One Step HIV 1/2 Oral Fluid Test
Catalog No. W76-C

INTENDED USE
One Step HIV 1/2 Oral Fluid Test is a one step rapid test for the qualitative detection of HIV 1/2 antibodies in human oral fluid at specified cut-off level.

For in vitro diagnostic use only. For professional use only.

SUMMARY
HIV (human immunodeficiency virus) is the pathogen of AIDS (acquired immunodeficiency syndrome). HIV belongs to family Retroviridae genus Lentivirus, and there are two groups, HIV-1 and HIV-2. HIV-1 is highly mutagenous, and can be divided into 9 subtypes by the mutations in its membrane protein, which are A, B, C, D, E, F, G, H and O. HIV-2 has 60% nucleotide acid homology with HIV-1, but they are different in their ability of infection. HIV-1 is the most prevailing virus strain. Once infected, it mutates quickly and has bad prognosis. HIV-2 has a longer latent period and relative weaker in its pathogenesis.

PRINCIPLE
One Step HIV 1/2 Oral Fluid Test is a rapid immunochromatographic test for the visual detection of HIV antibodies in oral fluid samples in the diagnosis of HIV infection.

There are two coated lines in the result window. One is the test line (T), coated with HIV-1 gp41 and HIV-2 gp36 recombinant antigens, the other is control line (C), coated with goat anti-rabbit IgG. When add specimen to the sample well, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the pre-coated membrane.

When the HIV antibody levels are at or above the detection limit of the test, HIV antibodies in the specimen bind to the antibody-dye conjugate and are captured by antigen immobilized in the test region (T) of the device. This produces a colored test band and indicates a positive result.

When the HIV antibody levels are zero or below the detection limit of the test, there is not a visible colored band in the test region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

PRECAUTIONS
1. This kit is for in vitro use only. Do not swallow.
2. Do not drink, eat, or smoke in areas where specimens are being handled.
3. Remove dentures before collecting the specimen.
4. All specimens should be treated as potential infectious diseases. Protection glove should be worn when handling the specimen. If gloves come in contact with specimen, change gloves to avoid cross-contamination. Take care of the wastes discarded, such as the test device and buffer solution.
5. Icteric, lipemic, hemolysed, heat treated and contaminated blood may cause erroneous results.
6. Do not use test kit beyond the expiration date.
7. Do not use test kit if the pouch is punctured or not well sealed.
8. Keep out of the reach of children.
9. DISPOSAL OF THE DIAGNOSTIC: The used-device has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

CONTENT OF THE KIT
1. 20 Tests per kit. One test in one pouch.
2. One pouch contains a test cassette, a dropper and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
3. 20 oral fluid samplers, 20 droppers and 20 extraction tubes.
4. Two dropping bottles of extraction buffer (each 15ml): 0.02M phosphate buffer solution (PBS) + 0.05% Tween-20 + 1% BSA (pH 7.4 ± 0.2).
5. Leaflet with instructions for use.

STORAGE AND STABILITY
1. Store at 4ºC - 30ºC in the sealed pouch up to the expiration date.
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION
Read the package insert completely before using the product. Follow the instructions carefully. Failure to follow instructions may result in inaccurate test results.

Reagents Preparation
1. Invert the dropping bottle containing extraction buffer for 3 times, to mix the solution well.
2. Remove the cap of bottle (Fig.1), transfer 1ml of extraction buffer from the dropping bottle to the extraction tube (Fig.2). Insert the dropper back to the bottle immediately, and screw the cap tightly.
3. Before collecting specimen, please gargle gently with warm boiled water.
4. Remove an oral fluid sampler from the sealed package by tearing at the notch (Note: Before collection, hold the handle side of the sampler. Do not touch the sampling side.).
5. Wipe gently along the upper and lower gums from one
corner of the mouth slowly to the other corner (Fig.3),
then wipe from the upper gum line to the beginning
corner (Fig.4). Wipe about 5~6 seconds.
4. Turn over the oral fluid sampler (Fig.5).
5. Wipe the lower gum line from one corner of the mouth,
and end to the other corner by the opposite side of the
sampler (Fig.6), then wipe from the lower gum line to the
beginning corner (Fig.7). Wipe about 5~6 seconds.

