세로퀵

Seroquick

HIV 1/2 RAPID TEST DEVICE
BLOOD

INTENDED USE

Seroquick HIV 1/2 Rapid Test Device is a rapid chromatographic immunoassay intended for the qualitative detection of antibodies to Human Immunodeficiency Virus types 1 and 2 (HIV-1 and HIV-2) in human whole blood, serum, or plasma. It is intended as a screening tool to aid in the identification of HIV infection.

It offers a convenient and efficient solution for use in clinical laboratories, healthcare facilities, and point-of-care settings, providing clear results within minutes. Its simple procedure and quick turnaround time make it especially valuable in environments where timely decision-making is essential.

PRINCIPLE

Seroquick HIV 1/2 Rapid Test Device is a qualitative, membrane-based immunoassay used for the detection of antibodies to HIV-1 and/or HIV-2 in human whole blood, serum, or plasma samples. The test membrane is pre-coated with recombinant HIV antigens specific to both virus types. During the test procedure, the specimen reacts with HIV antigen-conjugated particles contained within the test cassette. This mixture migrates upward along the membrane by capillary action, allowing any HIV-specific antibodies in the specimen to bind to the immobilized recombinant HIV antigens in the test region.

If HIV-1 or HIV-2 antibodies are present, a colored band will appear in the test region, indicating a positive result. If no such antibodies are detected, no band appears in the test region, indicating a negative result. A control band will always appear in the control region, regardless of the test outcome. This ensures that the specimen has flowed correctly through the membrane and that the test device is functioning as intended.

The formation of the visible band is based on immunochromatographic principles, where antigen-antibody interactions generate a colored band due to the presence of colloidal gold. The test's design allows for rapid screening without the need for specialized equipment, making it ideal for both clinical and home settings.

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. HIV 1/2 Blood 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.

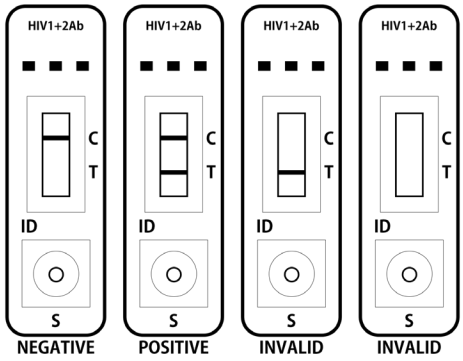
D. Specimen Handling and Storage

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 (50 µL) drop 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 HIV antibodies. 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 HIV antibodies 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 HIV 1/2 antibodies present in the specimen. A darker band indicates a higher antibody concentration. Even a faint band in the T region should be considered positive if the C band is also present.

PERFORMANCE

A. Sensitivity

Seroquick HIV 1/2 Rapid Test Device was evaluated against the HIV-1/HIV-2 Antibody Differentiation Immunoassay, a widely accepted confirmatory method for detecting antibodies to HIV-1 and HIV-2. In this study, all 161 antibody-positive samples identified by the confirmatory method were also correctly detected by Seroquick, yielding a sensitivity of 100% in the evaluated sample set. Unlike laboratory-based immunoassays, Seroquick HIV 1/2 Rapid Test is intended for point-of-care use, delivering rapid and reliable results without the need for specialized equipment. These findings underscore its strong diagnostic accuracy and practical utility in screening for established HIV infections.

B. Specificity

Seroquick HIV 1/2 Rapid Test Device was evaluated for specificity using 431 specimens confirmed negative by a laboratory-based 4th generation ELISA assay, which detects both HIV-1/2 antibodies and the HIV-1 p24 antigen. Of these, 430 were correctly identified as negative by the test, resulting in a specificity of 99.8%. One false positive was recorded during the evaluation. These results demonstrate the high accuracy of the test in identifying non-infected individuals, supporting its reliability as a rapid screening tool for HIV-1/2 antibodies.

C. Performance Summary

Parameter	Result	Notes
Total Samples	592	161 positive, 431 negative
Sensitivity	100% (161/161)	Verified by differentiation assay
Specificity	99.8% (430/431)	One false positive vs ELISA
Overall Accuracy	99.8% (591/592)	Correctly identified samples
True Positives	161	All results correctly identified
False Negatives	0	No missed infections
True Negatives	430	Verified by ELISA
False Positives	1	Single incorrect positive
Time to Result	~15 minutes	Typical visual result time

D. Cross-reactivity

A cross-reactivity study was performed to evaluate whether commonly encountered substances in blood, serum, or plasma specimens could interfere with the performance of Seroquick HIV 1/2 Rapid Test Device. The study included a wide range of compounds such as medications, anticoagulants, preservatives, and endogenous biological substances. Each was tested at concentrations exceeding typical clinical or physiological levels to simulate worst-case scenarios.

Analgesics, antibiotics, antihistamines, antimalarials, over-the-counter drugs, and recreational substances were spiked into pooled HIV-negative samples. Interferents like bilirubin, hemoglobin, lipids, and autoantibodies were also included due to their potential to impact immunoassay performance. None of the tested substances caused false positive or false negative results, confirming the test's high specificity and resistance to cross-reactivity in diverse clinical conditions.

Parameter	Concentration	Parameter	Concentration	Notes
Acetaminophen	200 µg/mL	Quinine	200 µg/mL	No interference
Acetylsalicylic Acid	200 µg/mL	Ranitidine	200 µg/mL	No interference
Amikacin	200 µg/mL	Sodium Salicylate	200 µg/mL	No interference
Ascorbic Acid	200 µg/mL	Tryptophan	200 µg/mL	No interference
Aspartame	200 µg/mL	Tetracycline	200 µg/mL	No interference
Atropine Sulfate	200 µg/mL	Tetrahydrozoline	200 µg/mL	No interference
Benzoic Acid	200 µg/mL	Ethanol	1%	No interference
Caffeine	200 µg/mL	Methanol	1%	No interference
Deoxyephedrine	200 µg/mL	Heparin	1%	No interference
Dextromethorphan	200 µg/mL	Citrate	3.2%	No interference
EDTA	800 µg/mL	Albumin	2 mg/mL	No interference
Gentisic Acid	200 µg/mL	Glucose	2 mg/mL	No interference
Histamine	200 µg/mL	Bilirubin	2 mg/mL	No interference
Methaqualone	200 µg/mL	Hemoglobin	2 mg/mL	No interference
Phendimetrazine	200 µg/mL	Penicillin G	200 µg/mL	No interference
Triglycerides	3 g/L	Cholesterol	5 g/L	No interference
Rheumatoid Factor (RF)	100 IU/mL	HAMA	500 ng/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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