Instructions For Use

* Please carefully read the instructions before use

# *Coretests*™ One Step HCV Test

(HCV Test Cassette)

CE 2265

Format: Cassette

Specimen: Serum/Plasma

## INTENDED USE

The Coretests™ One Step HCV Test is a rapid and convenient immunochromatographic assay for qualitative detection of antibodies against HCV in human serum/plasma sample. It is intended for professional use as an aid in diagnosis of Hepatitis C Virus (HCV) infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

## SUMMARY

Hepatitis C virus (HCV) is a leading cause of hepatitis. The worldwide prevalence of HCV is 0.2% to 2% in blood donors and up to 80% in intravenous drug users. Hepatitis C virus (HCV) is single-stranded RNA virus, that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids or blood, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes without prompt medical intervention, including cirrhosis and liver cancer (heptatocellular carcinoma). Diagnosis of HCV infections could be based on serological tests.

## PRINCIPLE

The test is an antibody-capture immunochromatographic assay, detecting HCV antibodies in blood specimens. The membrane is pre-coated with specific HCV antigens on the test line region (T) and goat anti-mouse on the control line region (C). During testing, the specimen is allowed to react with the gold colored conjugate (specific HCV antigens-colloidal gold conjugate), which has been pre-dried on the test. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored line with the specific HCV antigens-gold conjugate complex will form in the test line region (T) of the membrane. Absence of this pink-colored line in the test line region (T) indicates a negative result.

To serve as an internal process control, the control line should always appear in the control region (C) after the test is completed indicating that the test is performed properly and the reagents of the test are working. Absence of the colored line in the control region is an invalid result regardless of the presence or absence of the test line.

## MATERIALS PROVIDED

Coretests™ One Step HCV Test contains the following items to perform the assay:

1. One Step HCV Test Device
2. Instruction for use
3. Pipette
4. Sterile lancet
5. Alcohol wipes

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Sample container
3. Glove

## WARNING AND PRECAUTIONS

1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test device beyond the expiration date.
4. The test device should remain in the sealed pouch until use. Do not use the test device if the pouch is damaged or the seal is broken.
5. Do not reuse the device.
6. Treat and properly handle the specimens and used device as if they were potentially infectious. Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
7. There should be no eating, drinking or smoking where specimens are being handled.
8. Do not mix and interchange different specimens.
9. Wear disposable gloves, lab coat and eye protection while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
10. Clean spills thoroughly using an appropriate disinfectant.
11. Keep out of children's reach.
12. Do not swallow the desiccant.

## SPECIMEN PREPARATION

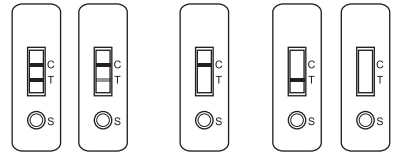
1. Centrifuge whole blood to get serum or plasma specimen.
2. If specimen is not tested immediately,it should be refrigerated at 2-8℃. For storage period greater than three days, freezing is recommended. Such specimen should be brought and equilibrated to room temperature prior to use.
3. Serum containing precipitate may yield inconsistent test result. Such specimens must be clarified prior to assaying.

## TEST PROCEDURE

Review specimen preparation instructions and bring the pouched test device together with patients specimens or controls to room temperature (15-30℃) prior to testing. Do not open the pouch until ready to perform the assay.

1. Remove the test device from its protective pouch. Label the device with patient or control identifications. Lay it on a flat, clean and dry surface.
2. Use the pipette packed in pouch to draw and slowly add 2 drops of serum/plasma to the sample well.
3. Wait for colored lines to appear within 10-15 minutes. Do not interpret result after 20 minutes.

## INTERPRETATION OF RESULTS




Positive Negative Invalid

**POSITIVE:** Two distinct colored lines appear, one in the control region (C) and another one in the test region (T). The color intensity of the test line may be weaker or stronger than that of the control line.

**NEGATIVE:** Only one colored line appears in the control region (C). No line is visible in the test region (T).

**INVALID:** Control Line fails to appear.

**NOTE:** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, please contact your local distributor.

## QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored line in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

## STORAGE AND STABILITY

The test device should be stored at 2-30℃ in the sealed pouch. Avoid humidity, heat and direct sunlight. The test device is stable through the expiration date printed on the sealed pouch. DO NOT FREEZE.

