Reference

1. Blumberg, B.S. The Discovery of Australian Antigen and its Relation to Viral Hepatitis. Vitro. 1971; 7:223.
2. Krugman, S. Glies J.P. Viral Hepatitis, Type B (MS-2-Strain). Further Observations on Natural History and Prevention. New England Journal of Medicine. 288, 755.
3. Krugman, S. Overby L.R, et al. Viral Hepatitis Type B Studies on Natural History and Prevention Re-examined. New England Journal of Medicine. 300, 101.

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

Rev No: 01

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Revital®

CADY® Hepatitis B Rapid Test

Intended Use

CADY® Hepatitis B Rapid Test is intended for detection of Hepatitis B Surface Antigen (HBsAg) in serum, plasma and whole blood.

Intended User

Pathology Labs, Blood Banks, Hospitals and any Healthcare facility.

Clinical Significance

Hepatitis B virus surface antigen (HBsAg) is one of the earliest markers that appear in the blood following infection with Hepatitis B virus (HBV). 1 This infection of the liver is transmitted through sexual contact, blood borne exposure, transmission from mother to child during delivery, sharing of objects that pierce the skin, child-to-child and household contact. The HBV infection causes a wide variety of liver damage such as acute self-limiting infection, fulminating hepatitis, chronic hepatitis with progression to cirrhosis and liver failure, and asymptomatic chronic carrier state. In HBV infected people, the virus persists for the rest of their lives and can be passed on to others. Therefore, Hepatitis B has become a global public health problem. Infection with HBV results in the appearance of a number of serological markers and one of the first of such markers is Hepatitis B Surface Antigen (HBsAg). HBsAg appears 1-10 weeks after exposure and before biochemical evidence of liver disease or jaundice. 2,3 Three weeks after the onset of acute hepatitis almost half of the patients will still be positive for HBsAg. In the chronic carrier state, Hbs Ag persists for 6-12 months with no seroconversion to the corresponding antibodies. Therefore, screening for HBsAg is highly recommended for all donors, pregnant women and people in high-risk groups.

Principle of the Test

HBsAg rapid test utilizes the principle of immunoassay chromatography, a unique assay based on antigen capture of sandwich principle. The method uses monoclonal antibody conjugated to colloidal gold and polyclonal antibodies immobilized on nitrocellulose strip in thin line. As the test samples flows through the membrane assembly of the test device, the coloured monoclonal anti-HBsAg-colloidal gold conjugate complexes membrane to the test region where it is immobilized by polyclonal anti-HBsAg antibody coated on the membrane leading to formation of first purple band (T zone) confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membranes and are subsequently immobilized by the anti-rabbit Ig G coated on the membrane and are at the control region, forming a pink-purple band. This control band serves to validate the test results. 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.

Kit Composition

1. Test devices (25 pieces individually packaged devices. In each individual pack, it contains test kit cassette, silica gel and a dropper)
2. One buffer vial
3. One copy of Product insert

Materials required but not provided

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

Description of components

- Nitrocellulose Membrane: The membrane coated with monoclonal HBsAg and control line coating antibody.
- Gold Conjugate Pad: Gold conjugated with monoclonal anti-HBsAg and control line conjugation antibody.
- Sample Release Pad
- Absorbent Pad

Warning & Precautions

- Wear protective gloves while handling specimens wash thoroughly afterwards.
- Do not mix reagents from different lot.
- For professional in vitro diagnostic use only. Does not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Humidity and temperature can adversely affect results.
- Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
- Follow the testing procedure exactly as mention in the insert.

Storage and Stability

- The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

Specimen Collection & Preservation

- Fresh serum/plasma/whole blood: if testing is not performed within 3 days of collection of specimens, the specimen should be refrigerated immediately at 2-8°C. Specimen: Human Serum / Plasma / Whole Blood. Use non haemolysed serum / plasma / whole blood collected without prolonged venous stasis. Specimen are stable for at least 3 days when stored at 2 - 8°C. For long term storage, specimens should be kept below -20°C.

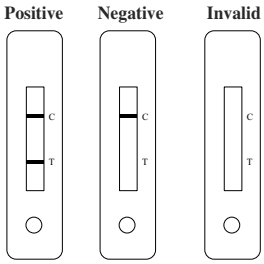
Directions For Use

- Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15 - 30°C) prior to testing.

1. Bring the sealed pouch to room temperature, open the pouch and remove the device and place it on a clean flat surface.
2. Add 2 drops (50µl) of serum/plasma/whole blood in sample well “S” using the dropper provided
3. Add 1 drop (40µl) of assay buffer.
4. Allow reaction to occur in next 15-20 minutes.
5. The test should be read between 15-20 minutes after addition of Human Serum / Plasma / Whole Blood

Note: Please do not interpret after 20 minutes.

Interpretation of Results



1. **Negative:** Only one pink-purple coloured line appears at the control zone ‘C’ (Control line) the test result is negative
2. **Positive:** In addition to the coloured line in the control region a clearly distinguishable pink purple coloured line also appears in the test region ‘T’ (Test line) indicating a positive result and that the sample contains Hepatitis B Antigen. A difference of intensity may occur between the lines in the test region and the test region but this does not affect the interpretation of the result.
3. **Invalid:** If no line appears in the control as well as the test region, the test should be repeated with fresh card.

Quality Control

- A procedural control is included in the test. A purple line appearing in the control region C is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Performance Charactertistcs

Diagnostic Sensitivity & Specificity:

- CADY® Hepatitis B Rapid Test was evaluated with clinical specimens (including reactive and non-reactive specimens) and the results were compared with that of CE marked Hepatitis B Rapid Test.

Results were shown as below

		Onsite HBsAg Rapid Test (CE)		Total
		Positive	Negative	
CADY® Hepatitis B Rapid Test	Positive	53	0	53
	Negative	2	240	242
	Total	55	240	295

Relative Sensitivity: 94.54% (95% C.I:0.8854-1.0057) with CE marked HBsAg Rapid Test

Relative Specificity: 100% with CE marked HBsAg Rapid Test

Overall Agreement: 99.32% with CE marked HBsAg Rapid Test

Sensitivity: CADY Hepatitis B Rapid Test can detect Hepatitis B antigen in serum/plasma/whole blood in a concentration as low as 1.0 ng/ml.

Limitation

1. Though HBsAg Card Test is a reliable screening assay, it should not be used as a sole criterion for diagnosis of Hepatitis B infection.
2. The test will only indicate the presence or absence of Hepatitis B surface antigen in the specimen and other consideration like clinical symptoms should be noted before making final diagnosis.
3. Interference due to heterophile antibodies, RF (Rheumatoid Factors) and other non-analyte substances in high titre in patient's serum express erroneous analyte detection in immunoassays interferences. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interferences.
4. Most positive results develop within 15-20 minutes. However, certain sera samples may take longer time to flow. Do not read results after 20 minutes.