

Instant-View[®] HBsAg ONE-STEP Serum Test (Cassette)

Simple Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE

Instant-View[®] HBsAg serum cassette test is designed as an initial qualitative screening test to detect Hepatitis B surface antigen (HBsAg) in human serum or plasma at a concentration equal to or greater than 2 ng/ml.

PRINCIPLE OF THE PROCEDURE

Hepatitis B is one of the major causes of hepatitis in humans¹. Individuals carrying this virus may not have symptoms, but could be a source of infection².

This test device is a chromatographic lateral-flow immunoassay, including membrane pre-coated with anti-HBsAg antibodies and a pink colored pad with colloidal gold reagents labeled with anti-HBsAg antibodies. The membrane has two coated lines: a test line (T line) and a control line (C line). At the T line, a pink colored band develops if HBsAg is present in the specimen tested. If antigen is not present, no T line will develop. At the C line, a pink colored band should appear regardless of the presence of HBsAg. The C line serves as an internal qualitative control indicating that an adequate volume of solution was added to the test system.

MATERIALS PROVIDED

- 25 test devices, each sealed in a foil pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer

STORAGE

Store kit at 15-30°C (59-86°F) room temperature. Kit contents are stable for at least 2 years or until the expiration date printed on the label, whichever comes first.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F).



SPECIMEN COLLECTION

1. This test can be used for human serum or plasma test only.
2. Collect specimens following standard clinical procedures.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed as soon as possible after sample collection. Do not leave at room temperature for more than 24 hours. Specimens can be refrigerated at 2°-8°C up to 7 days or stored below -20°C for long term period.
5. Specimens should be packed and shipped in compliance with regulatory agencies regulations covering the transportation of etiologic agents.

PRECAUTIONS

1. Individuals performing the test should wear protective clothing such as laboratory coats and disposable gloves while collecting and testing samples and thoroughly wash hands afterwards.
2. Use a separate disposable pipette, and test kit for each specimen.
3. All spills should be wiped up thoroughly with sodium hypochlorite (0.5%), alcohol (70%) or an iodophor disinfectant.
4. Treat all materials in the test as if they were infectious. Dispose of all specimens and used assay materials as if they contained infectious agents. The preferred method is autoclaving for 60 minutes at 121°C or incineration.
5. Avoid any contact between hands and eyes and nose during specimen collection and testing.
6. DO NOT USE kit beyond the expiration date which appears on the package label or device in a damaged pouch..

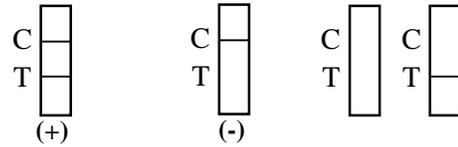
PROCEDURE

1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Remove the device from its pouch and place the device on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add two (2) drops of serum to the sample well, marked "S".

4. Strong positive results may be observed in 2-3 minutes. Weak positive results may take a longer time, up to 20 minutes.

IMPORTANT: Do not interpret the results after 20 minutes.

INTERPRETATION



POSITIVE NEGATIVE INVALID

Positive:

If both C line and T line appear in the viewing area, the test indicates that HBsAg is present in the specimen.

Samples with positive or inconclusive results should be confirmed with a more specific method before a determination is made.

Negative:

If only the C line appears, the test indicates that no HBsAg detected in the specimen and the result is negative.

Invalid:

If no C line becomes visible within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL PROCEDURE

Good Laboratory Practice recommends the use of control materials.

LIMITATIONS

1. The test is for *professional in vitro* diagnostic use only.
2. The test is intended for detection of HBsAg in human serum only.
3. This test 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 Virus infection.
4. As with all qualitative diagnostic tests, all results must be considered with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis B virus infection.

PERFORMANCE CHARACTERISTICS

Sensitivity: The Instant-View[®] HBsAg One-Step Test can detect HBsAg in human serum at concentration equal to or greater than 2ng/ml.

Specificity: The Instant-View[®] HBsAg One-Step Test is specific for the two major HBsAg subtypes, ad and ay.

REFERENCES

1. Ruben, E. (1979) Acute and chronic viral hepatitis. Federation Proceedings. 28: 2665.
2. Magnus, L.O., et al. (1975) New antigen-antibody system. Clinical significance in long-term carriers of Hepatitis B surface antigen. J. American Medical Association. 231: 356

	Temperature limitation		Use by YYYY-MM
	Batch/Lot code		In vitro diagnostic medical device
	Manufacturer		Catalog number
	Contains sufficient for < n > tests		Consult instructions for use
	For IVD performance evaluation only		Do not reuse
	Caution, consult accompanying documents		

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