iCARE HIV 1&2 Home Use Rapid Test Kit

(Oral Swab)

Updated Aug.2018 Cat. No. IT1001F-HIV-ORAL

【QUESTION & ANSWER】

Why and Who Should Test For HIV?

HIV is a virus that causes AIDS (Acquired Immune Deficiency Syndrome). Anyone can be at risk. Most infected people do know their HIV status as they look and feel well. Most common routes of infection are:

- Unprotected sexual contacts with infected person(s).
- Repeated use of needles in connection with drugs.
- Use of unsafe blood products or transfusion with infection blood.
- Transfer of infection from a positive mother to her child.
- Intravenous drug users.
- Health care workers who take blood samples.

What is iCARE HIV 1&2 Home Use Rapid Test Kit (Oral Swab) Used For?

iCARE HIV 1&2 Home Use Rapid Test Kit (Oral Swab) will give the user a private, sensible, quick and accurate rapid test results in 15 minutes to ascertain if the user infected with HIV virus. It is an aid only to identify infected individuals.

*Please note that the Test Kit is an aid only to identify individual at this point of time. Doctors advise that the typical period of time between first contact and a positive test indication is about 90 days.

When Should I Test?

If you have reasons to suspect a possible infection of yourself or your sexual partner(s), it is wise to take a test. We advise you to wait for 3 months before you do another test; although most people will manifest antibody levels between 30 days - a significant percentage do not show these anti-bodies until about 90 days. The National CDC has said that in same rare cases, it may even take up to six months for one to be tested positive. We recommend you do 2 tests 30 days' apart.

What If I Am Tested Positive?

If you are tested positive, please consult your doctor immediately.

【Disclaimer】

When performing the HIV test, the steps involved must be followed closely. If there has been a possible exposure to infected oral fluid, and the person tests negative for HIV, the test be repeated in 90 days. It is imperative that a positive HIV test result be followed by a Western Blot or PCR test performed by a doctor or clinic to confirm if you are indeed HIV positive. Since NO test, nor test kit is infallible, it is best to confirm test results by using a licensed medical testing facility. For one time usage only.

【INTENDED USE】

The iCARE HIV 1&2 Home Use Rapid Test Kit (Oral Swab) 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 oral mucosal transudate swab. It is intended to aid in the diagnosis of infection with HIV-1 and HIV-2.

【SUMMARY AND TEST PRINCIPLE】

iCARE HIV 1&2 Home Use Rapid Test Kit (Oral Swab) 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.

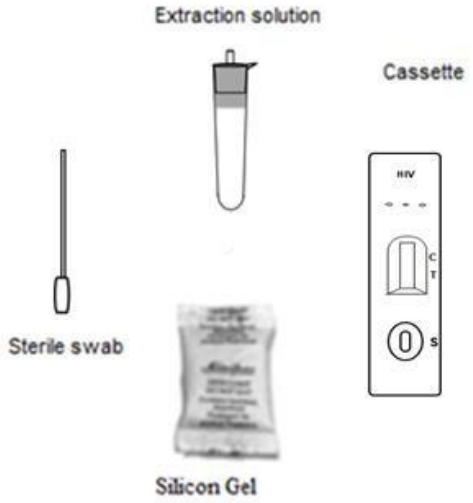
The extracted specimen (oral mucosal transudate) is applied to the Sample Pad and migrated by capillary action through the Conjugate Pad and then through the nitrocellulose membrane.

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.

【MATERIALS PROVIDED】

Contents	1 Test / Kit
Test Card (Individually foil pouched with a desiccant)	1
Extraction Tube (Pre-filled with Extract Solution)	1
Sampling Swab	1
Package Insert	1



【MATERIALS REQUIRED BUT NOT PROVIDED】

Clock, watch, or other timing device.

【WARNINGS AND PRECAUTIONS】

1. For *in vitro* diagnostic use only.
2. Do not reuse the test.
3. Do not freeze the test kit or its components.
4. These instructions must be carefully read and strictly followed. All users have to read the instructions before performing test.
5. Fresh samples are recommended for use to ensure optimal performance. Freshly collected specimens should be tested immediately.
6. Inadequate or inappropriate specimen collection, storage, and transportation are likely to result in false negative test results.
7. Do not eat, drink or smoke in the area where handling specimens or performing the test.
8. Do not use the test kit beyond its expiration date.
9. Do not mix components from different kit lots.
10. Leave test card sealed in its foil pouch until just before use. Do not use the test card if the pouch is damaged or the seal is broken.
11. To avoid contamination or inaccurate test result, do not touch the absorbent tip of swab or reaction area of test card when performing the test.
12. Dispose of all used test devices and potentially contaminated materials in a biohazard container as if they were infectious waste and dispose according to applicable local laws and regulations.

【STORAGE AND STABILITY】

1. The test kit should be stored at a temperature between 2-30°C, away from direct sunlight. Do not freeze the kit or its components.
2. The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
3. This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30°C) before use.
4. Perform the test immediately after taking out the test card from the foil pouch.

【SAMPLE COLLECTION AND STORAGE】

1. Specimen Collection

To achieve accurate test result, good sample collection is the most important first step. Therefore, carefully follow the instructions below to collect swab specimens.

(Fig. 1): Have the patient open the mouth to expose the upper and lower gums. Take the swab and rub it back and forth along the upper gums four times;
(Fig. 2): Then turn the swab to the opposite side;
(Fig. 3): Using the opposite side of the swab, rub back and forth along the lower gums four times (Fig. 3).

