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HIV 1&2 ORAL SWAB RAPID TEST

For Self-Test & Professional Use

INTENDED USE

The ICare Advanced Anti-HIV (1&2) Rapid Saliva Test is an in vitro, visually read, qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in saliva. It is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

SUMMARY AND BIOLOGICAL PRINCIPLE

The ICare Advanced Anti-HIV (1&2) Rapid Saliva Test is an immunochromatographic test for the antibodies to HIV-1 and HIV-2. The test device is consisting of a Conjugate Pad containing HIV-1 and HIV-2 recombinant antigen-colloidal gold and rabbit IgG antibody-colloidal gold, and a nitrocellulose membrane with an immobilized mixture of recombinant HIV-1 and HIV-2 antigens in the Test Area, and Goat-anti-rabbit IgG antibody in the Control Area.

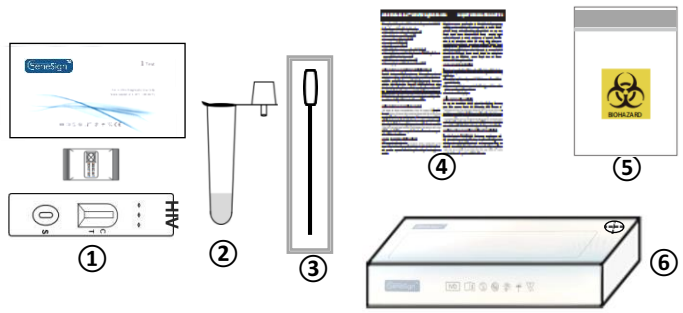
The extracted specimen (Saliva) is applied to the Sample Pad and migrated by capillary action through the Conjugate Pad and then through the nitrocellulose membrane.

If antibodies to HIV-1 and/or HIV-2 are present in the specimen, the antibodies bind to recombinant HIV-1 and/or HIV-2 antigen-colloidal gold conjugates from the Conjugate Pad. The complex migrates through the solid phase by capillary action until it is captured by immobilized HIV-1 and HIV-2 recombinant antigen at the Test Area (labeled "T") and forms a single purplish/red "T" line. If antibodies to HIV-1 and HIV-2 are absent or are below the detection limit of the test, no purplish/red "T" line is formed.

To ensure assay validity, a procedural "Control" line (labeled "C") containing Goat-anti-rabbit IgG antibody is incorporated in the nitrocellulose membrane. A purplish/red "C" line will always be presented regardless of whether antibodies to HIV-1 and/or HIV-2 are present in the specimen or not. It is the standard to determine whether there are enough samples and whether the chromatography process is normal. If the "C" line does not appear, indicating the test result is meaningless, this sample must be re-tested.

COMPONENTS

REF / Components		GS110208C01
		1 Test /Kit
①	Test card (Individually foil pouched with a desiccant)	1
②	Extraction Tube (Pre-filled with Extract Solution)	1
③	Sampling Swab	1
④	Package Insert	1
⑤	Disposable Bag	1
⑥	Tube Stand (on the outer package)	1



MATERIALS REQUIRED, BUT NOT PROVIDED

Clock, watch, or other timing device

WARNING AND PRECAUTION

1. Read the package insert completely before using the product. Follow the instructions carefully. Failure to do so may result in an inaccurate result.

2. This kit is for in vitro diagnostic use only, do not swallow.
3. Avoid getting the extraction solution into the eyes or skins.
4. Keep out of reach children.
5. The test kit is for single use only, do not reuse any components of the test kit.
6. Do not use this test beyond the expiration date printed on the outer package. Always check expiry date prior to testing.
7. Do not touch the reaction area of the test cassette.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. DISPOSAL: All specimens and the used kit contents has the infectious risk. Discard all the test components in the provided disposable bag after use. The process of disposing the test kit must follow the local, state and federal infectious disposal laws/regulations.
10. Do not eat, drink or smoke in the area where handling specimens or test kits.

