세로퀵

Seroquick

HIV 1/2 RAPID TEST DEVICE
SALIVA

INTENDED USE

Seroquick HIV 1/2 Rapid Test Device is a lateral flow chromatographic immunoassay designed for the qualitative detection of antibodies to Human Immunodeficiency Virus types 1 and 2 (HIV-1 and HIV-2) in human oral fluid specimens. It serves as a reliable screening tool to support the early identification of HIV infection, especially in settings where immediate results are beneficial.

Seroquick provides a convenient, non-invasive solution suitable for use in clinical laboratories, healthcare facilities, community outreach programs, and home-based testing. The test yields clear, easy-to-read results within minutes, eliminating the need for complex equipment or specialized training. Its simple oral fluid collection method, combined with rapid turnaround time, makes it particularly valuable in environments where accessibility, patient comfort, and swift decision-making are critical.

PRINCIPLE

Seroquick HIV 1/2 Rapid Test Device is a qualitative, membrane-based lateral flow immunoassay developed to detect antibodies to HIV-1 and HIV-2 in human oral fluid specimens. The test membrane is pre-coated with synthetic recombinant HIV antigens representative of both virus types, ensuring broad antibody recognition across diverse HIV subtypes.

During testing, the oral fluid sample reacts with colloidal gold-conjugated HIV antigens embedded in the sample pad. The resulting immunocomplex migrates along the nitrocellulose membrane via capillary action. If HIV antibodies are present, they bind to immobilized HIV antigens in the test region, producing a visible colored band. In their absence, no colored band appears. A colored band in the control region confirms sufficient sample volume and proper flow, validating the result.

This assay is optimized for oral fluid matrices, enabling non-invasive sampling without compromising accuracy. Its engineered antigen formulation and membrane design minimize nonspecific binding and cross-reactivity, supporting reliable performance in clinical, outreach, or self-testing environments.

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.

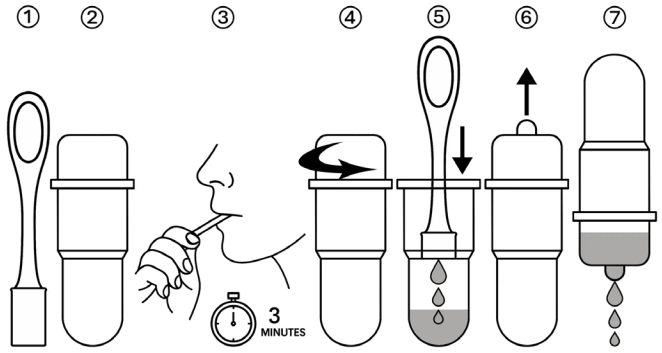
PACKAGE CONTENTS

1. Instruction Manual
2. HIV 1/2 Saliva Test Cassette
3. Absorbent Rod (see illustration ①)
4. Extraction Tube (see illustration ②)

SPECIMEN COLLECTION

1. Do not eat, drink, smoke, or chew gum for at least 10 minutes before collecting the specimen to avoid contamination.
2. Rinse the mouth thoroughly with warm water to clear any residual food, drink, or debris.
3. Carefully open the absorbent rod packaging and hold it only by the plastic handle. Do not touch the absorbent tip, as contact may contaminate the sample and affect test results.
4. Gently place the tip of the absorbent rod under the tongue or between the lower cheek and gum (see illustration ③), ensuring full contact with the oral mucosa. Allow it to remain in place for 3 minutes to passively absorb oral fluid. For optimal collection, you may alternate between these sites during the collection period. Do not chew, bite, or suck on the absorbent tip.
5. Open the extraction tube (see illustration ④).
6. While holding the rod by the handle, insert it into the extraction tube and press the absorbent tip firmly against the bottom of the tube to extract as much fluid as possible. Once done, remove and discard the used rod (see illustration ⑤).
7. Securely close the extraction tube, then lift and open the dropper cap (see illustration ⑥). The specimen is now ready for testing.

