

HIV 1+2 Saliva Rapid Test (Colloidal Gold)

(Cat. No.: HG-10005)

This test is for *In Vitro* Diagnostic test only.

PRINCIPLE OF THE TEST

This test is for qualitative detection of HIV 1/2 antibody in saliva specimen. The kit components include single-use test strips, sample dilution buffer and sample collection swabs. The assay utilizes the principle of lateral flow immunoassay with a proprietary formulation.

The HIV-1/2 is a qualitative immunochromatographic assay for the detection of HIV-1/2 in human oral mucosal transudate specimens. The Test Zone is pre-coated with HIV-1 and HIV-2 recombinant protein, and the control zone is pre-coated with *goat-anti-human IgG* fragment antibody.

For the testing, wipe the collection swab for oral fluid specimen across the upper and lower gums of the patient, place the swab into the oral fluid sample buffer in a test tube. Press out the liquid in the swab and discard it.

Place a test strip vertically into the test tube with the diluted sample and buffer. The liquid mixture would move upwards along the strip. Then the colloidal conjugate is solved by the liquid mixture and reacts with IgG in the sample to form a IgG-conjugate complex. The IgG-conjugate complex moves upwards along the test strip.

If there is HIV antibody in the saliva sample, the IgG-conjugate complex will react with recombinant HIV protein in the test zone and a reddish line is formed. For a valid test, it would be interpreted as positive result. The reddish density is not necessarily proportional to the amount of antibody in the specimen.

If there is no HIV antibody in the saliva sample, the reddish line will be absent of the test zone.

Not matter whether there is HIV 1/2 antibody in saliva sample, it is supposed there is a purple line in the control Zone for a valid test.

Please interpret the test result within 20 minutes after the operation. Test result is invalid after 45 minutes.

Note: As the density of HIV antibody in saliva is much lower than HIV antibody in serum. This test with saliva is for reference only.

COMPONENTS

1. Oral Fluid Sample Collection Swabs	20 Pieces
2. Foil Pouch	20 Pouches
3. Sample Dilution buffer	20 ML
4. Test tubes	20 per kit
5. Package Insert	1 sheet

MATERIALS USED BUT NOT PROVIDED

1. 20-45 minute timer
2. Disposable gloves

SAMPLE

For detection of HIV antibody in saliva only.

PRECAUTIONS AND NOTES

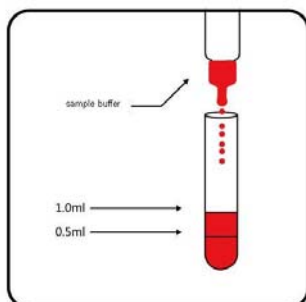
Note: This test is for *In Vitro* Diagnostic test only.

Before operation, please read the instruction sheet carefully and perform all the procedure carefully according to the instruction sheet in case of inaccurate result.

1. This test is for scientific research only, and the test result should be interpreted combined with other test method.
2. When deal with the body fluid, used strips or the test tube with sample, please take the full protection method to prevent any transmission.
3. Smoking, drinking or eating is totally forbidden in the test lab.
4. When hold the used strips and test tubes, please wear the lab protection suit and protective gloves and wash hands thoroughly after testing after each testing. The disposable gloves should be discarded in the dustbin.
5. After testing, put all the samples and material used in the testing into dustbin. The discarded liquid should be dealt with chemical sanitizer. It is suggested that 10% bleach or 0.5% Javel water is applied for at least 60 minutes for sanitization.
6. The strip is used only once. For new testing, please use a new strip according to the instruction steps.
7. Use only strips within expired date. Strips out of the expired date are not valid.
8. Interpret the test result with good lighting. If there are two lines, even very pink lines, it is deemed as positive result. (Detailed information please read the interpretation of result)
9. If collect the samples soon after the first sample collection of oral fluid, the sensitivity of second oral fluid might become lower for about 30 minutes. To get accurate result, please don't collect the oral fluid twice within 30 minutes.
10. Please collect the oral fluid 10 minutes after drinking or eating.
11. This testing should be operated in room temperature of 15~30°C.

PREPARATION OF REAGENTS

1. Pipette 1 ml the sample buffer of the dropper bottle into a test tube. Note: there are two calibration lines in the bottom of the test tube, and the upper line means 1 ml.;
2. Put the test tube into a test tube holder;



1 Pipette 1 ml the sample buffer of the dropper bottle into a test tube

Figure 1

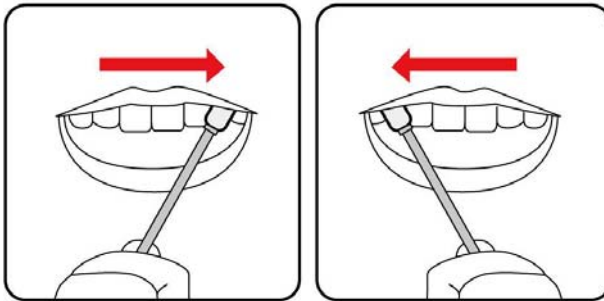
SPECIMEN COLLECTION

1. Remove one of the clean swabs provided from the bag. Grasp the swab by the handle. Avoid touching the cloth end of the swab.