## LIMITATION OF THE TEST

1. This product is an in vitro diagnostic test designed for professional use only.
2. Humidity and temperature can adversely affect results.
3. There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
4. Although the test demonstrates superior accuracy in detecting HCV infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## PERFORMANCE CHARACTERISTICS

**1. Diagnostic Sensitivity**

A multi-center prospective study was conducted to evaluate the diagnostic sensitivity of Coretests™ One Step HCV Test in serum/plasma specimens. A total of 430 positive samples from patients clinically diagnosed as HCV infected were tested with the Coretests™ One Step HCV Test and the test results were compared with that of a CE marked HCV EIA test. Of the 430 HCV positive samples, 428 were tested positive and 2 were tested negative by the Coretests™ One Step HCV Test. The two samples that were tested negative were further confirmed positive by PCR. All the samples with known HCV genotype 1-6 were tested positive and they had unknown HCV genotype. The diagnostic sensitivity of Coretests™ One Step HCV Test was 99.53% (428/430).

Table 1 Summary of Diagnostic Sensitivity of Coretests™ One Step HCV Test

| Genotype | | Results of Coretests™ One Step HCV Test | | Results of CE Marked EIA Test | | Subtotal |
|---|---|---|---|---|---|---|
| | | Positive | Negative | Positive | Negative | |
| 1 | 1a | 6 | 0 | 6 | 0 | 53 |
| | 1b | 47 | 0 | 47 | 0 | |
| 2 | 2a | 26 | 0 | 26 | 0 | 39 |
| | 2b | 10 | 0 | 10 | 0 | |
| | 2a/2b | 3 | 0 | 3 | 0 | |
| 3 | 3a | 19 | 0 | 19 | 0 | 31 |
| | 3b | 12 | 0 | 12 | 0 | |
| 4 | 4 | 8 | 0 | 8 | 0 | 22 |
| | 4a | 8 | 0 | 8 | 0 | |
| | 4c/4d | 6 | 0 | 6 | 0 | |
| 5a | | 9 | 0 | 9 | 0 | 9 |
| 6 | 6a | 25 | 0 | 25 | 0 | 34 |
| | 6e | 9 | 0 | 9 | 0 | |
| 1b/2a | | 4 | 0 | 4 | 0 | 4 |
| Unknown genotype | | 236 | 2 | 238 | 0 | 238 |
| Subtotal | | 428 | 2 | 430 | 0 | 430 |

**2. Diagnostic Specificity**

A multi-center prospective study was conducted to evaluate the diagnostic specificity of the Coretests™ One Step HCV Test. A total of 1740 negative samples were collected from different populations including blood donors, inpatients, pregnant women, and patients with potentially interfering diseases. These samples were tested with the Coretests™ One Step HCV Test and the results were compared with that of a CE marked HCV EIA. Of the 1740 negative samples, 8 were tested positive by Coretests™ One Step HCV Test. The diagnostic specificity of Coretests™ One Step HCV Test was 99.54% (1732/1740), and the false positive rate was 0.46% (8/1740).

Table 2 Summary of Diagnostic Specificity of Coretests™ One Step HCV Test.

| | Results of Coretests™ One Step HCV Test | | Results of CE Marked EIA Test | | Subtotal |
|---|---|---|---|---|---|
| | Negative | Positive | Negative | Positive | |
| Blood Donors | 1096 | 4 | 1097 | 3 | 1100 |
| inpatients | 199 | 1 | 200 | 0 | 200 |
| Pregnant Women | 199 | 1 | 199 | 1 | 200 |
| potentially interfering diseases | 238 | 2 | 239 | 1 | 240 |
| Subtotal | 1732 | 8 | 1735 | 5 | 1740 |

**3. Analytic Sensitivity**

**Reactivity with Low Titre HCV Antibody Performance Panel and Worldwide Panel**

A low titre HCV antibody panel consisting of 13 members and a Worldwide panel consisting of 20 members derived from multiple geographics representing six genotyoes and 12 subtypes(1a, 1b, 2a, 2b, 3, 3a, 4, 4a, 5a, 6, 6a and 1), were tested with the Coretests™ One Step HCV Test and CE marked HCV EIA test. Study results demonstrated that Coretests™ One Step HCV Test was capable of detecting HCV antibodies and its sensitivity was similar to that of the CE licensed HCV EIA test.