STORAGE AND STABILITY

1. The new iCare Advanced Anti-HIV (1&2) Rapid Saliva Test should be stored unopened at 2°C-30°C (36°F-86°F). Do not freeze the kit or its components. If stored refrigerated, ensure all test components are at room temperature (15°C-30°C, 50°F-86°F) before use.
2. The test cassette is sensitive to humidity and temperature. Do not open the foil pouch until you are ready to perform a test. Once removed from foil pouch, test cassette should be used within 1 hour.
3. The test kit is stable until the expiration date printed on outer package. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND TESTING PROCEDURE

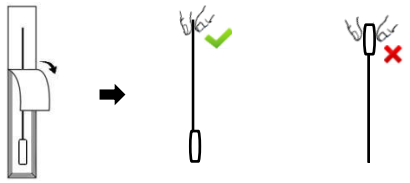
A. PRE-TEST PREPARATION

1. Wash and dry hands before you begin to perform the test.
2. Choose a location to do this test where it can sit undisturbed for 30 minutes at least. Bring the test components to room temperature (15°C-30°C, 50°F-86°F).
3. Take out the kit, check each component and expiration date printed on the kit . Do not use it if the foil pouch is damaged, the test cassette is damp or beyond the expiration date.

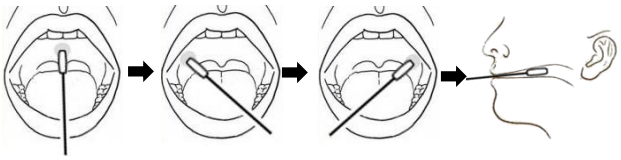
B. SPECIMEN COLLECTION

1. Do NOT eat, drink, smoke, or chew gum and using running water to clean mouth 30 minutes before saliva collection.
2. Take out the Extraction Tube, peel off the sealing film and place the tube in the Tube Stand.

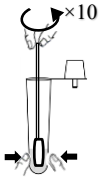
3. Remove the sampling swab from the package, do NOT touch the soft end of the swab, which is the absorbent tip.



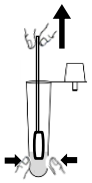
4. Place the absorbent tip of swab into the mouth, slowly wipe the oral upper palate and the inside of the left & right cheeks, and hold it in the mouth for a while until the swab is completely saturated with the saliva (no less than 15 seconds） . Withdraw the swab from the mouth.



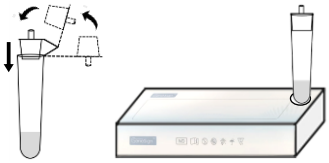
5. Insert the swab specimen into the Extraction Tube and immerse the entire tip of swab into the Extraction Solution. Rotate about 10 times and squeeze the absorbent tip through the lower buffer tube.



6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of swabs according to biohazard waste disposal method.

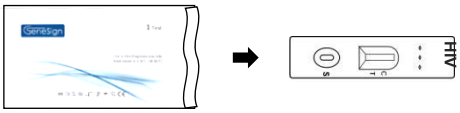


7. Cover the Extraction Tube with the dropper tip tightly, then place the tube in the Tube Stand.

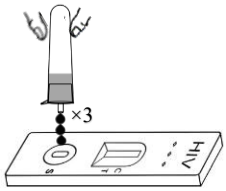


C. TESTING PROCEDURES

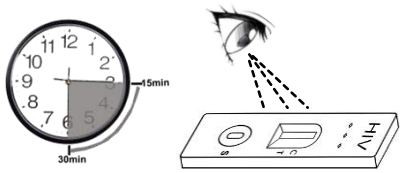
1. Remove the test cassette from the sealed foil pouch. Place the test cassette on a dry and flat surface.



2. Take and hold the extraction tube upright (dropper tip down), add 3 drops (approximately 100µl) slowly to the sample well of the test cassette.

