TEST IT
for healthy generations

in vitro diagnostic test

Anti-HCV Test, WB/S/P

CE 1434

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for healthy generations

INSTRUCTION FOR USE

Anti-HCV TEST, WB/S/P

Anti-HCV (HCVab) Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: TIHC02
Hepatitis C Virus Antibody Cassette Test

BACKGROUND INFORMATION

Hepatitis C virus (HCV) is a major cause of chronic liver disease, frequently progressing to cirrhosis and increased risk of hepatocellular carcinoma. HCV is a positive, single-stranded RNA virus in the Flaviviridae family. The genome is approximately 10.000 nucleotides and encodes a single polyprotein of about 3.000 amino acids. The polyprotein is processed by host cell and viral proteases into three major structural proteins and several non-structural proteins necessary for viral replication. Several different genotypes of HCV with slightly different genomic sequences have since been identified that correlate with differences in response to treatment with interferon alpha.
HCV can be classified into six genetically distinct genotypes and further subdivided into at least 70 subtypes, which differ by approximately 30% and 15% at the nucleotide level, respectively. The different genotypes may exhibit differing phenotypic properties. Immunochromatographic membrane tests can be performed in a few minutes and the results are read visually and could be suitable for use in laboratories that have limited facilities. In addition, even if there is no prophylactic HCV treatment after a needle-stick injury, it can be important to know rapidly the HCV status of a source patient.

INTENDED USE

Anti-HCV Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies generated against proteins that are encoded by conserved sequences of CORE, NS3, NS4, NS5 parts of HCV genome in human whole blood / serum / plasma.

REAGENTS

Recombinant HCV antigens (CORE, NS3, NS4, NS5), anti-HCV monoclonal antibodies, colored particles conjugated recombinant HCV antigens (CORE, NS3, NS4, NS5).

METHOD

Anti-HCV Test uses immunochromatographic technology for the qualitative detection of antibodies against HCV antigens in human whole blood / serum / plasma. Sample is introduced from sampling pad. If there is anti-HCV in the sample at detectable level, anti-HCV binds to the mobile recombinant HCV antigens conjugated with colored particles. Together they move to the test area "T". A visible colored signal due to the accumulation of colored particles in the test area "T" (a colored test line) indicates positive test result. If there is no anti-HCV in the sample at detectable level then sample moves to the test area "T" together with unbound recombinant HCV antigens conjugated with colored particles. Therefore, there is no visible colored signal in test area "T" (no colored test line) be obtained, indicating negative test result. Regardless of anti-HCV content of the liquid sample, accumulation of colored particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line always appears in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
4. Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
5. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
6. Use a new pipette for each sample. Close the buffer bottle cap after using. Buffer is stable until expiry date after the first use in routine.
7. Adequate lighting is required to read the test results.
8. The test device should be discarded in a proper biohazard container after testing.
9. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. Do not freeze and thaw the serum, plasma samples repeatedly. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
12. Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
13. Hemolytic samples should not be used since they can lead to invalid or false results.
14. A negative result does not exclude the possibility of HCV infection. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is required.
15. A false negative result can occur in the following a recent exposure to HCV; an antibody response to recent exposure may take several months to reach detectable levels due to recent infection. In exceptional cases; presence of mutant virus and infection with a variant of the virus may lead to observation of false negative results.
16. Positive samples should be retested using another method and the results should not be used as the only basis for the diagnosis of hepatitis viral infection.
17. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze. The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

Kit components: Test cassettes, pipettes, diluents and instructions for use.

Additional materials required but not provided: Sample collection tube, centrifuge, timer, for fingerstick whole blood: sterile lancet and capillary tubes.

Additional materials recommended but not provided: Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood (venous blood and capillary blood), serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible and tested immediately after collection. If the sample cannot be tested on the day of collection, serum or plasma samples should be refrigerated at 2 to 8°C for up to 3 days prior to testing. If testing within 3 days is not possible, serum or plasma samples should be frozen at -20°C or colder. Frozen serum, plasma samples must be completely thawed and mixed well prior to testing. Bring the samples to room temperature before testing.