**4. Analytic Specificity**

In order to evaluate the specificity of the Coretests™ One Step HCV Test, 115 normal negative specimens and 85 negative specimens containing the following seromarkers were tested: Human immunodeficiency virus(HIV), hepatitis B virus (HBsAg, anti-HBc IgG/IgM, and HBsAb), hepatitis A virus IgM (anti-HAV), herpes simplex virus IgG (HSV), cytomegalovirus (CMV) IgG/IgM, Epstein-Barr Virus (EBV) IgG/IgM, human T-Lymphotrophic virus (HTLV), rubella IgM (RV), anti-E. Coli, Helicobacter pylori (HP) IgG/IgM, syphilis reagin (RPR/TPPA), mycoplasma IgM, C-reactive protein (CRP), antistreptolysin O titre (ASOT), rheumatoid factor (RF). Two tests from each of the two lots of Coretests™ One Step HCV Test were carried out for each of the panel samples. Results demonstrated that Coretests™ One Step HCV Test has no significant cross-reactivity with the seromarkers listed above.

**5. Interference**

The following substances and conditions were found not to interfere with the test. List of potentially interfering compounds (chemical analytes and biological analytes) and concentrations tested are as follows:

| Chemical analytes | Concentrations | Chemical analytes | Concentrations |
|---|---|---|---|
| Acetaminophen | 200 ug/ml | Methaqalone | 200 ug/ml |
| Acetylsadicylic Acid | 200 ug/ml | Pendimetrazine | 200 ug/ml |
| Amikacin | 200 ug/ml | Penicillin G | 200 ug/ml |
| Ascorbic acid | 200 ug/ml | Quinine | 200 ug/ml |
| Aspartame | 200 ug/ml | Ranitidine | 200 ug/ml |
| Atropine Sulfate | 200 ug/ml | Sodium Salicylate | 200 ug/ml |
| Benzoic Acid | 200 ug/ml | Tryptophan | 200 ug/ml |
| Caffeine | 200 ug/ml | Tetracycline | 200 ug/ml |
| Deoxyephedrine | 200 ug/ml | Tetrahydrozoline | 200 ug/ml |
| Dextromethorphan | 200 ug/ml | Ethanol | 1% |
| EDTA | 800 ug/ml | Methanol | 1% |
| Gentesic acid | 200 ug/ml | Heparin | 1% |
| Histamine | 200 ug/ml | Citrate | 3.2% |
| Biological analytes | Concentrations | Biological analytes | Concentrations |
| Albumin | 2 mg/ml | Bilirubin | 2 mg/ml |
| Glucose | 2 mg/ml | Hemoglobin | 2 mg/ml |

**6. Reproducibility**

Three lots of the Coretests™ One Step HCV Test were tested with both positive and negative samples to evaluate its precision. The resultant data indicated that all three lots of the test were able to produce accurate and consistent results.

## REFERENCES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2. Colombo M, Rumi MG, Donato MF, et al. Hepatitis C antibody in patients with chronic liver disease and hepatocellular carcinoma. Dig Dis Sci 1991;36:1130-3.
3. Simmonds P, Holmes EC, Cha TA, et al. Classification of hepatitis C virus into six major genotypes and a series of subtypes by phylogenic analysis of the NS-5 region. J Gen Virol 1993;74:2391-9.
4. CDC, Updated U.S. Public Health Service Guidelines for the Management of occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-exposure Prophylaxis. MMWR 2001; 50 (RR-11):1-42.
5. Choo Q-L, Weiner AJ, Overby, LR, et al. Hepatitis C virus: the major causative agent of viral non-A, non-B hepatitis. Br Med Bull 1990;46:423-41.
6. S. Osborne, E. et al, Expression in E. coli and purification of a chimeric p22-NS3 recombinant antigen of Hepatitis C Virus (HCV). Federation of European Biochemical Societies, Volume 324, number 3, 253-257


## INDEX OF SYMBOLS

| | | | |
|---|---|---|---|
| | Do not re-use | | Manufacturer |
| IVD | In vitro diagnostic medical device | | Use-by date |
| | Store at 2-30℃ | | Consult instructions for use |
| EC REP | Authorized representative in the European Community | LOT | Batch code |
| n | Contains sufficient for <n>tests | CE | CE Mark |
| | Caution | REF | Catalogue number |

## MANUFACTURER CONTACT INFORMATION


Core Technology Co., Ltd.
Registered Address:
Room 100, C Building, No.29 Life Park Rd.,
Changping District, Beijing 102206, China
Manufacture Address:
No.30, Area 9,Douda Avenue,Fangshan
District,Beijing,102433,P.R. China
Tel: +86(10)69390616
Fax:+86(10)69390660
E-mail: sales@coretests.com

EC REP Wellkang Ltd.
Enterprise Hub, NW Business Complex, 100
Belgrade Rd, Derry, BT48 8SE, N. Ireland, UK





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