Saliva HCV lgG Antibody Detection Kit

(Lateral Flow Immunochromatography Method)

Instructions

【Product Name】

Generic name: Saliva HCV IgG Antibody Detection Kit

【Package Specification】

Single Test package: 1 test cassette, 1 sample collection swab, 1bottle of sample diluent buffer.

【Intended Use】

This product is used for qualitative detection of Hepatitis C Virus (HCV) IgG antibody in human oral mucosal exudate(saliva).

HCV can be infected through blood or blood products transfusion; Infected blood contacts through damaged skin and mucous membranes; Unclean needle injection; Mother-to-child; Unprotected sexual behaviors. It is an important pathogen to cause hepatitis. Previous studies have shown that HCV antibody exists in oral mucosal exudate of HCV infected people. Oral mucosal exudate as a detection sample has the advantages of non-invasive, easy collection, easy operation, economic and rapid.This product is suitable for non-invasive detection of hepatitis c virus IgG antibody by collecting oral mucosal exudate.

【Detection Principle】

This kit uses colloidal gold immunochromatography technology to qualitatively detect hepatitis C virus IgG antibody (HCV Ab) in human oral mucosal exudate by indirect immunoassay. Recombinant protein A (SPA) and quality control antigen were conjugated with colloidal gold particles and were dried onto a fiber glass pad. Recombinant HCV antigen (HCV Ag, containing core/NS3/NS4 fragments) and quality control antibody were respectively coated on the detection line and quality control line of the nitrate cellulose membrane. If there is an appropriate concentration of hepatitis c virus antibody (HCV) in the test sample, it will bind with on the recombinant protein A on the fiberglass pad to form a complex "Au - SPA - HCV Ab". And it will move forward along the strip due to the chromatography effect to the detection line which has pre-coated recombinant hepatitis C virus antigen (HCV Ag) to form an "Au-SPA-HCVAb-HCV Ag" complex to appear red color, indicating the HCV antibody is present in the sample. The unbound gold conjugated recombinant protein A and the gold labeled quality control antigen continue to move forward and react with the quality control line to form a "Au-SPA/control antigen-control antibody" complex and red color line appears. Negative samples only show color at the quality control line.

【Main Component】

The test cassette includes test strip, plastic clip, desiccant and aluminum foil bag; The test strip consists of absorbent paper, cellulose nitrate film, gold conjugate pad, sample pad and PVC backing.The nitrate cellulose membrane is coated with recombinant HCV antigen and quality control antibody, and the gold pad is fiber glass pad coated with recombinant protein A and quality control antigen.

2. The sample diluent was 0.01m PBS (pH7.4).

【Storage Conditions & Shelf Life】

The test kit should be stored at 2℃ - 30℃, sealed and away from light. It is valid for 24 months. Please do not freeze.

Production Date: see label.

Expiration Date: see label.

【Sample Requirements】

1. This product is suitable for oral mucosal exudate samples collected as instructed.

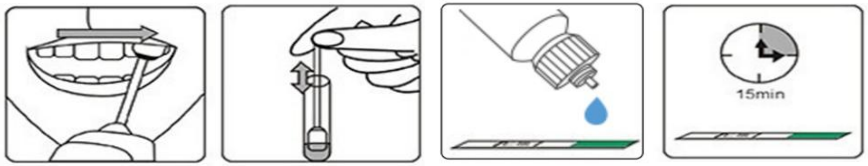
2. It is recommended to use the oral mucosal exudate samples after collection. The sample can be stored at 2℃ ~ 8℃ for no more than 7 days and at -20℃ for a longer time。 Avoid freeze-thaw repeatedly. Samples transportation should be carried out at 2℃ ~ 8℃.

3. The samples to be tested stored at low temperature should be brought to room temperature before use.

【Directions for Testing Use】

1. Remove the test box from the storage environment and equilibrate it to room temperature if stored at 2℃ ~ 8℃ before testing;

2. Tear off the outer package of the sample swab, put it in the mouth between the upper and lower cheeks and the gums, wipe it back and forth for several times, and then put into the mouth for 2 minutes to soak the swab with oral fluids



3. Put the sample swab into the sample diluent, repeatedly stir and squeeze it, then take it out and throw it away. The diluent buffer-saliva mix is used for nest step assay.

4. Take out the test cassette from the aluminum foil pouch,and place it on the test table horizontally;

5. Add 3 drops (about 100 μl) of the thoroughly mixed oral mucosa exudate sample(collected at last step) vertically to the sample loading Well(S) on the cassette (FIG. 1 S);

6.Read the result within 15 to 20 minutes.

【Interpretation of Test Result】

1. Positive HCV antibody (+) : both the quality control line (C line) and the test line (T line) appear.

2. Negative HCV antibody (-) : only the quality control line (C line) appears.

3. Invalid: If no line appears in the position of quality control line (line C), the test strip is invalid due to deterioration damage or improper operation.