Plasma and venous blood can be collected with the following anticoagulants: K3EDTA, K2EDTA, sodium citrate (3,2%), sodium citrate (3,8%), lithium heparin, sodium heparin.

Serum Samples : Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).

Plasma Samples : Collect blood into a collection tube with anticoagulants to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).

Whole Blood Samples : Collect venous blood into a collection tube with anticoagulants to avoid coagulation, test should preferably be performed immediately. Otherwise, whole blood samples should be stored at 2 - 8 °C until they are being tested in a period of 2 days after collection. Do not freeze whole blood sample.

For Capillary Blood; according to the laboratory practice, use a sterile lancet and an appropriate capillary tube to collect blood by capillary action. Test should be performed immediately.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. **For Serum / Plasma Samples:** Draw serum / plasma into pipette and put 1 drop (25 µl) into the sample well of the cassette. Immediately after, 2 drops of diluent is added into the sample well and allowed to soak in.

   For Whole Blood Samples: Draw whole blood into pipette and put 2 drops (50 µl) into the sample well of the cassette. Immediately after, 2 drops of diluent is added into the sample well and allowed to soak in.

   When using Capillary Blood Samples: Collect 50 µl of fingerstick whole blood using the capillary tube (not provided) and transfer it into the sample well of the cassette. Immediately after, 2 drops of diluent is added into the sample well and allowed to soak in.

   Avoid the formation of any air bubbles.
3. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

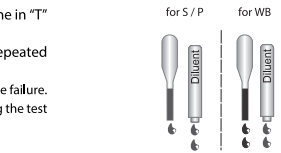
Negative: Only one colored line is visible in "C" area.

Positive: Two colored lines are visible in "C" and "T" areas.

Low concentration of hepatitis C antibody may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".

Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

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, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Anti-HCV Test can detect antibodies generated against proteins that are encoded by conserved sequences of CORE, NS3, NS4, NS5 parts of HCV genome.

Sample Status	Sample Anti-HCV Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Positive samples (including all available genotypes)	Positive	412	EIA	100 %	60	EIA	100 %
Blood donors	Negative	1045	EIA	100 %	-	-	-
Clinical samples	Negative	312	EIA	100 %	215	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity and Specificity

Using results of positive samples (472/472) and negative samples (1882/ 1882); sensitivity, specificity with the 95% confidence interval values are calculated as;

Sensitivity : 100 % [95% CI = 99,22% - 100%] Specificity : 100 % [95% CI = 99,80% - 100%]

Seroconversion panels: 30 seroconversion panels were studied with Türklab Anti-HCV Test and compared to results from CE Marked EIAs as reference assays. Türklab Anti-HCV Test was capable of detecting antibodies to HCV in a similar manner of the CE Marked EIA tests.

Interferences: Following potentially interfering substances were tested with Anti-HCV Test: Hemoglobin, Bilirubin, Triglycerides, Rheumatoid Factor (RF). No interference was observed.

Hemolytic samples should not be used since they can lead to invalid or false results.

Cross Reactivity: Cross reactivity has been tested with below samples, no cross reactivity was found with the Anti-HCV Test.

- Anti-HBs whole blood / serum / plasma samples,
- HBsAg whole blood / serum / plasma samples,
- Whole blood / serum / plasma samples from pregnant women.

Capillary Blood: Positive and negative capillary whole blood specimens collected by fingerstick were performed with Anti-HCV Test. The results showed that there was a good correlation of testing results between venous whole blood and capillary blood.

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CE 1434

Manufacturer | Attention, see instruction for use | For single use only | REF Catalog number | LOT Lot number

Consult instruction for use | IVD *In vitro* diagnostic medical device | Number of test | Storage temperature | Expiry date

Instruction For Use Preparation Date: 06.07.2023 • Rev.01

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