^: Naturally-occurring specimens high in glucose, triglycerides, bilirubin, creatinine, hemoglobin, or cholesterol. In addition, no interference was observed when the following common interfering substances were spiked (at high concentrations above physiological levels) into positive and negative specimens during in-house testing: human IgG, acetaminophen, aspirin, caffeine, ethanol, Fluconazole (antifungal medication), Quinine (antimalarial medication), Ethambutol (tuberculosis medication), heparin, EDTA, sodium citrate, albumin, triglycerides, glucose, HIV medication, bilirubin, creatinine, and haemoglobin.

Limitations of Test

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HCV in serum, plasma or whole blood. Failure to follow the procedure may give inaccurate results.
2. The CADY Hepatitis C Antibody Rapid Test is limited to the qualitative detection of antibodies to HCV in human serum, plasma or whole blood. The intensity of the test line does not correlate with the antibody titer of the specimen.
3. Specimens that produce very faint lines (indeterminate) should be re-tested with two new devices or an alternative method(s). However, a non-reactive or negative test result does not preclude the possibility of exposure to or infection with HCV.
4. A negative or non-reactive result can occur if the concentration of HCV Ab present in the specimen is below the level detectable by the assay or HCV Ab was not present during the stage of disease in which a sample was collected.
5. Infection may progress rapidly. If the symptoms persist, while the result from the CADY Hepatitis C Antibody Rapid Test is negative or non-reactive, it is recommended 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.

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Symbol	Meaning	Symbol	Meaning
	Caution/Warning (Read instruction before use)		Date of Expiry
	Manufacturer	LOT	Batch/Lot Number
	Date of Manufacturing		Don't re-use
REF	Catalogue number	IVD	Invitro Diagnostic device
	Temperature Limitation		Consult IFU
	Keep away from sunlight		Do not use if package damaged

RHEL/TCF-RDT/09 Issue No.: 01
Issue Date: 01/06/2023
Rev No.: 00
Doc No.:R/IFU/RDT/HepC/08

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Revital®

CADY® Hepatitis C Antibody Rapid Test.

Intended Use

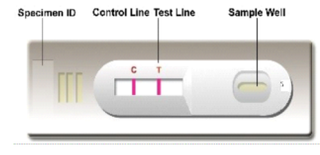
The ***CADY Hepatitis* C Antibody Rapid Test** is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA) in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with the hepatitis C virus. Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be used to confirm the test result obtained by this device.

Clinical Significance

The hepatitis C virus (HCV) is the causative agent of significant acute and chronic liver disease worldwide. According to the WHO, approximately 71 million people globally live with chronic HCV infection, with 1.75 million new cases in 2015[1]. 15-25% of acute HCV infections are cleared, while 75-85% of cases result in chronic infections[2]. Sequelae of chronic HCV infection include liver scarring (cirrhosis), liver failure, and liver cancer, causing 400,000 deaths in 2016 and 20% of all liver cancer cases in 2012[1,3]. Although no HCV vaccines are available, oral antiviral medications can cure chronic HCV infections in 90% of individuals in 8-12 weeks[4]. ***CADY Hepatitis C Antibody Rapid Test*** detects anti-HCV antibodies (IgG, IgM, IgA) in human serum, plasma or whole blood. The test can be performed within 15 minutes by minimally skilled personnel without the use of cumbersome laboratory equipment.

Principle Of The Test

The ***CADY Hepatitis C Antibody Rapid Test*** is a double antigen lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a burgundy-colored conjugate pad containing recombinant HCV fusion antigens (core, NS3, NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold; and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The test line is pre-coated with unconjugated recombinant HCV fusion antigen (core, NS3, NS4 and NS5), and the control line is pre-coated with a control antibody. When an adequate volume of specimen is dispensed into the sample well of the cassette, it migrates by capillary action across the cassette. Antibodies to HCV, if present in the specimen, will migrate through the conjugate pad and bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated HCV fusion antigen forming a colored T line, indicating an HCV Ab positive or reactive test result. Lack of color development on the test line indicates a negative or non-reactive result for HCV Ab. The test contains an internal control (C line) which should exhibit a colored line by capture of the control immunocomplex by 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.



