screening safety. BIPL HCV Ab Rapid Test was developed to detect anti-HCV antibodies (IgG, IgM, IgA) in human serum, plasma.

TEST PRINCIPLE

BIPL HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoas say. The test cassette consists of:

1) a burgundy colored conjugate pad containing recombinant HCV fusion antigen (core, NS3,NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugates) 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 precoated with recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and C line is precoated with a control line antibody.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. 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 antigen forming a burgundy colored T line, indicating an HCV positive 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 the control antibodies, regardless of color development on the 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

1. Individually sealed foil pouches containing:
   - One cassette device
   - One desiccant
2. Plastic droppers
3. One package insert (instruction for use)

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED

1. Positive Control
2. Negative Control

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 may lead to 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 reagents 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 hemolyzed 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. 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 test result should be read 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the result after 20 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 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 s ealed pouch. Do not freeze the kit or expose the kit to temperatures over 30°C.

SPECIMEN COLLECTION AND HANDLING

Plasma

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

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by venipuncture.
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 -8 °C if not testedimmediately. 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.

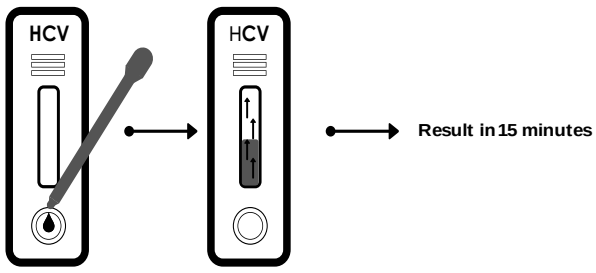
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

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

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

Step4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 50-70 µL) of specimen into the sample well making sure that there are no air bubbles.



2-3 drops of serum/plasma specimen

Note: Add 1 drop of Saline or Phosphate-Saline buffer (common buffers used in clinics not provided in the kit) to the sample well if flow migration is not observed in the result window within 30 seconds, which could occur with a highly viscous specimen.

Step 5: Set up timer.

Step 6: Result can be read in 15 minutes. Positive results may be visible in as soon as 1 minute.

Do not read result after 20 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. If the C line does not develop, review the entire procedure and repeat the test with a new device.

2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay, particularly under the following circumstances:

a. 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 kit falls 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.

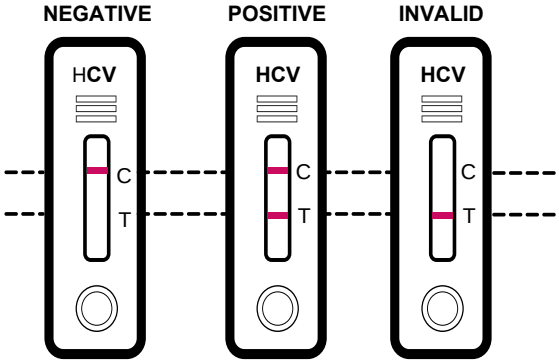
INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C line is developed, the test indicates that the level of HCV antibodies in the specimen is undetectable. The result is negative or non-reactive.

2. **POSITIVE RESULT:** If both the C and the T lines are developed, the test indicates that the specimen contains HCV antibodies. 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.

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 733 samples from susceptible subjects were tested with the BIPL HCV Rapid Test and with a commercial HCV ELISA kit. Comparison for all subjects is shown in the following table.

	BIPL HCV Rapid Test		
HCV ELISA	**Positive**	**Negative**	**Total**
Positive	325	3	328
Negative	2	403	405
Total	327	406	733

Relative Sensitivity: 99.1%, Relative Specificity: 99.5%, Overall Agreement: 99.3%

2. Cross-Reactivity

Cross-reactivity with specimens from other infectious diseases:

Specimen	Sample Size	HCV Reactivity
Dengue Positive Serum	10	Negative
HAV Positive Serum	10	Negative
HBsAg Positive Serum	10	Negative
HIV Positive Serum	10	Negative
Syphilis Positive Serum	10	Negative
TB Positive Serum	10	Negative
H. pylori Positive Serum	10	Negative
ANA Positive Serum	6	Negative
HAMA Positive Serum	4	Negative
RF Positive Serum (≤2,500 IU/ml)	3	Negative

3. Interference

Common substances (such as pain and fever medication and blood components) may affect the performance of the BIPL HCV Rapid Test. This was studied by spiking these substances into three levels of HCV standard controls. The results are presented in the following table and demonstrate that at the concentrations tested, the substances studied do not affect the performance of the BIPL HCV Rapid Test.

Note: -: Negative; +: Positive; ++: Medium Positive

Potential Interfering Substances Spiked	HCV Reactivity		
	Negative	Weak Positive	Medium Positive
Control	-	+	++
Bilirubin 20 mg/dL	-	+	++
Creatinine 442 µmol/L	-	+	++
Glucose 55 mmol/L	-	+	++
Albumin 50 g/L	-	+	++
Salicylic Acid 4.34 mmol/L	-	+	++
Heparin 3,000 U/L	-	+	++
EDTA 3.4 µmol/L	-	+	++
Human IgG 1,000mg/dL	-	+	++
Sodium citrate 3.8%	-	+	++

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of HCV Ab in serum/plasma from individual subjects. Failure to follow the procedure may lead to inaccurate results.

2. The BIPL HCV Rapid Test is limited to the qualitative detection of HCV Ab in human serum/plasma. The intensity of the test line does not have a linear correlation the HCV Ab titer in the specimen.
3. 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 HCV Ab present in the specimen is below the detection limits of the assay or the HCV Ab that is detected was not present during the stage of disease in which a sample is collected.
5. If the symptoms persist when the result from BIPL HCV Rapid Test is non-reactive, it is recommended to re-sample the patient a few days later or to test with an alternative test method.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

WASTE MANAGEMENT & DISPOSABLE

The contents of RDTs can be divided into :
Infectious waste:
• sharps (lancets, needles, scalpel blades)
• blood collection devices (tubes, straws, and loops); gloves; swabs; and cotton
• used cassettes.
Non-infectious waste (Recyclable):
• packaging materials, desiccant, buffer, and unused or unusable RDTs.

*****You must collect and dispose each type of waste in separate containers as per your waste management policies.***

REFERENCES

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Document No. BIPL-IFU-068