Size : 137 x 218 mm

# VioTUBE™ HCV

## Rapid Immunochromatography Test for HCV

DIPSTICK

### INTENDED USE

**VioTUBE™ HCV**, is a 3rd generation, rapid, qualitative immunoassay for detection of antibodies to Hepatitis C virus (HCV) in human serum / plasma. The test employs a cocktail of genotype cross-reactive recombinant antigens derived from the core, NS3, NS4, and NS5 regions of multiple HCV genotypes. For professional use.

### SUMMARY

HCV is a single-stranded RNA virus containing a linear genome with a length of about 9,600 nucleotides with positive polarity. It is now recognized that HCV infection is the major etiological agent of post transfusion hepatitis type non-A, non-B. HCV infection frequently progresses to chronic liver disease. On the basis of phylogenetic analysis, HCV has been grouped into six major genotypes, each of which contains one or more subtypes. The distribution of HCV genotypes varies in different geographical areas.

**VioTUBE™ HCV** is a third generation assay that uses a cocktail of recombinant antigens that is broadly cross-reactive to all major HCV genotypes. The antigens are derived from multiple HCV genotypes apart from genotype - 1.

### PRINCIPLE

**VioTUBE™ HCV** utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. The membrane is stripped with a cocktail of recombinant antigens derived from the core, NS3, NS4, and NS5 regions of multiple HCV genotypes at the test region. The conjugate pad contains Protein-A gold conjugate. As the test specimen flows through the membrane test assembly, the Protein-A colloidal gold conjugate complexes with the HCV specific antibodies in the specimen and travels on the membrane due to capillary action. This complex moves further on the membrane to the test region where it is immobilized by the HCV antigens coated on the membrane. This leads to the formation of a colored band. The development of a colored band in the test region indicates the presence of antibodies to HCV in the specimen.

The unreacted Protein-A gold conjugate and unbound complex, move further on the membrane and are subsequently immobilized by the control reagent coated on the membrane at the control region (C), forming a colored band. This control band acts as a procedural control and serves to validate the results.

### REAGENTS AND MATERIALS SUPPLIED

**VioTUBE™ HCV** kit contains:

A. Individual sealed pouches containing:
   1. DIPSTICK : Membrane test assembly stripped with HCV specific recombinant antigens and control reagent along with Protein-A gold conjugate. Each dipstick is individually pouched along with desiccant.
   2. Desiccant pouch.
B. BUF : Sample Running Buffer: Buffer containing surfactant and preservatives: Sodium Azide 0.1%.
C. TUBE : Test tube with result reading zones.
D. CAP : Test tube caps.
E. Package insert.

| | |
|---|---|
| REF | 702020010 |
| Σ | 10 Tests |

### OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

Disinfectant, Disposable gloves, Biohazard waste container, Micropipette.

### STORAGE AND STABILITY

**VioTUBE™ HCV** is stable up to the expiry date mentioned on the label when stored at 4°C to 30°C. Once the pouch is opened, the dipstick must be used immediately. After first opening of the sample running buffer bottle, it can be stored at 4°C to 30°C for the entire duration of its shelf-life.

### NOTES

Read the instructions carefully before performing the test. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. Do not use beyond expiry date. Do not intermix the reagents from different lots. The dipstick and test tube are for single use only. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

| Colour | C | M | Y | K |
|---|---|---|---|---|
| Mauve | 30 | 100 | 0 | 0 |
| Black | 0 | 0 | 0 | 100 |

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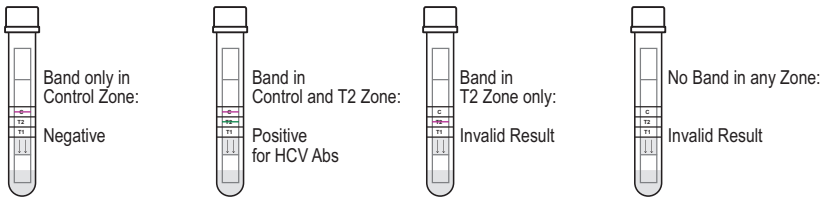
## SPECIMEN COLLECTION AND PREPARATION