Intended User

1.Pathology Labs 3.Hospitals
2.Blood Banks 4.Individual users

Kit Components : Test Device, Assay buffer, Sample Dropper, and Product Insert

Materials Required But Not Provided : 1. Clock & Timer 2. Disposable gloves

Description Of Components

Each test device contains

1.Nitrocellulose Membrane: The membrane coated with recombinant Antigen of HCV and control antibody.
2.Gold Conjugate Pad: Gold-conjugated HCV recombinant antigen and control antibody
3.Sample Release Pad
4.Absorbent Pad

Warning and Precaution

For In Vitro Diagnostic Use Only

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 or components.
4. Use only one specimen per device. Do not combine specimens.
5. Bring all reagents to room temperature (15-30°C) before use.
6. Do not use components from any other test kit/lot as substitutes for components in this kit/lot.
7. Do not use haemolyzed blood specimens for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow US CDC Universal Precautions for the prevention of transmission of HIV, HBV and other bloodborne pathogens: https://www.cdc.gov/niosh/topics/bbp/universal.html
10. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as biohazardous waste.
12. Handle external controls in the same manner as patient specimens.
13. Test results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Reading the test result after 20 minutes should be considered invalid and must be repeated.
14. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning

Storage and Stability

All kit components are ready to use as supplied. Store unused test device 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 sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C

Specimen Collection and Preparation

CADY Hepatitis C Antibody Rapid Test can be performed with Human Serum / Plasma / Whole Blood. Use nonhaemolysed serum/plasma/ whole blood collected without prolonged venous stasis. Specimens are stable for at least 3 days when stored at 2 - 8°C. For long-term storage, specimens should be kept below -20°C.

1.Plasma/Serum

Step 1: Collect blood specimen by venipuncture into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum.
Step 2: To prepare plasma specimen, centrifuge collected specimen and carefully withdraw the plasma into a new pre-labeled tube.
Step 3: To prepare serum specimen, allow blood to clot, centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

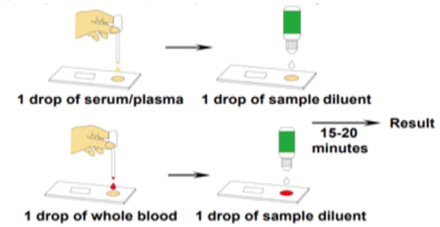
Test specimen immediately after collection or store refrigerated at 2-8°C for up to 5 days after collection. The specimen should be frozen at -20°C for longer storage.
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing 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.

2.Whole Blood

Step 1: Collect blood specimen by venipuncture into a blood collection tube containing EDTA, citrate or heparin. Do not use hemolyzed blood for testing.
Test whole blood specimens immediately after collection or store them refrigerated at 2-8°C for up to 24 hours after collection. Do not freeze specimens.

Description Of Components

Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Consider any materials of human origin as infectious and handle them using standard biosafety procedures
Step 1: Ensure that specimen and test components are equilibrated to room temperature. If frozen, mix the specimen well after thawing, prior to performing the 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: Label the device with the specimen's ID number.
Step 4: Fill the plastic dropper with the specimen.
Step 5: Holding the dropper vertically, dispense 1 drop (about ~25 µL) of serum/plasma or 1 drop of whole blood (~25 µL) into the center of the sample well making sure that there are no air bubbles.
Step 6: Immediately add 1 drop (about ~40 µL) of Sample Diluent to the sample well with the bottle positioned vertically.



Step 5: Set up timer.
Step 6: Read results at 15-20 minutes. Positive results may be visible as soon as 1 minute. Negative results must be confirmed at the end of the 20 minutes. ***Any results interpreted outside 15-20 minute window should be considered invalid and must be repeated. Discard used device after interpreting the results following local laws governing the disposal of device.***

Quality Control

1.Internal Control: This test contains a built-in control feature, the C line that develops whether the specimen is positive or negative. 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 positive and negative controls to ensure the proper performance of the assay, particularly under the following circumstances:

·A new operator uses the kit, prior to performing testing of specimens.
·A new lot of test kits is used.
·A new shipment of test kits is used.
·The temperature during storage of the kits falls outside of 2- 30 C.
·The temperature of the test area falls outside of 15-30 C.
·To verify a higher-than-expected frequency of positive or negative results.
·To investigate the cause of repeated invalid results.

Intended User

1.NEGATIVE RESULT: If only the C line develops, the test indicates that there is no detectable HCV antibodies in the specimen. The result is HCV Ab negative or non-reactive.

2.POSITIVE RESULT: If both the C and T lines develop, the test indicates that the specimen contains detectable HCV antibodies. The result is HCV Ab positive or reactive.