SPESERA
Sağlık Ürünleri İç ve Dış Tic. Ltd. Şti.

One Step HBsAb Test

(Serum/Plasma)

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

Intended Use

The One Step HBsAb Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface Antibody (HBsAb) in serum or plasma.

Summary

Hepatitis B is caused by a virus that affects the liver. Adults who get hepatitis B usually recover. However most infants infected at birth become chronic carriers i.e. They carry the virus for many years and can spread the infection to others. The One Step HBsAb Test utilizes a double antigen combination of a HBsAg coated particle and HBsAg to detect Hepatitis B surface Antibody qualitatively and selectively in serum or plasma.

Principle

The One Step HBsAb Test is a qualitative membrane strip based immunoassay for the detection of Hepatitis B surface Antibody in serum or plasma. In this test procedure, HBsAg is immobilized in the test line region of the device. After a specimen is placed in the specimen well, it reacts with HBsAg coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized HBsAg. If the specimen contains Hepatitis B surface Antibody, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain Hepatitis B surface Antibody, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Storage and Stability

- Store as packaged in the sealed pouch at room temperature or refrigerated (4-30℃ or 40-86℉). The test device is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.

Additional Special Equipment

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Timer
- Centrifuge
- Specimen collection containers

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 and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures 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 assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

Specimen Collection and Preparation

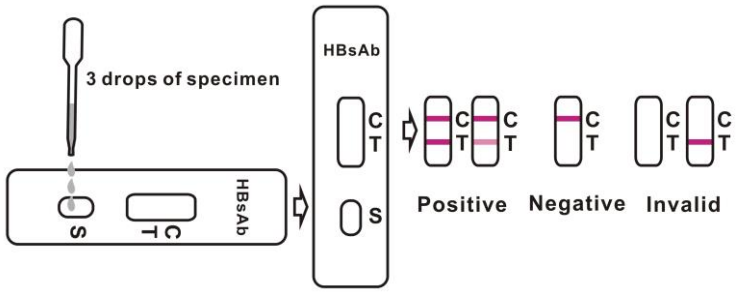
1. The One Step HBsAb Test can be performed used on serum or plasma.
2. To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃.

5. 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.

Test Procedure

Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
3. Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 100 μl) to the specimen well(S) of the test device, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of specimen (serum or plasma) to the specimen well.

Interpretation of Results

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region.

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations

1. The One Step HBsAb Test is for in vitro diagnostic use only. The test should be used for the detection of Hepatitis B surface Antibody in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Hepatitis B surface Antibody can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

Manufacturer

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