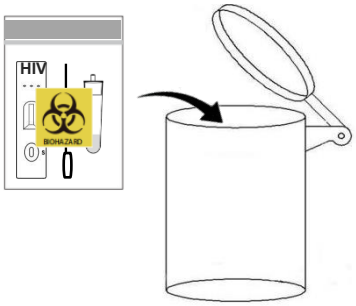


3. Start the timer and wait for colored lines to appear. Interpret the results at 15 minutes. Do NOT read the results after 30 minutes.



D. GENERAL TEST CLEAN-UP

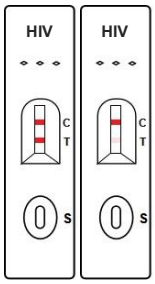
1. When using gloves, change your gloves between each test to prevent contamination.
2. The all used test materials and gloves should be putted into the biohazard waste bag, disposed in a waste container and discarded according to the local biohazard waste disposal policy.



INTERPRETATION OF TEST RESULTS

POSITIVE **(Two Lines - Control Line and Test Line)**

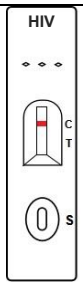
A PURPLISH/RED Control line appears in the Control Area (labeled "C") AND a PURPLISH/RED Test line must appear in the Test Area (labeled "T") of the Test Cassette. The color intensity of the Test and Control lines may be different. Any visible PURPLISH/RED line in both the Control and Test Areas, regardless of intensity, is considered POSITIVE. A POSITIVE test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies.



NEGATIVE

(One Line–Control Line)

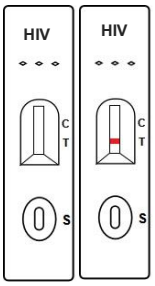
A PURPLISH/RED Control line appears in the Control Area (labeled "C") of the Test Cassette, and no PURPLISH/RED Test line appears in the Test Area (labeled "T"). A NEGATIVE test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen.



INVALID

(No Control Line)

If there is no PURPLISH/RED Control line in the Control Area (labeled "C") of the Test Cassette, even a PURPLISH/RED line appears in the Test Area (labeled "T") of the Test Cassette, the result is INVALID. An Invalid test result means that there was a problem running the test, either related to the specimen or to the Test Device. The test MUST be repeated with a new test cassette. If the problem persists, contact ICare Advanced Technical Support.



LIMITATIONS OF THE TEST

1. The ICare Advanced Anti-HIV (1&2) Rapid Saliva Test is designed to detect HIV-1 and/or HIV-2 antibodies in human Saliva swab specimen only. Any use of other type of specimens, may not yield accurate results.
2. The ICare Advanced Anti-HIV (1&2) Rapid Saliva Test must be used in accordance with the instructions in this package insert to obtain an accurate result.
3. Reading test results earlier than 15 minutes or later than 30 minutes may lead to incorrect results.
4. The incorrect sample collection process will affect the accuracy of the test, such as improper sample collection, improper sample storage, etc.
5. This reagent is a qualitative assay, for screening use only. As it is with any diagnostic procedure, a confirmed HIV infection diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
6. A NEGATIVE result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
7. Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.

PERFORMANCE CHARACTERISTICS

Clinical Performance Study Compared to Reference ELISA Test for Anti-HIV 1&2 Rapid Saliva Test

The performance iCare Advanced Anti-HIV (1&2) Rapid Saliva Test was performed at clinical cooperation unit, and a commercial HIV 1&2 ELISA Test was used as the compared method. A total of 1,857 saliva swab specimens were tested, and the results are presented in the table below:

ICare Advanced Anti-HIV (1&2) Rapid Saliva Test	HIV 1&2 ELISA Test		
	Positive	Negative	Total
Positive	655	0	655
Negative	2	1200	1202
Total	657	1200	1857
Sensitivity(%)= 655÷657×100%=99.70%; 95% CI: 98.90%~99.92%;			

Specificity(%)=1200÷1200×100%=100.00%; 95% CI: 99.68%~100.00%;
Accuracy(%)=(655+1200)÷1857×100%=99.89%; 95% CI:99.61%~99.97%;

※ The 657 positive Oropharyngeal swab specimens were consisting of 560 HIV-1 positive specimens and 97 HIV-2 positive specimens.