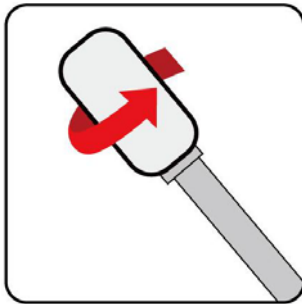
2 Remove one of the clean swabs provided from the bag.

2. Apply moderate pressure while gently swabbing the upper gum line back and forth with the cloth end of the swab. Begin at one corner of the mouth, swabbing gently and slowly until reaching the other corner of the mouth, and then swab back across the upper gum line to where you started (about 5-6 seconds).



3 Apply moderate pressure while gently swabbing the upper gum line back and forth with the cloth end of the swab. Begin at one corner of the mouth, swabbing gently and slowly until reaching the other corner of the mouth, and then swab back across the upper gum line to where you started (about 5-6 seconds).

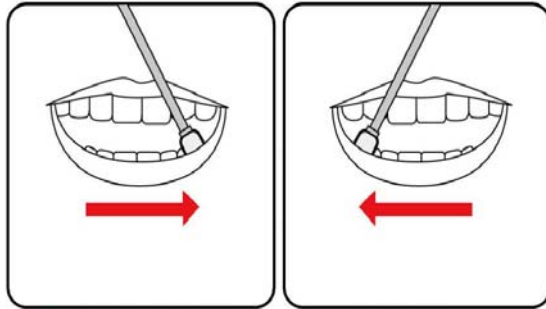
3. Turn the swab around (Figure 4).



4 Turn the swab around

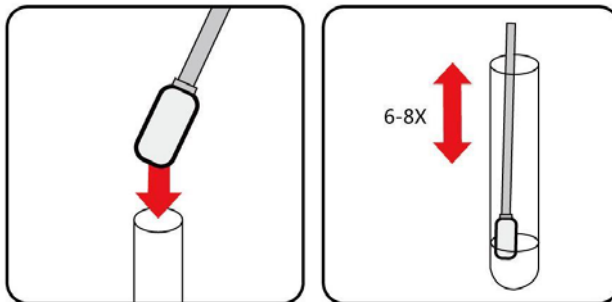
Figure 4

- Use the other side of the cloth for swabbing the lower gum line back and forth. Begin at one corner of the mouth, end at the other corner of the mouth and then swab back across the upper gum line to where you started (about 5-6 seconds).



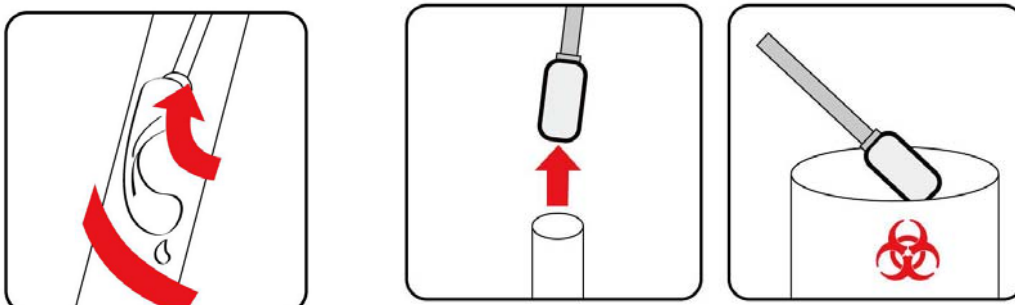
5 Use the other side of the cloth for swabbing the lower gum line back and forth. Begin at one corner of the mouth, end at the other corner of the mouth and then swab back across the upper gum line to where you started (about 5-6 seconds).

- Immediately place the swab in the tube containing the Sample Buffer. Grasp the swab handle firmly. Plunge the swab into the Sample Buffer test tube and move up and down for 6-8 times while rubbing both sides of the swab against the sides of the tube next to the test tube wall.



6 Immediately place the swab in the tube containing the Sample Buffer. Grasp the swab handle firmly. Plunge the swab into the Sample Buffer test tube and move up and down for 6-8 times while rubbing both sides of the swab against the sides of the tube next to the test tube wall.

- Grasp the swab handle firmly. Plunge the swab into the Sample Buffer test tube and move up and down for 6-8 times while rubbing both sides of the swab against the sides of the tube next to the test tube wall. Remove the swab from the tube (Figure 11) and discard the swab. The sample is now ready for testing.