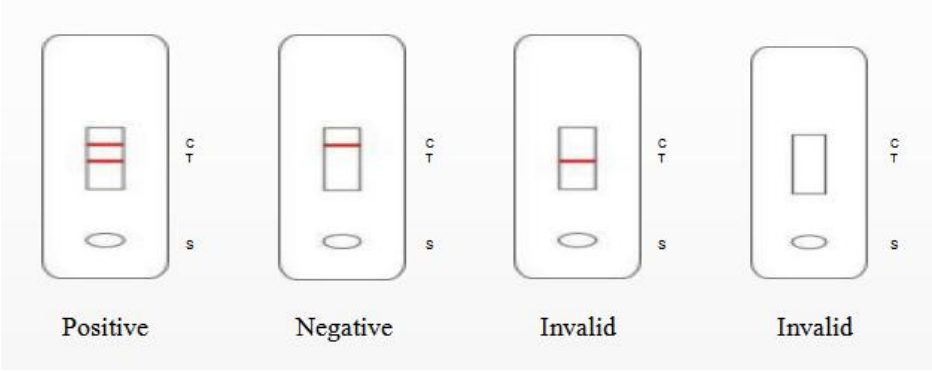


FIG. 1 Schematic Diagram of Cassette Test Results

【Limitations of the Test】

1. Samples used for testing must be collected, processed and stored correctly following the instruction.

2. This product is used for qualitative detection of HCV antibody.The test results should not be used for clinical diagnosis as the only sole evidence. The diagnosis of HCV shpuld be made based on comprehensive laboratory and clinical information.

3. Limited by the test sensitivity, the negative result cannot absolutely

exclude the presence of low-concentration antibody in the sample, so negative results cannot completely exclude the possibility of HCV infection.It is recommended that other methods can be used to retest the negative results in question.

4. Patients with autoimmune diseases may have positive result, while dialysis and immunodeficiency may have false negative result, which should be further confirmed by other testing methods.

5. For the positive result measured by this method, it is recommended to combine with clinical symptoms and by additional testing, such HCV virus loading test.

【Performance Characteristics】

The products should meet the following requirements:

1. Liquid Move Speed: Not lower than 5mm/min (n=3).

2. Minimum Test Amount: L1 should be positive, L2 should be weakly positive, and L3 should be weakly positive or negative;L4 should be negative.

3. Positive Reference Product Compliance Rate:(+/+) 10/10.

4. Negative Reference Product Compliance Rate:(-/-) 10/10.

5. Precision: The results are all positive with uniform color rendering.

Sensitivity and specificity:

Statistical table of qualitative results of test reagent and comparison reagent

The test reagent (Oral mucosal exudate)	Predicate Test (serum)		total
	Positive (+)	Negative (-)	
Positive (+)	506	7	513
Negative (-)	27	971	998
total	533	978	1511

classification	Sensitivity	Specificity	Overall accordance	Kappa value
	94.93%	99.28%	97.75%	0.9503
95% confidence interval	(93.83%, 96.04%)	(98.86%, 99.71%)	(97.00%, 98.50%)	(0.9393, 0.9613)

Comparison of the Test reagent and OraQuick Test

The test reagent (Oral mucosal exudate)	OraQuick reagent (oral mucosal exudate)		total
	Positive (+)	Negative (-)	
Positive (+)	155	5	160
Negative (-)	1	66	67
total	156	71	227

classification	Sensitivity	Specificity	Overall accordance	Kappa value
	99.36%	92.96%	97.36%	0.9376
95% confidence interval	(98.32%, 100%)	(89.63%, 96.29%)	(95.27%, 99.44%)	(0.9061, 0.9690)

Interference Factors: Consumption of tobacco, diet, cola and commercially available mouthwash do not interfere with the test results after 10 minutes of use.

Common drugs (antibiotics, antipyretic and analgesic drugs and oral

drugs) have no interference to the positive detection.

Cross-reaction: No cross-reaction was observed with the positive samples including anti-HAV, anti-HBV, anti-HEV, anti-HIV, as well as common oral microorganisms (bacteria, fungi and viruses).

【Precautions】

1. Please read the full text of this manual carefully before testing, and operate according to the requirements.
2. As an in vitro diagnostic reagent, this product is only suitable for the detection of human oral mucosal exudate(saliva).
3. Do not use outdated, damaged products.
4. Do not wet your hands when taking out the test cassette from the aluminum foil bag.
5. This product is one-time use only.
6. After the aluminum foil pouch is opened, the test cassette should be prevented from moisture absorption and used it within 30 minutes. The test should be completed as soon as possible in high temperature and high humidity environment.
7. It is recommended to collect fresh oral mucosal exudate samples for testing. If the samples are stored for too long, deterioration.
8. The color depth of the positive result may be varied due to the amount of anti-HCV antibodies in the sample, but within the specified observation time, as long as there is colored band visible to the naked eye, it can be read as a positive result.
9. If there is sample spilled during the operation, disinfect the possible contaminated area with disinfectant.
10. The following operations may result in inaccurate test results:

(1) Samples were not collected as required in the instruction.

(2) Insufficient sample mixing.

(3) Insufficient sample amount collection.

(4) Samples were added too quickly or excessively.

(5) The interval between sample addition and observation results is too long or too short.

11. The test paper after testing should be treated as biological infectious waste.

【Interpretation of Signs】

IVD In Vitro Diagnostic ® Trade Mark Temperature Limitation Manufacture Date of Production Date of Expiration LOT Lot Number No secondary use Do not use if the package is damaged. EC REP European Authorized Representative

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[9} "Guidelines for the preparation of instructions for in vitro diagnostic reagents" Issued by the State Food and Drug Administration 2014 No. 17

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