Cross Reactivity

Cross-reactivity was evaluated using a HIV-1 and HIV-2 antibodies negative saliva samples added with a high interference level of antibodies of the pathogens, or using the saliva samples spiked with a low HIV-1 and/or HIV-2 antibodies concentration and a high interference level of antibodies of the pathogens to represent the worst-case scenario, and no interference was found with the following antibodies to the pathogens listed below.

Antibodies to the pathogens	No. of sample	HIV 1&2 Antibody (-)	HIV 1&2 Antibody (+)
Anti-Flu A	3	No Interference	No Interference
Anti-Flu B	3	No Interference	No Interference
Anti-HKU1	3	No Interference	No Interference
Anti-OC43	3	No Interference	No Interference
Anti-NL63	3	No Interference	No Interference
Anti-229E	3	No Interference	No Interference
Anti-rhinovirus	3	No Interference	No Interference
Anti-respiratory syncytial virus	3	No Interference	No Interference
Anti-Haemophilus influenzae	3	No Interference	No Interference
Anti-Adenovirus	3	No Interference	No Interference
Anti-Human Metapneumovirus	3	No Interference	No Interference
Anti-Enterovirus	3	No Interference	No Interference
Anti-Rhinovirus	3	No Interference	No Interference
Anti-Streptococcus pneumoniae	3	No Interference	No Interference
Anti-Mycobacterium tuberculosis	3	No Interference	No Interference
Anti-Mycoplasma pneumoniae	3	No Interference	No Interference
Anti-EB Virus	3	No Interference	No Interference
Anti-HCV	3	No Interference	No Interference
Anti-HBV	3	No Interference	No Interference
Anti-TP	3	No Interference	No Interference

No interference was found with the microorganisms presented in the table below when added at the concentration of 10^6 cfu/mL to a HIV-1 and HIV-2 antibodies negative saliva samples or a saliva sample with low HIV-1 and HIV-2 antibodies concentration.

Potential Cross-Reactant		
Adenovirus 71	Enterovirus	Haemophilus influenzae
Parainfluenza virus 1	Rhinovirus	Streptococcus pneumoniae
Parainfluenza virus 2	SARS-coronavirus	Streptococcus pyogenes
Parainfluenza virus 3	MERS-coronavirus	Mycoplasma pneumoniae
Parainfluenza virus 4	Candida albicans	Staphylococcus epidermidis
OC43	Bordetella pertussis	Chlamydia pneumoniae
NL63	Human coronavirus HKU1	Legionella pneumophila
229E	Respiratory syncytial	Staphylococcus aureus
Influenza A	Influenza B	Pooled human nasal wash
Human Metapneumovirus (hMPV)		

Endogenous Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the ICare Advanced Anti-HIV (1&2) Rapid Saliva Test, HIV-1 and HIV-2 antibodies positive and negative samples were tested with different potentially interfering substances.

All samples tested produced expected results, demonstrating that the performance of the ICare Advanced Anti-HIV (1&2) Rapid Saliva Test was not affected by any of the following potentially interfering substances when tested at the concentrations listed in the table below.

Substances	Concentration	HIV 1&2 Antibody (-)	HIV 1&2 Antibody (+)
Whole Blood	0.04	No Interference	No Interference
Mucin	0.005	No Interference	No Interference

Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No Interference	No Interference
Naso GEL (NeilMed)	5% v/v	No Interference	No Interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No Interference	No Interference
Afrin (Oxymetazoline)	15% v/v	No Interference	No Interference
CVS Nasal Spray (Cromolyn)	15% v/v	No Interference	No Interference
Zicam	5% v/v	No Interference	No Interference
Homeopathic (Alkalol)	1:10 dilution	No Interference	No Interference
Sore Throat Phenol Spray	15% v/v	No Interference	No Interference
Tobramycin	4 µg/mL	No Interference	No Interference
Mupirocin	10 mg/mL	No Interference	No Interference
Fluticasone Propionate	5% v/v	No Interference	No Interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No Interference	No Interference

QUESTIONS & ANSWERS

Q1. What are the known or potential benefits of product testing?