INTERPRETATION OF RESULTS

Positive (+)
Color bands are visible in both the control region and the test
region. A positive result indicates presence of HIV1/2 is equal
to or higher than the detection limit of the test.

Negative (-)
A color band is visible in the control region. No color band
appears in the test region. It indicates that the concentration of
the HIV1/2 antibodies is zero or below the detection limit of the
test.

Invalid
No visible band at all, or there is a visible band only in the test
region but not in the control region. Repeat with a new test kit.
If test still fails, please contact the distributor, where you
bought the product, with the same lot number.

Note: There is no meaning attributed to line color intensity or
width.

SPECIMEN PREPARATION

1. Insert the oral fluid sampler into the extraction tube
contains 1 ml extraction buffer (Fig.8).
2. Clench the handle of oral fluid sampler and immerse the
sampling side into the buffer. Scratch up and down 6~8
times by against the inside of extraction tube (Fig.9).
Remove the sampler from the extraction tube (Fig.10).

TEST PROCEDURE

Allow the device and specimen to equilibrate to room
temperature (10°C ~30°C) prior to testing.
1. Remove a testing device from the foil pouch by tearing at
the notch and place it on a level surface.
2. Holding a sample dropper vertically, add four drops (80ul)
of the prepared specimen to the sample well (Fig 11 and
Fig 12).
3. Wait for 15 minutes and read the results. Do not read
after 30 minutes.

QUALITY CONTROL

Though there is an internal procedural control line in the test
device of control region, the use of external controls is
strongly recommended as good laboratory testing practice to
confirm the test procedure and to verify proper test
performance.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing oral fluid
samples only. The performance of this test using other
specimens has not been substantiated.
2. The test must be used in accordance with these
instructions to obtain an accurate result.
3. Oral fluid specimens for the test must be collected as
detailed in the procedure.
4. This test is a qualitative screening assay. It is not
designed to determine the quantitative concentration of
HIV.
5. The intensity of the test line in a reactive result does not
necessarily correlate with the amount of anti-HIV
antibody in the specimen.
6. If a red background makes it difficult to read the test at
15 minutes, wait until the background clears to read the
result (but not more than 30 minutes after starting the
test)
7. A negative result does not rule out infection by HIV for
the antibodies to HIV may be absent or may not be
present in sufficient quantity to be detected at early
stage of infection.
8. A positive result should be made by a physician after
evaluating all clinical and laboratory findings.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and specificity
Totally 1183 samples, including 514 samples which are HIV
antibody positive; 669 samples which are HIV negative
(including 85 HBV positive samples, 33 HCV positive smaples,
20 syphilis positive samples and 10 Rheumatoid samples).
Test these samples by Aware™ HIV-1/2 OMT Test (colloidal
gold method) and One Step HIV 1/2 Oral Fluid Test and
compare the results between. The results are as follows:
In a comparison of the One Step HIV 1/2 Oral Fluid Test versus Aware™ HIV-1/2 OMT Test, results gives a sensitivity of 99.61% (505/507) and a specificity of 100.00% (676/676) for One Step HIV 1/2 Oral Fluid Test.

**B. Precision**

1. Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of HIV antibody. The negative and positive values were correctly identified 100% of the time.

2. Between run precision was determined by using 3 different batches of test devices testing the four different specimens containing different concentrations of HIV antibody. The negative and positive results were correctly identified 100% of the time.

**BIBLIOGRAPHY**


**INDEX OF SYMBOLS**

- Keep away from sunlight
- Store between 4°C and 30°C
- Keep dry
- Do not re-use