세로퀵

Seroquick

HEPATITIS B SURFACE ANTIGEN RAPID TEST DEVICE

INTENDED USE

Seroquick Hepatitis B Surface Antigen Rapid Test Device is a rapid chromatographic immunoassay designed for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum, plasma, or whole blood samples. This test serves as a screening tool for identifying current hepatitis B virus infection, including in individuals who may not show symptoms.

With its fast results and simple procedure, the test is suitable for use at home or in community settings, as well as in clinical and medical environments. It does not require specialized equipment, making it ideal for both well-equipped and resource-limited conditions. Early detection of HBsAg allows for timely medical intervention and supports efforts to prevent the spread of hepatitis B, especially in high-risk and high-prevalence groups.

PRINCIPLE

Seroquick Hepatitis B Surface Antigen Rapid Test Device is based on a lateral flow immunochromatographic assay that employs a two-site sandwich detection method. The test strip contains anti-HBsAg antibodies conjugated to colloidal gold particles, which are deposited onto the conjugate pad. When a sample of whole blood, serum, or plasma is applied to the sample well, it interacts with the gold-labeled antibodies, forming an antigen–antibody complex that migrates along the nitrocellulose membrane by capillary action.

As the complex moves upward, it encounters a second set of anti-HBsAg antibodies immobilized in the test region. These capture the complex and produce a visible colored band, indicating the presence of HBsAg. If the sample does not contain HBsAg, no colored band appears in the test region. A separate control band is included to validate proper test function, confirming that an adequate specimen was applied and fluid migration occurred as intended. The control band must be visible for the result to be considered valid. This internal procedural control ensures the reliability of the test even in decentralized or non-laboratory settings. The test delivers results within 15 minutes and requires no specialized instruments, making it suitable for home, clinical, and point-of-care use.

STORAGE

1. Store in a cool, dry place between 2°C and 30°C. Do not freeze.
2. Keep away from direct sunlight and excess humidity.
3. Do not open the sealed pouch until ready to use.
4. Use before the expiration date printed on the packaging.
5. Before use, allow all test components to gradually reach and stabilize at room temperature (15°C to 30°C) to ensure proper fluid migration.
6. For best results, test samples immediately after collection. Avoid using damaged or unsealed test devices.

PACKAGE CONTENTS

1. Instruction Manual
2. HBsAg Test Cassette
3. Buffer Tube with Dropper Tip
4. Automatic Sterile Lancet
5. Manual Sterile Lancet
6. Pipette
7. Alcohol Pad
8. Bandage

SPECIMEN COLLECTION

If the specimen is to be tested immediately, open the sealed foil pouch beforehand, and ensure that all test kit components are at room temperature and ready for use before specimen collection.

A. Whole Blood Specimen

1. Clean the fingertip with the alcohol pad and allow it to air dry.
2. Squeeze the fingertip firmly and pierce it using the sterile lancet.
3. Wipe away the first drop of blood using a fresh cotton pad.
4. Gently massage or squeeze the fingertip again to promote blood flow.
5. Use a disposable pipette to collect blood from the puncture site. Apply controlled pressure and avoid drawing the blood all the way into the bulb, as it may become trapped and difficult to dispense.

B. Plasma Specimen

1. Collect venous blood into an anticoagulant tube via venipuncture.
2. Mix the tube gently by inversion to prevent clotting.
3. Centrifuge the specimen at the appropriate speed and duration as per laboratory protocol to separate plasma.
4. Using a sterile pipette, carefully transfer the plasma into a properly labeled, sterile secondary tube, avoiding the buffy coat.

C. Serum Specimen

1. Collect venous blood into a plain or serum separator tube via venipuncture.
2. Allow the blood to clot at room temperature for 30 to 60 minutes.
3. Centrifuge the clotted blood as per protocol to separate the serum.
4. Carefully transfer the serum into a properly labeled, sterile secondary tube using a sterile pipette, avoiding any residual cellular material.

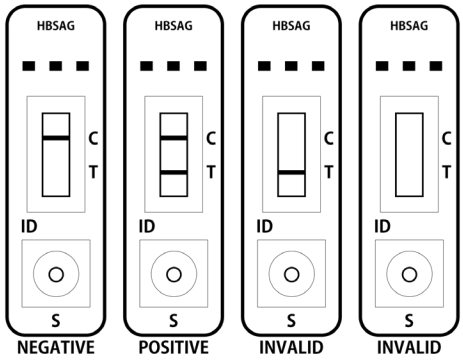
D. Specimen Handling and Storage

1. Test specimens as soon as possible after collection for optimal results.
2. If immediate testing is not feasible, store specimens at 2 to 8°C for up to 5 days.
3. For longer storage, freeze specimens at –20°C or lower.
4. Avoid multiple freeze-thaw cycles, as repeated freezing and thawing may compromise analyte stability.
5. Before testing, thaw frozen specimens slowly at room temperature and mix gently by inversion.
6. If specimens contain visible particulate matter, clarify by centrifugation prior to testing to ensure sample integrity.

TEST PROCEDURE

1. Open the foil pouch and remove the test device. If testing multiple specimens, clearly label the device with the corresponding patient or control identification. Place the device on a flat, clean, and dry surface.
2. Using the pipette, dispense 1 drop (50 µL) of whole blood, serum, or plasma into the sample well of the test cassette.
3. Dispense 2 drops (100 µL) of buffer solution to the same sample well.
4. Start the timer. Results may begin to appear as early as 30 seconds, but final interpretation should be made between 10 and 15 minutes.
5. Do not interpret results after 20 minutes, as results may become unreliable.

