HCV FIA Rapid Test Device
(Whole Blood/Serum/Plasma)
FI2-HCV-001

A qualitative rapid test for the detection of antibodies to Hepatitis C in whole blood, serum or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE
The HCV FIA Rapid Test Device is based on Fluorescence Immunoassay for the qualitative detection of antibodies to Hepatitis C (HCV) in whole blood, serum or plasma. It is intended to aid in the diagnosis of Hepatitis C Virus infections.

SUMMARY
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]

PRINCIPLE
The HCV FIA Rapid Test Device detects HCV antibodies based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains HCV antibodies, it attaches to the fluorescent microspheres-conjugated HCV antigens. Then the complex will be captured by the capture antigens coated on the nitrocellulose membrane (Test line). The concentration of HCV antibodies in the sample correlates with the fluorescence signal intensity captured on the T line, which can be read by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). The test results of the HCV FIA Rapid Test will be displayed on the Fluorescence Immunoassay Device screen.

REAGENTS
The test contains HCV antigen conjugated fluorophores and HCV antigen coated on the membrane.

PRECAUTIONS
1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Biopanda HCV FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device by approved medical professionals.

STORAGE AND STABILITY
1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. 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 equipment, containers or reagents can lead to false results.

KIT COMPONENTS
- 25 x foil wrapped HCV test devices
- 1 x Buffer Tube
- 1 x ID card (HCV)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION
For Venipuncture Specimens
1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Sodium Citrate, and Potassium Oxalate can be used as the anticoagulant for collecting the specimen. A clean tube without anticoagulants can be used to collect serum specimens.

DIRECTIONS FOR USE
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. **Whole Blood/Serum/Plasma:** Transfer **20 µl of whole blood, serum, or plasma** into the specimen well.
5. After the sample has absorbed into the specimen well (about 5-10 seconds), add **2 drops of buffer** (about 80 µL) into the specimen well. Start the timer at the same time.
6. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS
The result of tests for HCV is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cut-off value.
- Test results of Value ≥ 1.00 are considered positive for HCV.
- Test results of Value < 1.00 are considered negative for HCV.

The Reference Value is not a quantitative value or the rate of antibodies to HCV concentration. This is only a qualitative test.

QUALITY CONTROL

Each Biopanda HCV FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The HCV FIA Rapid Test Device is for *in vitro* diagnostic use only. The test should be used for the detection of HCV antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HCV antibodies can be determined by this qualitative test.
2. The HCV FIA Rapid Test Device will only indicate the presence of HCV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HCV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HCV infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HCV FIA Rapid Test Device has correctly identified specimens of seroconversion panel and has been compared to a leading commercial ELISA HCV test using clinical specimens. The results show that the relative sensitivity of the HCV Test Cassette is >99.9% and the relative specificity is 99.00%.

Method		ELISA		Total Results
HCV FIA Rapid Test Device	Results	Positive	Negative	
	Positive	146	2	148
	Negative	0	198	198
Total results		146	200	275

Relative Sensitivity: >99.9% (95%CI*: 97.51%-100%) *Confidence Interval
Relative Specificity: 99.00% (95%CI*: 96.43%-99.88%)
Accuracy: 99.42% (95%CI*: 97.93%-99.93%)

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of three specimens: a negative, a HCV low titer positive and a HCV high titer positive. The negative, HCV low titer positive and HCV high titer positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same three specimens: a negative, a HCV low titer positive and a HCV high titer positive. Three different lots of the HCV FIA Rapid Test Device have been tested using these specimens. The specimens were correctly identified 100% of the time.

Cross-reactivity `

The HCV FIA Rapid Test Device has been tested by anti-HAMA IgG, anti-RF IgG, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis IgG, anti-HIV, anti-*H.Pylori* IgG, anti-MONO IgM, anti-CMV IgG, anti-CMV IgM, anti-Rubella IgG, anti-Rubella IgM, anti-TOXO IgG and anti-TOXO IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HCV negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1000 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 60 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley,and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362
3. van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337:317
4. Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204

Index of Symbols

	Manufacturer	Σ	Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's HCV FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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