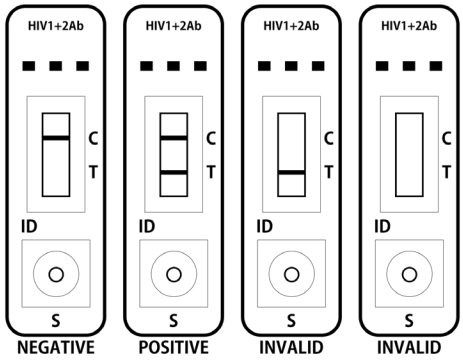
Note: If not tested immediately, store the specimen at 2 to 8°C for up to 72 hours. For longer storage, freeze below -20°C. Thaw and mix thoroughly before use.



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 dropper cap of the extraction tube, dispense 3 drops (150 µL) of the extracted oral fluid into the sample well of the test cassette ensuring no air bubbles are introduced (see illustration ⑦).
3. Start the timer. Results may begin to appear as early as 30 seconds, but final interpretation should be made between 10 and 15 minutes.
4. 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 using saliva specimens and compared with a validated HIV-1/HIV-2 Antibody Differentiation Immunoassay. Among 117 confirmed antibody-positive samples, all were accurately identified by the test, resulting in a sensitivity of 100%. This underscores the test's strong diagnostic capability in detecting HIV antibodies using non-invasive oral fluid specimens. Its ease of use and rapid turnaround make it ideal for both clinical and community-based screening.

B. Specificity

A total of 346 saliva specimens, previously confirmed negative for HIV by 4th generation ELISA, were tested using Seroquick HIV 1/2 Rapid Test Device. Of these, 344 were correctly identified as negative, while two produced false positive results, yielding a specificity of 99.4%. These findings demonstrate the test's strong ability to accurately identify HIV-negative individuals, with minimal false positives. While oral fluids contain lower antibody concentrations than blood, the test still showed reliable performance, making it suitable for large-scale screening, home use, and community outreach programs. Its non-invasive and convenient sample collection, combined with rapid turnaround time, further supports its practicality in settings where traditional blood-based methods may not be feasible or where accessibility, comfort, and ease of use are especially essential for conducting effective screening.

C. Performance Summary

Parameter	Result	Notes
Total Samples	463	117 positive, 346 negative
Sensitivity	100% (117/117)	Verified by differentiation assay
Specificity	99.4% (344/346)	Two false positives vs ELISA
Overall Accuracy	99.6% (461/463)	Correctly identified samples
True Positives	117	All results correctly identified
False Negatives	0	No missed infections
True Negatives	344	Verified by ELISA
False Positives	2	Two incorrect positives
Time to Result	~15 minutes	Typical visual result time

D. Cross-reactivity

A cross-reactivity study was conducted to evaluate the potential interference of commonly encountered chemical and biological substances in oral fluid specimens. Since saliva may contain trace amounts of ingested compounds, endogenous substances, medications, and oral care products, this study assessed a wide range of agents at concentrations exceeding typical physiological or oral exposure levels to simulate worst-case conditions.

Substances tested included analgesics and antipyretics such as acetaminophen and acetylsalicylic acid; antibiotics and antimicrobials like penicillin G and tetracycline; antihistamines and gastrointestinal agents including histamine and ranitidine; common components of the oral cavity such as glucose, albumin, bilirubin, and hemoglobin; food additives and sweeteners such as benzoic acid, citrate, and aspartame; household oral care products including toothpaste, ethanol-based mouthwash, and sodium lauryl sulfate; preservatives and excipients like EDTA and sodium salicylate; and recreational, over-the-counter, or miscellaneous compounds including caffeine, dextromethorphan, and methaqualone.

All substances were spiked into pooled negative oral fluid matrices at exaggerated concentrations. None of the tested agents interfered with the performance of the assay or produced false-positive or false-negative results. These findings confirm the high analytical specificity and robustness of Seroquick HIV 1/2 Rapid Test Device when used in the presence of potentially cross-reactive compounds commonly found in oral environments.

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
Mouthwash	2% ethanol	Toothpaste (slurry)	1:2 dilution	No interference
Sodium Lauryl Sulfate	0.5%	—	—	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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