READING RESULT



Negative Result: If only the C band is visible and no band appears in the T region, this indicates that the specimen contains no detectable HBsAg. The result should be interpreted as negative.

Positive Result: If a colored band appears in the T region along with the C band, this indicates the presence of HBsAg in the specimen. The result is interpreted as positive.

Invalid Result: If the C band does not appear, the test is invalid regardless of a visible band in the T region. The test should be repeated using a new device.

Note: The intensity of the band in the T region may vary depending on the concentration of HBsAg present in the specimen. A darker band indicates a higher antigen concentration. Even a faint band in the T region should be considered positive if the C band is also present.

PERFORMANCE

A. Sensitivity

Seroquick Hepatitis B Surface Antigen Rapid Test Device was evaluated against a third-generation enzyme immunoassay (EIA), a widely accepted reference method for detecting hepatitis B surface antigen (HBsAg). In this study, all 82 HBsAg-positive specimens confirmed by the reference method were accurately identified by Seroquick, resulting in a sensitivity of 100% within the evaluated sample set. Designed for both clinical and point-of-care use, Seroquick provides rapid, visual results without the need for specialized instruments. These findings highlight the test's strong diagnostic performance and reliability for hepatitis B screening.

B. Specificity

Seroquick Hepatitis B Surface Antigen Rapid Test Device was evaluated for specificity using 248 specimens confirmed negative by a third-generation enzyme immunoassay (EIA). Of these, 247 were correctly identified as negative by Seroquick, with only one specimen producing a false-positive result. This yields a calculated specificity of 99.6% within the evaluated sample set. The high specificity demonstrates Seroquick's ability to accurately rule out non-infected individuals, making it a dependable option for rapid hepatitis B screening across a wide range of healthcare settings. This level of diagnostic accuracy helps reduce unnecessary follow-up procedures and ensures greater confidence in negative results.

C. Performance Summary

Parameter	Result	Notes
Total Samples	330	82 positive, 248 negative
Sensitivity	100% (82/82)	Verified by third-generation EIA
Specificity	99.6% (247/248)	One false positive vs EIA
Overall Accuracy	99.7% (329/330)	Correctly identified samples
True Positives	82	All results correctly identified
False Negatives	0	No missed infections
True Negatives	247	Verified by EIA
False Positives	1	Single incorrect positive
Time to Result	~15 minutes	Typical visual result time

D. Cross-reactivity

A cross-reactivity study was conducted to evaluate the potential interference of common pharmaceutical agents, biological compounds, and endogenous substances that may be present in patient specimens. The study included analgesics, antibiotics, antihistamines, recreational and prescription drugs, anticoagulants, food additives, and naturally occurring substances such as proteins, sugars, and pigments.

All substances were tested at elevated concentrations exceeding normal therapeutic or physiological levels to simulate worst-case clinical conditions. Under these conditions, none of the tested compounds caused false positive or false negative results with Seroquick Hepatitis B Surface Antigen Rapid Test Device. These results confirm that the assay maintains its specificity and accuracy in the presence of commonly encountered interfering substances.

Parameter	Conc.	Parameter	Conc.	Result
Acetaminophen	200 µg/mL	Acetylsalicylic Acid	200 µg/mL	No interference
Amikacin	200 µg/mL	Ascorbic Acid	200 µg/mL	No interference
Aspartame	200 µg/mL	Atropine Sulfate	200 µg/mL	No interference
Benzoic Acid	200 µg/mL	Caffeine	200 µg/mL	No interference
Deoxyephedrine	200 µg/mL	Dextromethorphan	200 µg/mL	No interference
EDTA	800 µg/mL	Gentisic Acid	200 µg/mL	No interference
Histamine	200 µg/mL	Methaqualone	200 µg/mL	No interference
Phendimetrazine	200 µg/mL	Penicillin G	200 µg/mL	No interference
Quinine	200 µg/mL	Ranitidine	200 µg/mL	No interference
Sodium Salicylate	200 µg/mL	Tryptophan	200 µg/mL	No interference
Tetracycline	200 µg/mL	Tetrahydrozoline	200 µg/mL	No interference
Ethanol	1%	Methanol	1%	No interference
Heparin	1%	Citrate	3.2%	No interference
Albumin	2 mg/mL	Glucose	2 mg/mL	No interference
Bilirubin	2 mg/mL	Hemoglobin	2 mg/mL	No interference

LIMITATIONS

1. This product is intended for in vitro diagnostic use only and should not be used for any other purpose.
2. Environmental factors such as excessive humidity, extreme temperatures, or improper storage may adversely affect performance.
3. Interfering substances in the specimen, as well as technical or procedural errors, may lead to false results. These are factors that may fall outside the manufacturer's control.
4. While the test demonstrates high accuracy and performance comparable to laboratory-based methods, a small possibility of false positive or false negative results still exists.
5. In cases of inconclusive or unexpected results, further evaluation with confirmatory laboratory testing is recommended. As with all diagnostic tools, results should be interpreted alongside the patient's clinical presentation, medical history, and other relevant laboratory findings.

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