HIV 1/2 Oral Rapid Screen Test

A lateral flow, one step immunoassay for the rapid qualitative determination of HIV-1/2 antibodies in human oral swab. For *in vitro* diagnostic use.

INTENDED USE

The iCARE HIV 1/2 Oral Rapid Screen Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus type 1 and 2 (HIV-1/2) in human oral swab.

PRINCIPLE

It has been shown that the acquired immunodeficiency syndrome (AIDS) is caused by viruses transmitted via sexual contact, transfusion, or using contaminated blood products such as sharing contaminated needles. HIV-1 and 2 viruses have been isolated from patients with AIDS and AIDS-related complex (ARC), and high risk persons for AIDS. HIV-1/2 viruses deplete T helper cells, a subpopulation of T cells for body defense, thus causing AIDS patients to be susceptible to opportunistic infections and developing malignant tumours.

The iCARE HIV 1/2 Oral Rapid Screen Test is a chromatographic immunoassay for the detection of antibodies to HIV-1/2 in human oral swab. HIV-1/2 antibodies binding protein are precoated onto a membrane as capture reagents in the Test region (T). During the testing, the oral swab specimen is allowed to react with the colloidal gold reagents which have been labelled with HIV-1/2 specific antigens. If antibodies to HIV-1/2 are present, a pink coloured band will develop on the membrane in proportion to the amount of HIV-1/2 antibodies present in the specimen. Absence of this pink coloured band in the Test region (T) suggests a negative result. To serve as a procedural control, a pink coloured band in the Control region (C) will always appear regardless of the presence or absence of antibodies to HIV-1/2 in the specimen.

MATERIALS PROVIDED

Each HIV 1/2 Oral Rapid Screen Test package contains:

1. 1 Foil pouch containing a test device (assay test cassette) and a desiccant.
2. 1 Mixing chamber (with lid) containing 1 ml of diluent solution
3. 1 Oral swab collector (single pouch)
4. 1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or clock

STORAGE AND STABILITY

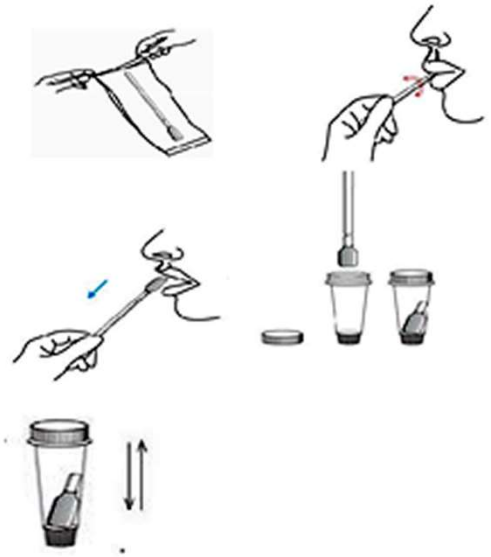
The test device is to be stored refrigerated or at room temperature (2-30°C) under dry conditions for the duration of its shelf life. **DO NOT FREEZE.** The test device is stable through the expiration date printed on the sealed pouch. The test device must be kept sealed in the pouch until use.

PRECAUTION

1. For *in vitro* diagnostic use only.
2. Do not use a test device beyond the expiration date imprinted on the back of the foil pouch.
3. Nothing should be placed into the mouth of the subject for at least 10 minutes prior to oral swab collection. This includes food, drink, tobacco products or any other materials.
4. Avoid cross contamination of oral swab samples by using a new oral swab collector and mixing chamber for each sample.
5. Oral swab specimens may be potentially infectious. Properly handle and dispose of all used test devices.
6. High humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND STORAGE

1. Remove the oral swab collector from the sealed pouch.
2. Insert the sponge end of the collector into the mouth. Then place the sponge in the upper gum line position, and gently swipe the sponge along the upper gums from one end of mouth to the other end, and back and forth. Then swipe the sponge in the same way for the lower gums. (NOTE: Both sides of the sponge need to be swabbed along upper gums and lower gums for 5-6 times)