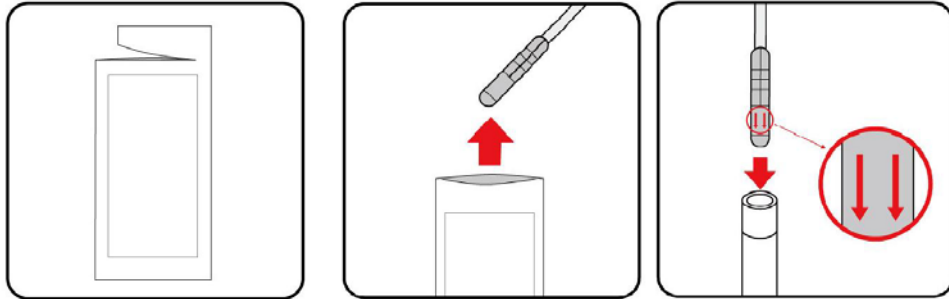


7 Discard the swab into dustbin

Note: The specimen should be tested within 60 minutes after collection at room temperature. For specimen stored at 2~8°C, it should be tested within 12 hours after collection.

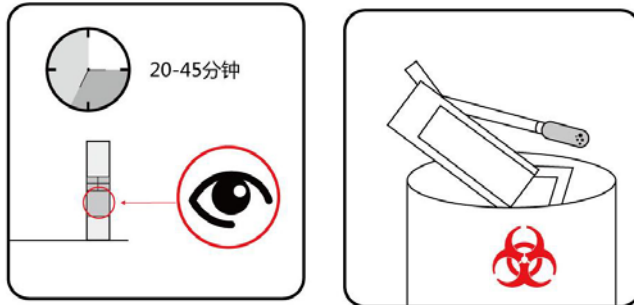
8. Testing

1. Take out the test strip from the pouch. Put the strip into the test tube with diluted specimen in the arrow direction. (See the following graph)



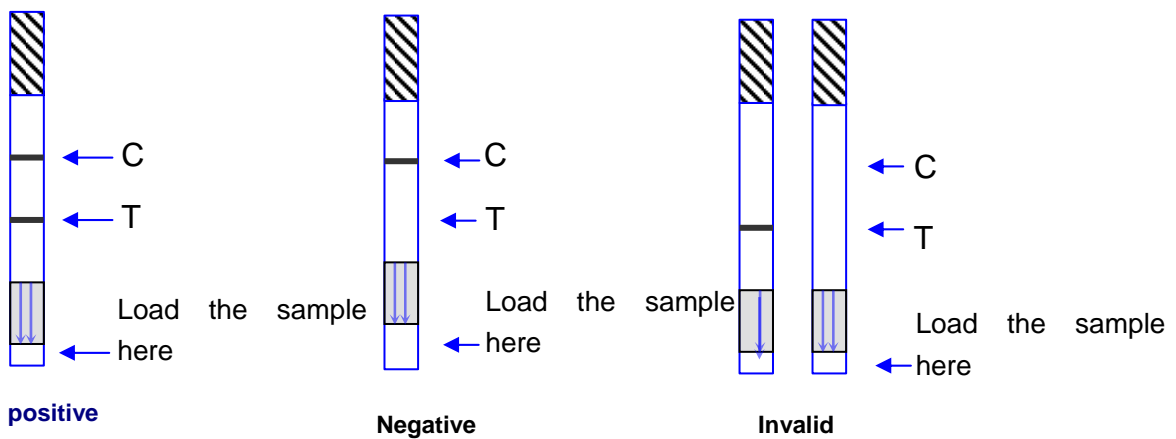
8 Take out the test strip from the pouch. Put the strip into the test tube with diluted specimen in the arrow direction

2. Begin timing for 20 minutes. 20 minutes after the testing, read the results as the following graph.
3. After testing, discard the swab into dustbin.



INTERPRETATION

Interpret the results according to the following graph.



LIMITATION

1. To get accurate result, the instruction step should be followed carefully;

2. Results interpreted within 20~45 minutes after testing are valid;
3. The oral fluid should be collected carefully according to the step instructions;
4. This test is only valid for oral fluid. Other fluid is not valid for this test;
5. The reddish density of the positive line is not necessarily proportional to the amount of HIV antibody in the sample;
6. HIV *ELISA* test could detect HIV IgG, IgM and IgA antibodies, whereas this test could only detect HIV IgG.
7. The HIV antibody density in oral fluid is much lower than in serum. The sensitivity of saliva rapid test is lower than that of serum.

REFERENCE DATA

Clinical study shows that, 349 cases of patients infected with HIV shows positive with this saliva HIV rapid test. In 513 cases of non-infected, one case shows positive. The specificity of this saliva HIV rapid test is 99.8% (512/513).

		Reference test	
		Positive	Negative
HIV-1/2	Positive	349	0
	Negative	1	512

STORAGE AND SHELF LIFE

Store the test at 2-30°C with a shelf life of 18 months

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