(Fig. 1) (Fig. 2) (Fig. 3)

2. Specimen Storage

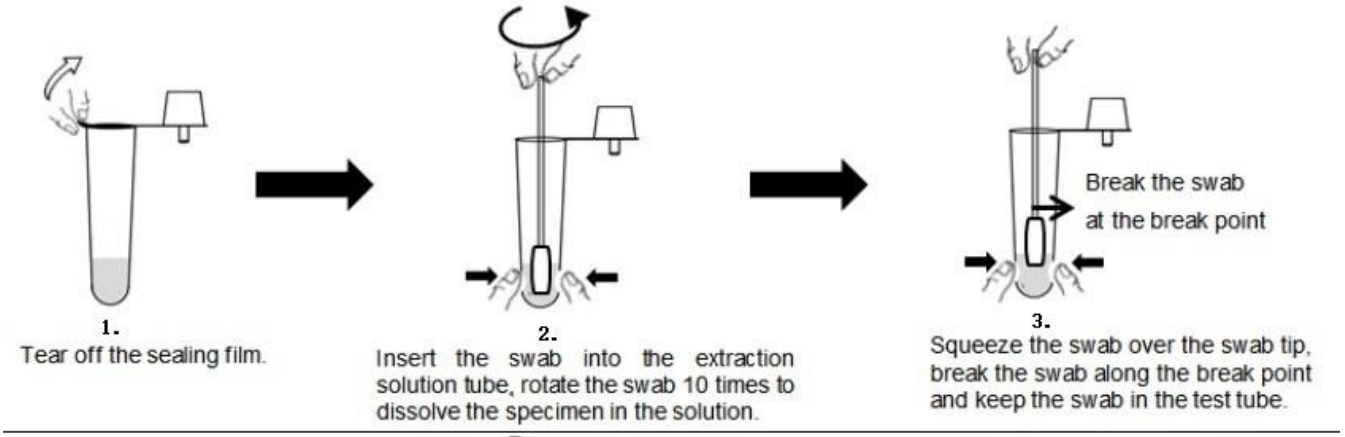
If the specimen cannot be tested immediately after collection, properly store the specimen in a Viral Transport Media (VTM) or Universal Transport Media (UTM) contained in a lidded storage container. The specimens contained in VTM or UTM can be stored for up to 72 hours when refrigerated (2~8°C) or frozen (-20°C).

【TEST PREPARATION】

Before testing, open the package and equilibrate the test card, extraction solution and specimens to room temperature, and shake the extraction solution gently before use. The most suitable temperature condition to perform the test is room temperature (15~30℃). If the test kit is stored at room temperature, it can be opened and used immediately.

【TEST PROCEDURES】

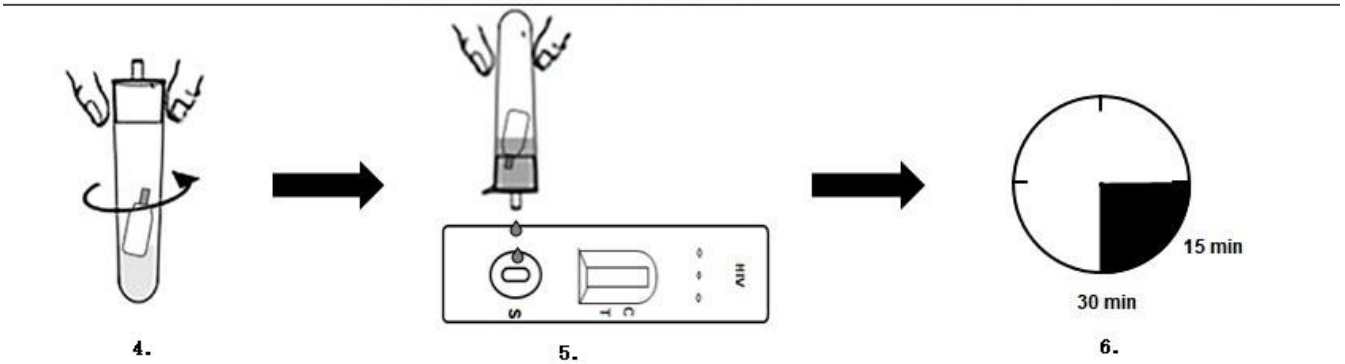
1. Tear off the sealing film of the extraction solution tube.
2. Insert the swab after sampling into the extraction solution tube and immerse the entire tip of swab into the Extraction Solution, rotate the swab against the inner wall of the tube approximately 10 times to dissolve the specimen in the solution as much as possible.
3. Squeeze the swab over the swab tip, break the swab along the break point and keep the swab in the test tube, Dispose of the end of the swab according to biohazard waste disposal method and local regulations.
4. Put on the cap of the tube. Shake well the tube.
5. Take out the test card from sealed foil pouch and place on a dry, clean and level surface. Add 2 drops of extracted specimen to the specimen well on the test card, and start the timer.
6. Read the results at 15 minutes, and the result after 30 minutes is no longer valid.



1. Tear off the sealing film.

2. Insert the swab into the extraction solution tube, rotate the swab 10 times to dissolve the specimen in the solution.

3. Squeeze the swab over the swab tip, break the swab along the break point and keep the swab in the test tube.



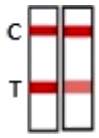
4. Put on the cap of the tube. Shake well the tube.

5. Add 2 drops of extracted specimen to the specimen well(S) on the test card, and start the timer.

6. Read the results at 15 minutes, and the result after 30 minutes is no longer valid.

【INTERPRETATION OF TEST RESULTS】

(Please refer to the illustrations below)

 **Positive**	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**	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**	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.

【INDEX OF SYMBOLS】

	Consult instruction for use		For *in vitro* diagnostic use only		Catalog number		Temperature limit
	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						

www.jalmedical.com