1. **VioTUBE™ HCV** uses human serum / plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Preferably use fresh sample. However, specimen may be stored refrigerated (2°C to 8°C) for short duration. For long storage, freeze at -20°C or below.
4. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not heat inactivate before use.
7. Do not use turbid, lipaemic and hemolysed serum/plasma.
8. Do not use hemolysed, clotted or contaminated specimens.
9. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
10. Refrigerated specimens must be brought to room temperature prior to testing.

## TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed aluminium foil pouch of **VioTUBE™ HCV** dipstick to room temperature.
2. Open the pouch and retrieve the dipstick (taking care not to touch the membrane area), and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the dipstick and use another dipstick. ***Once opened, the dipstick must be used immediately.***
3. Take the result area marked test tube provided with the kit and label it with patient's identity and number.
4. Tighten the cap of the sample running buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
5. Put 4 drops of sample running buffer in the tube and using a micropipette, add **5 µl** of patient's serum or plasma and mix well.
6. Place the dipstick into the tube, with the arrows on the dipstick pointing downwards and close the test tube with the cap.
7. Put the test tube vertically straight in the test tube stand.
8. Read the results at the end of **20 minutes** as follows based on the marking of T1/T2/C on the test tube:

## RESULT INTERPRETATION




9. The test should be considered invalid if the control band "C" does not appear. The test is also invalid if neither the control nor the test bands appear. Repeat the test with a new **VioTUBE™ HCV** dipstick.

## PERFORMANCE CHARACTERISTICS

***SENSITIVITY & SPECIFICITY DATA***

Six hundred and thirty samples - out of which one hundred and ten HCV positive specimen and five hundred and twenty HCV negative specimen were tested with **VioTUBE™ HCV** and compared with commercially available ELISA. The results are as shown below.

| Specimen Data | Total | VioTUBE™ HCV | Commercial ELISA |
|---|---|---|---|
| Total Number | 630 | 628 | 630 |
| HCV Positive | 110 | 110 | 110 |
| HCV Negative | 520 | 518 | 520 |

Based on this evaluation:
Sensitivity of **VioTUBE™ HCV** : 100%
Specificity of **VioTUBE™ HCV** : 99.6%

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***SEROCONVERSION DATA***

By using seroconversion panel from Boston Biomedica Inc., USA (Panel ID: PHV 901), that contains 11 samples; the sensitivity of **VioTUBE™ HCV** was evaluated. The results were found to be satisfactory and are as follows:

| Panel ID | Days since first bleed | Abbott HCV 3.0 | Ortho HCV 3.0 | Ortho RIBA 3.0 | VioTUBE™ HCV |
|---|---|---|---|---|---|
| PHV 901-01 | 0 | 0.2 | 0.0 | NEGATIVE | NEGATIVE |
| PHV 901-02 | 72 | 0.2 | 0.0 | NEGATIVE | NEGATIVE |
| PHV 901-03 | 104 | 1.0 | 5.9 | POSITIVE | POSITIVE |
| PHV 901-04 | 106 | 1.0 | 6.0 | POSITIVE | POSITIVE |
| PHV 901-05 | 111 | 1.2 | 6.1 | POSITIVE | POSITIVE |
| PHV 901-06 | 113 | 1.3 | 6.0 | POSITIVE | POSITIVE |
| PHV 901-07 | 138 | 9.0 | > 9.1 | POSITIVE | POSITIVE |
| PHV 901-08 | 146 | 6.8 | 7.4 | POSITIVE | POSITIVE |
| PHV 901-09 | 166 | > 10.6 | > 9.1 | POSITIVE | POSITIVE |
| PHV 901-10 | 173 | > 10.6 | 9.1 | POSITIVE | POSITIVE |
| PHV 901-11 | 209 | > 10.6 | > 9.1 | POSITIVE | POSITIVE |

