HBsAg Rapid Test Cassette (Serum/Plasma) Package Insert

REF L031-10231	English

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

ACON HBsAg Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in serum or plasma.

SUMMARY

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen. [1] The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.
ACON HBsAg Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

PRINCIPLE

ACON HBsAg Rapid Test Cassette (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- ACON HBsAg Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test Cassettes
- Package insert
- Specimen droppers

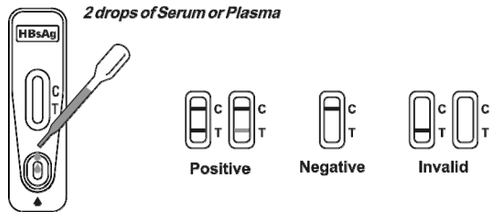
Materials Required But Not Provided

- Specimen collection container
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

Allow test cassette, serum or plasma specimen to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test Cassette on a non-absorbent flat surface. With arrows pointing toward the serum or plasma specimen, add two drops of specimen vertically to the sample pad under the arrows.
3. Start the timer and wait for the red line(s) to appear. The result should be read at 10 minutes.
   Note: A low HBsAg concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE:* Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of HBsAg present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.
NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: Control line fails to appear. 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that a positive control (containing 10 ng/mL HBsAg) and a negative control control (containing 0 ng/mL HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. ACON HBsAg Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBsAg in serum or plasma specimen.
2. ACON HBsAg Rapid Test Cassette (Serum/Plasma) will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. ACON HBsAg Rapid Test Cassette (Serum/Plasma) cannot detect less than 0.79 ng/mL of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

EXPECTED VALUES

ACON HBsAg Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity

ACON HBsAg Rapid Test Cassette (Serum/Plasma) has been tested with WHO International Standard Sample 12/226 and low titer specimens. The test can detect 0.79 ng/mL of HBsAg in 10 minutes, and 2 ng/mL of WHO International standard in 10 minutes.

Specificity

Antibodies used for ACON HBsAg Rapid Test Cassette (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of ACON HBsAg Rapid Test Cassette (Serum/Plasma) was also tested with Hepatitis A positive specimen, Hepatitis C positive specimen, Hepatitis D positive specimen and Hepatitis E positive specimen. They all yielded negative results.

HBsAg Reference Method

Method		EIA		Total Results
HBsAg Test Cassette	Results	Positive	Negative	
	Positive	184	0	184
	Negative	0	309	309
Total Results		184	309	493

Relative Sensitivity: 100% (98.02%-100%)* Relative Specificity: 100% (98.81%-100%)*
Overall Agreement: 99.6% (99.25%-100%)* *95% Confidence Interval

Precision

Intra-Assay
Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.
Inter-Assay
Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the ACON HBsAg Rapid Test Cassette (Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis.* Vitro. 1971; 7: 223

Index of Symbols

	Manufacturer	Σ	Tests per kit	30°C / 2°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
LOT	Lot Number	REF	Catalog #		

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