

One Step HBsAg Rapid Test

For detection of HBsAg in Human Serum, Plasma or Whole Blood.

IVD In-vitro diagnostic use only



Not reuse

Introduction

HBsAg Rapid Test is a, direct binding test for the visual detection of hepatitis B surface antigen (HBsAg) in serum, plasma or whole blood. It is used as an aid in the diagnosis of hepatitis B infection. The One Step HBsAg Whole Blood Test is based on the principle of sandwich immunoassay for determination of HBsAg in serum or whole blood. Monoclonal and polyclonal antibodies are employed to identify HBsAg specifically. This one step test is very sensitive and only takes 10 minutes. Test results can be read visually without any instrument.

Principle

This test strip contains a membrane strip, which is pre-coated with mouse monoclonal anti-HBs capture antibody on test band region. The mouse monoclonal anti-HBs-colloid gold conjugate and sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antibody-antigen-antibody gold particle complex forms. Both the Test Line and Control Line are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the reagents of control line are working.

Materials Included and Active Ingredients

- 1) HBsAg kit contains the following items to perform the assay.
 - HBsAg test device foil pouched with a desiccant
 - Instruction for use

Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C

Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

- 8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

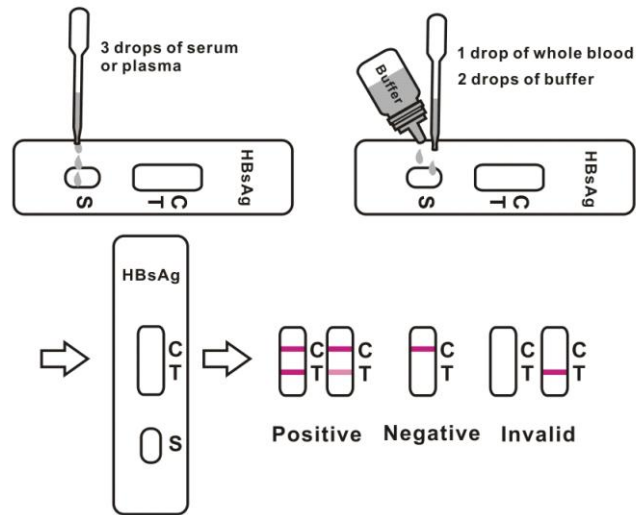
- 1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- 2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
- 3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card. Preferably, collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. If blood specimens are not immediately tested, they should be refrigerated at 2~8 °C . When stored at 2~8 °C, the blood specimens should be used within 3 days. For storage period longer than 3 days, freezing is recommended. They should be brought to room temperature (1~30 °C) prior to use. Using the blood specimens in the long-term keeping more than 3 days can cause nonspecific reaction.
- 4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8 °C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30 °C) prior to use.
- 5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
- 7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
- 8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure (Refer to Figure)

- 1) Allow all test components and specimen to come to room temperature prior to testing
- 2) Remove the test device from the foil pouch, and place it on a flat, dry surface
- 3) For Serum/Plasma specimen, with a micropipette (not provided) or a disposable dropper, add about 100 µL of serum/ plasma specimen into the sample well marked "S";
- 4) For Whole Blood specimen, : Hold the dropper vertically and transfer 1 drop of whole blood(approximately 35 µL) to the specimen well(S) of the test device, **Allow about 30 seconds for the specimen to be absorbed totally**. Then add 2 drops of buffer (approximately 70 µl) and start the timer. See illustration below.
- 5) As the test begins to work, you will see red color move across the result window in the center of the test device.
- 6) Interpret test results at 15 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

- 1) **Negative:** The control line is the only visible line on the test device. This indicates a negative result.
- 2) **Positive:** The presence of two color lines ("T" line and "C" line), no matter which line appears first, indicates a positive result.
- 3) **Invalid:** If the "C" line (control) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



Limitations of the Test

1. The One Step HBsAg Test is for in vitro diagnostic use only. The test should be used for the detection of Hepatitis B surface Antigen in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in Hepatitis B surface Antigen can be determined by this qualitative test.
2. The One Step HBsAg Test will only indicate the presence of Hepatitis B surface Antigen in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Hepatitis B infection.

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