세로퀵

Seroquick

HIV 4TH GENERATION RAPID TEST DEVICE

INTENDED USE

Seroquick HIV 4th Generation Rapid Test Device is a highly sensitive lateral flow immunochromatographic assay designed for the simultaneous qualitative detection and differentiation of anti-HIV-1 and anti-HIV-2 antibodies (IgG, IgM, IgA) and the HIV-1 p24 antigen in human serum, plasma, or whole blood. This advanced fourth-generation test enables earlier diagnosis by identifying HIV during both the acute phase, which is marked by the presence of p24 antigen before seroconversion, and the chronic phase, which is characterized by the production of antibodies. By detecting both the host's immune response and the viral core antigen, this test significantly shortens the diagnostic window period compared to earlier-generation tests. Its accuracy closely matches that of laboratory-based confirmatory methods, making it a reliable choice for point-of-care HIV screening.

PRINCIPLE

Seroquick HIV 4th Generation Rapid Test Device is a lateral flow immunochromatographic assay designed for the simultaneous detection of HIV-1/2 antibodies and the HIV-1 p24 antigen in human serum, plasma, or whole blood. The test cassette comprises a conjugate pad containing colloidal gold-labeled recombinant HIV-1/2 antigens, anti-p24 antibodies, and a control conjugate, along with a nitrocellulose membrane featuring three regions: an antibody (Ab) region, an antigen (Ag) region, and a control (C) region.

When a specimen is applied to the sample well, it migrates through the cassette via capillary action. If HIV-1 p24 antigen is present, it binds to the anti-p24 gold conjugates and forms an immunocomplex that is captured at the Ag region, producing a visible colored band. Similarly, if HIV-1/2 antibodies are present, they bind to the HIV-1/2 antigen-gold conjugates and are immobilized at the Ab region, also resulting in a colored band. The presence of either or both bands indicates a reactive result for the respective target. The control region, coated with a secondary IgG-binding antibody, captures the IgG-gold conjugates to verify proper test performance. The appearance of this band is required for the result to be considered valid. If the control band does not appear, the test is invalid and should be repeated with a new device.

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 4th Generation 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.

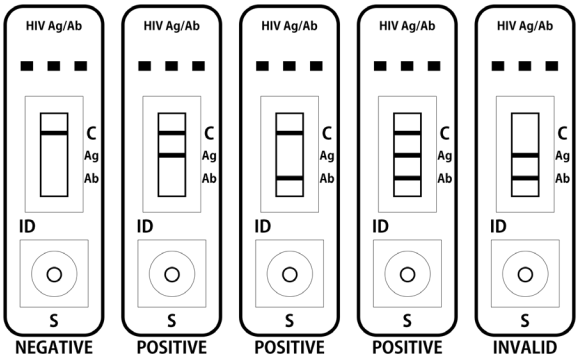
D. Specimen Handling and Storage

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 2 drops (100 µL) of whole blood, serum, or plasma into the sample well of the test cassette.
3. Dispense 1 drop (50 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 Ag or Ab test regions, the specimen contains neither HIV antibodies nor P24 antigen. The result should be interpreted as negative.

Positive Results:

- If a colored band appears in the Ag region along with the C band, this indicates the presence of P24 antigen in the specimen.
- If a colored band appears in the Ab region along with the C band, this indicates the presence of HIV-1 or HIV-2 antibodies in the specimen.
- If colored bands appear in both the Ag and Ab regions along with the C band, this indicates the presence of P24 antigen and antibodies to HIV-1 or HIV-2 in the specimen. Any of these results are interpreted as positive.

Invalid Result: If the C band does not appear, the test is invalid regardless of any colored bands in the test regions. The test should be repeated using a new device.

Note: The intensity of the bands in the Ag and Ab regions may vary depending on the concentration of antigens and antibodies present. A darker band indicates a higher concentration. Even faint bands in the Ag or Ab regions are considered positive, provided the C band is visible.

PERFORMANCE

A. Sensitivity

Seroquick HIV 4th Generation 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, 183 samples that tested positive by the confirmatory method were also correctly identified by Seroquick, yielding a sensitivity of 100% in the evaluated sample set. Unlike the differentiation immunoassay, Seroquick also detects the P24 antigen, enabling identification of early-stage HIV infections before seroconversion. This demonstrates that Seroquick offers reliable screening along with the advantage of early detection.

B. Specificity

Among 529 specimens confirmed negative by a laboratory-based 4th generation ELISA, which detects both HIV-1/2 antibodies and the p24 antigen, all 529 were correctly identified as negative by the test, yielding a specificity of 100%. No false positives were observed during the evaluation, further confirming the test's high reliability in clinical and point-of-care settings where accurate and rapid screening is essential.

C. Performance Summary

Parameter	Result	Notes
Total Samples	712	183 positive, 529 negative
Sensitivity	100% (183/183)	Verified by differentiation assay
Specificity	100% (529/529)	Verified by ELISA
Overall Accuracy	100% (712/712)	No incorrect results observed
True Positives	183	All results correctly identified
False Negatives	0	No missed infections
True Negatives	529	Verified by ELISA
False Positives	0	No false positives observed
Limit of Detection	~25–50 pg/mL	Estimated P24 detection range
Time to Result	~15 minutes	Typical visual result time

D. Cross-reactivity

A comprehensive cross-reactivity study was conducted to evaluate the potential impact of commonly encountered substances on the performance of Seroquick HIV 4th Generation Rapid Test Device. This study aimed to ensure assay reliability even in challenging clinical conditions by simulating worst-case exposure scenarios through spiked samples.

The test was challenged with a diverse range of chemical and biological agents including analgesics, antibiotics, antihistamines, antimalarials, recreational drugs, and common prescription medications. Substances such as bilirubin, hemoglobin, triglycerides, rheumatoid factor, and heterophilic antibodies were also included due to their known potential to interfere with immunoassays. Each substance was tested at concentrations above physiological levels to determine whether they could trigger false positive or false negative results.

None of the tested substances interfered with the antibody or antigen detection components of the assay. These findings confirm Seroquick's high analytical specificity and robustness, even in the presence of potentially interfering compounds commonly found in whole blood, serum, or plasma. This supports its reliability for routine use across a wide range of clinical and point-of-care settings.

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 interferenc
Rheumatoid Factor	100 IU/mL	Heterophile Ab	500 ng/mL	No interference
HAMA	500 ng/mL	Anti-nuclear Ab	100 IU/mL	No interference
pH Variation	pH 4–10	Elevated Proteins	8 g/dL	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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