Another seroconversion panel from Boston Biomedica Inc., USA (Panel ID: PHV 906), that contains 7 samples, was evaluated with **VioTUBE™ HCV.** The results were found to be satisfactory and are as follows:

| Panel ID | Days since first bleed | Abbott HCV 3.0 | Ortho HCV 3.0 | Ortho RIBA 3.0 | VioTUBE™ HCV |
|---|---|---|---|---|---|
| PHV 906-01 | 0 | 0.4 | 5.4 | INDETERMINATE | POSITIVE |
| PHV 906-02 | 2 | 0.6 | 6.4 | INDETERMINATE | POSITIVE |
| PHV 906-03 | 7 | 1.4 | > 7.8 | POSITIVE | POSITIVE |
| PHV 906-04 | 10 | 2.3 | > 7.8 | POSITIVE | POSITIVE |
| PHV 906-05 | 14 | 3.0 | > 7.8 | POSITIVE | POSITIVE |
| PHV 906-06 | 17 | 3.9 | > 7.8 | POSITIVE | POSITIVE |
| PHV 906-07 | 21 | 4.9 | > 7.8 | POSITIVE | POSITIVE |

Data other than that of **VioTUBE™ HCV** is supplied by BBI, USA. Numerical values are expressed as cut-off ratios. Ratios more than or equal to 1.0 are considered positive.

***INTRA-ASSAY PRECISION STUDY***

One PCR-positive sample was assayed 10 times on the same day.
**Results:** No variation in results was observed indicating 100% correlation.

***INTER-ASSAY PRECISION STUDY***

One PCR-positive sample was assayed 3 times on 3 different days.
**Results**: No variation in results was observed indicating 100% correlation.

**LIMITATIONS OF THE TEST**

1. Approximately 25-30% of individuals with chronic HCV infections have persistently normal alanine aminotransferase (ALT or SGPT) level and these individuals are usually referred to as "healthy carrier" of HCV. Therefore, such conditions should be ascertained before taking clinical decisions.
2. Though **VioTUBE™ HCV** is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HCV infection.
3. Absence of antibodies to HCV does not indicate that an individual is absolutely free of HCV infection, as the collection of sample and its timing vis-à-vis seroconversion will influence the test outcome.
4. Do not compare the intensity of test lines and the control lines to judge the concentration of antibodies in the test specimen.
5. Since various tests for HCV differ in their performance characteristics and antigenic composition, their reactivity patterns may differ.
6. Testing of pooled samples is not recommended.
7. Inaccurate sample volume dispensed may lead to false results. Therefore, pipettes should be regularly calibrated to dispense correct sample volume.
8. False-negative results can occur in persons with compromised immune systems, such as people with HIV infection, patients with renal failure and patients with HCV associated mixed cryoglobulinemia.
9. False-positive results are more common in persons without risk factors and in low-prevalence populations, including blood donors & healthcare workers.
10. Most positive results develop within 5 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 20 minutes. Do not read results after 20 minutes.

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11. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
12. **VioTUBE™ HCV** should only be used as a screening test and its results should be confirmed by other supplemental methods before taking clinical decisions.

## WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

## BIBLIOGRAPHY

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**SYMBOL KEYS**

| | | | |
|---|---|---|---|
| Temperature Limitation | Manufacturer | This side up | Contains sufficient for <n> tests |
| Use by | Consult Instructions for use | DIPSTICK — Dipstick | Do not reuse |
| Date of Manufacture | REF — Catalogue Number | TUBE — Test tubes | CAP — Test tube caps |
| LOT — Batch Number / Lot Number | BUF — Sample Running Buffer | IVD — In vitro Diagnostic Medical Device | |

Manufactured by:

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