

HIV-S35

HIV Antibody Oral Rapid Test Kit (Oral Fluid)

INTENDED USE

The HIV Antibody Oral Rapid Test Kit (Oral Fluid) is a rapid visual immunoassay for the qualitative, presumptive detection of antibodies to HIV-1 and HIV-2 in human oral fluid. This kit is intended for use as an aid in the diagnosis of HIV infection. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs.

HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with high potential risk for developing AIDS. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and HIV-2 elicit immune response. Detection of HIV antibodies in oral fluid is the most efficient and common way to determine whether an individual has been exposed to HIV.

PRINCIPLE

The HIV Antibody Oral Rapid Test Kit detects antibodies to HIV-1 and HIV-2 through visual interpretation of color development on the internal test strip. Recombinant HIV antigens are immobilized on the test region of the membrane, while mouse anti-human IgG antibodies conjugated to colored particles are immobilized on the conjugated pad.

During testing, sufficient oral fluid sample will be collected. And the sample collector is supposed to be inserted into the buffer tube by the user after sample collection, and the sample will migrate along the internal test strip by capillary action. If sufficient antibodies to HIV-1 and/or HIV-2 are present in the sample, these antibodies will bind the mouse anti-human IgG antibodies conjugated to colored particles. Consequently, the antibody-antibody complex will be captured by the recombinant HIV antigens immobilized at the test region.

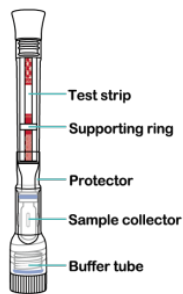
The presence of a colored band in the test region indicates a positive result, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- Individually packed test devices
- Package insert

Fig.1



Materials Required but Not Provided

- Clock, timer or stopwatch

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- DO NOT eat, drink, brush teeth, or chew gum 30 minutes before collecting oral fluid.
- To avoid choking, caution is advised when inserting the collector in the mouth. Do not use this test on anyone under 2 years of age.
- DO not bite the test kit when sampling. Do not swallow.
- DO not bite the device, buffer, or any other kit component.
- Only use the test kit one (1) time. Do not reuse the test.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Failure to bring test kits to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid eye, skin and mucous membrane contact with the buffer. In the event of contact with buffer, rinse with plenty of water.
- Do not eat, drink or smoke in the area where the specimen and kits are handled. Handle all specimens as if they contain infectious reagents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen are assayed.
- Use a separate test for each person.
- This test is for human use only.
- Do not use any expired test or component.
- The test kit is packaged in foil sachets to eliminate moisture during storage. Inspect each foil sachet before opening. Do not use a test kit if there are any holes in the foil or the sachet is not completely sealed. A false result may be produced if the test kit or any component has been incorrectly stored.
- Do not use the kit when any component including test device, protector, buffer and package insert is missing.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the collector into the buffer immediately after collecting the sample.
- Inaccurate or incorrect sampling can produce wrong test results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- Store the HIV Antibody Oral Rapid Test Kit at 2~30°C when not in use.
- DO NOT EXPOSE TO DIRECT SUNLIGHT. DO NOT FREEZE.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.
- The test must remain in the sealed pouch until use. It is recommended to use this product as soon as possible after opening the sealed pouch.

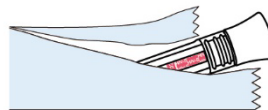
TEST PROCEDURE

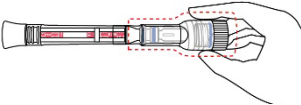
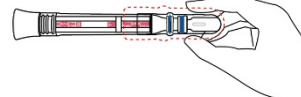
1. Before testing

NOTE: DO NOT eat, drink, smoke, brush teeth, or chew gum 30 minutes before collecting oral fluid. Please gargle with warm water before oral fluid collection.

- 1) Allow the test kit to reach room temperature (15-30°C) prior to testing.
- 2) Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it within 1 hour.

Fig.2

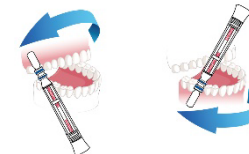


3) Take the test device out of the tube with buffer.	Fig.3 
4) Remove the protector.	Fig.4 

2. Specimen collection

Gently swipe the pad along your upper gums **once** and your lower gums **once** of the sample collector. You may use either side of the flat pad.
(Note: Make sure you **swipe each gum only once** or your results could be wrong)

Fig.5



3. Testing

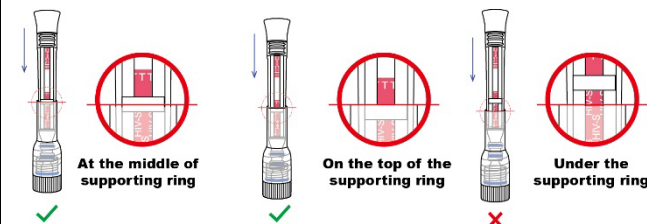
Place the test device **vertically** into the buffer tube until the top edge of the buffer tube **reach the middle of the supporting ring**

Fig.6



WARNING: When placing the test device vertically into the buffer tube, the edge of the buffer tube must reach the middle of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

Fig.7



Read the results at 15 minutes. Do not read the results after 30 minutes. When the test is finished. Please disposal all the components as biological waste.

Fig.8



15 minutes

RESULT INTERPRETATION



POSITIVE: One colored band appears in the control region (C), and one colored band in the test region (T).



NEGATIVE: Only one colored band appears in the control region (C), and no band appears in the test region (T).



INVALID: No colored band appears in the control region (C), whether a test band is present or not. Repeat invalid tests with a new sample, new test device and reagent. Insufficient sample volume, inaccurate operating procedure or expired tests may yield an invalid result. Contact your local distributor if the problem continues.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- The HIV Antibody Oral Rapid Test Kit (Oral Fluid) is for in vitro diagnostic use, and should be only used for the qualitative detection of antibodies to HIV-1 and HIV-2.
- The HIV Antibody Oral Rapid Test Kit (Oral Fluid) will only indicate the presence of HIV-1 and/or HIV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV viral infection.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of HIV-1 and/or HIV-2 antibodies in oral fluid, as antibodies may be present below the minimum detection level of the test.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

The performances of the HIV Antibody Oral Rapid Test Kit have been established in comparison with EIA test. The testing results were shown in the table below:

Table: HIV Antibody Oral Rapid Test Kit vs. EIA

		EIA		Total
		+	-	
HIV Antibody Oral Rapid Test Kit	+	103	1	104
	-	9	464	473
Total		112	465	577

Relative Sensitivity: 92.0% (85.4% ~ 95.7%)*

Relative Specificity: 99.8% (98.8% ~ 100.0%)*

Overall Agreement: 98.3% (96.8% ~ 99.1%)*

*95% Confidence Interval

LITERATURE REFERENCES

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- Janssen RS, Satten GA, Stramer SL, Rawal BD, O'Brien TR, Weiblen BJ, Hecht FM, Jack N, Cleghorn FR, Kahn JO, Chesney MA, Busch MP. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. *JAMA*. 1998 Jul 1; 280(1): 42-8.
- Travers K, Mboup S, Marlink R, Guèye-Nidaye A, Siby T, Thior I, Traore I, Dieng-Sarr A, Sankalé JL, Mullins C, et al. Natural protection against HIV-1 infection provided by HIV-2. *Science*. 1995 Jun 16; 268(5217): 1612-5.
- Greenberg AE, Wiktor SZ, DeCock KM, Smith P, Jaffe HW, Dondero TJ Jr. HIV-2 and natural protection against HIV-1 infection. *Science*. 1996 Jun 28; 272(5270): 1959-60.

GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse		



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