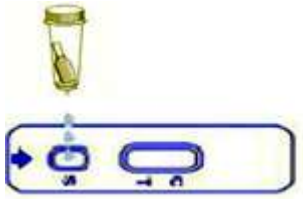


3. Remove the collector out of the mouth and open the lid of the mixing chamber. Place the saturated collector into the chamber which contains 1 ml of diluent solution, and then stir the collector fully along the wall of the chamber. Break off the collector, leaving the sponge end of the collector in the chamber.
4. Close and turn the lid of the chamber tightly and shake and mix the liquid in the chamber (shake up and down about 20 times).

ASSAY PROCEDURE

Do not open foil pouch until you are ready to begin testing. Refrigerated test devices should be allowed to come to room temperature (15-28°C) before opening.

1. Remove the test device from the protective pouch. The product is sensitive to moisture in air. After opening the package, the test device should be used immediately.
2. To perform the test, twist open the screw cap of the dropper tip assembly of the mixing chamber to expose the dropper tip. Transfer 3-4 drops (100 µl) of mixed sample solution from the mixing chamber, slowly and vertically into the sample well of the test device. Replace the cap cover on the collection chamber.



3. Start the timer.
4. Read the result after exactly 10 minutes.

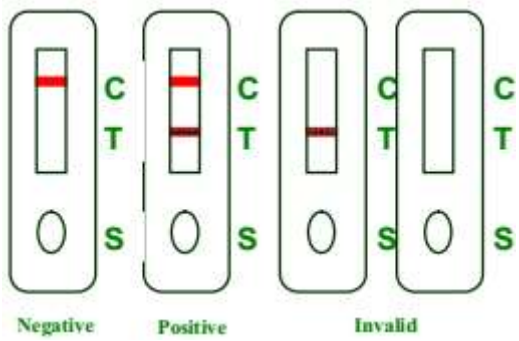
IMPORTANT: In order to prevent an incorrect reading, do not read the test results after 15 minutes. If the test is read after 15 minutes, the intensity of the coloured bands may change or a new band may appear in Test region (T). To avoid confusion, discard all test devices after interpreting results.

INTERPRETATION OF RESULTS

POSITIVE: Presence of two visible, pink-coloured bands, one in the Control region (C) and another in the Test region (T), indicating the presence of HIV-1/2 antibodies in the sample.

NEGATIVE: Presence of a single coloured band in the Control region (C), indicating the absence of HIV-1/2 antibodies or the concentration of antibodies in the sample is below the detection cut-off level.

INVALID: Results are invalid if no band appears in the Control region, or a band appears only in the Test region after 10 minutes. An invalid result may be due to improper assay procedure or damage to the device. The assay is inconclusive and the specimen should be re-tested using a new test device.



LIMITATIONS

- The test procedure and the interpretation of results must be followed closely. A test result read after 15-20 minutes may not be consistent with the original reading obtained at the 10 minute mark.
- This assay is designed for testing antibodies against HIV-1/2 in human oral swab. Any results derived from the test of other body fluids may not be interpreted correctly based on the current criteria. Other body fluids and pooled samples are not recommended in this assay.
- For positive specimens, it is recommended that more specific supplemental tests should be conducted and clinical evaluation on the patient's situation should be performed before a final conclusion is made. HIV-1/2 rapid testing alone cannot be used to diagnose AIDS, even if the antibodies against HIV-1/2 are present in the patient's oral swab. The test result will only indicate the qualitative level of antibodies of HIV 1/2 in the specimen and should not be used as the sole criteria for the diagnosis of HIV. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
- A negative result does not rule out infection by HIV, because the antibodies to HIV may be absent or may not be present in sufficient quantities to be detected at a very early stage of infection, or could result from improper sample collection.