- ✓ The test results can help your family doctor or professional make accurate or effective recommendations;
- ✓ Test results may help limit the spread of HIV to your family and others in your community.

Q2. What are the known or potential risks in product testing?

- ✓ Discomfort during the sampling;
- ✓ Incorrect test results (see “Interpreting of the test results” and “Limitations of the test” Sections).

Q3. When should/can I test myself?

- ✓ You can test yourself when your exposure to HIV or have suspected symptoms of HIV.

Q4. What factors will affect the test results? What should I pay attention to?

- ✓ For saliva swab specimen only;
- ✓ The sample must not contain bubbles when dripping;
- ✓ Do not add too much or too little sample;
- ✓ Test immediately after sample collection;
- ✓ Strictly follow the Instructions for Use.

Q5. No red line band on test card or abnormal fluid flow? What is the reason?

It should be clear that the test result is invalid. The reasons are as follows:

- ✓ The table on which the test card is placed is not smooth, affecting the flow of liquid;
- ✓ Sample volume does not meet the requirements specified in the Instructions for Use;
- ✓ The test card is damp.

Q6. I have taken the test, but I don’t see the control line I. What should I do?

- ✓ Your test result is invalid, please repeat the test strictly according to the Instructions for Use.

Q7. Unsure about the test result, what should I do?

- ✓ For uncertain results, it can be retested. If you're still unsure of the test result, please contact the nearest medical institution according to the advice of your local government.

Q8. If result is positive, what should I do?

- ✓ A positive result means that HIV-1 and/or HIV-2 antibodies may have been detected in the specimen. The test result is interpreted as PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies, and you can contact the nearest medical institution for further clinical and laboratory testing to obtain a confirmed diagnosis.

Q9. If result is negative, what should I do?

- ✓ A negative result means that HIV-1 and/or HIV-2 antibodies were not detected in the specimen. But A negative result does not preclude the possibility of infection with HIV, if you have ever been exposed to HIV. An antibody response to recent exposure may take several months to reach detectable levels;
- ✓ Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.

Q10. Is there any chance that I get an incorrect result?

- ✓ The ICare Advanced Anti-HIV (1&2) Rapid Saliva Test is designed to detect HIV-1 and/or HIV-2 antibodies in human saliva swab specimen only. Use of other types of specimens, may not yield accurate results;
- ✓ Inadequate saliva samples or incorrect handling will result in erroneous results;
- ✓ Reading test results earlier than 15 minutes or later than 30 minutes may yield erroneous results.

BIBLIOGRAPHY

1. Pilcher C, Eron JJ, Galvin S, Gay S and Cohen MS (2004) Acute HIV revisited: new opportunities for treatment and prevention. The Journal of Clinical Investigations 113(7): 937-945.
2. Respess RA, Rayfield MA and Dondero TJ (2001) Laboratory testing and rapid HIV assays: applications for HIV surveillance in hard to-reach populations. AIDS 15 Supplement 3: S49-S59.
3. Gallo RC, Salahuddin SZ, Popovic M, et al. Frequent detection and isolation of cytopathic retroviruses (HTLV III) from patients with AIDS and at risk for AIDS. Science 1984; 224:500-3.
4. Clavel F, Guetard D, Brun-Vezinet F, et al. Isolation of a new human retrovirus from West African patients with AIDS. Science 1986; 233:343-6.
5. CDC: Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women. MMWR 2001; 50(19):32-35.

INDEX OF SYMBOLS

	Consult instruction for use	IVD	For *in vitro* diagnostic use only	REF	Catalog number
	Temperature limit	LOT	Lot number		Use by
	Do not reuse		Contains sufficient for <X> tests		Keep dry
	Manufacturer		Date of manufacture		Keep away from sunlight
	Do not use if package is damaged				

Date Issued: 2021.12
GS110208C-EN-A1

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