

# Detection Kit for Human Papilloma Virus (HPV) IgG antibody (Colloidal Gold Immunofiltration Assay)

Cat. No.: HPV 3522

## INTENDED USE

Human Papilloma Virus (HPV) stays in skin and mucosa of the site of infection, and can cause verruca vulgaris, flat wart and condyloma of the skin and mucosa, cervical cancer and anal genital tract cancer. This test kit is used to qualitatively detect anti-HPV antibodies in human serum.

## PRINCIPLE

The kit employs gene reengineering human Papilloma Virus antigen, combines with the principle of Dot Gold Immunofiltration Assay (DGIFA) to detect HPV antibodies in serum indirectly.

## REAGENTS

HPV antigen (Test Point), goat anti-mouse IgG antibody (Control Point), mouse anti-human IgG monoclonal antibody colloidal gold conjugates (colloidal gold conjugate liquid), 1% BSA pH7.4 Tris-HCL solution (Diluent), 0.5% BSA pH7.4 Tris-HCL solution, 0.25% TritonX-100 (Wash Buffer).

## SPECIMEN PREPARATION

Collect venous blood according to clinical lab procedure, and put it into a clean disposable container without anticoagulant or coagulant; incubate it at 37°C for 20 – 30 minutes, or set it at room temperature for more than 1 hour; Centrifuging it at a speed of 4000RPM for at least 5 minutes; separate the serum for use.

If the test can not be carried out in time, the sample should be stored at -20°C (within 3 months, the result won't be affected) or lower. Dissolve it, centrifuge it, and take the clear serum immediately prior to use. The titer of the antibody in the sample freeze-thawed may be reduced. All samples must be centrifuged well immediately prior to use and take the clear serum for testing.

## TEST PROCEDURE

Test Steps:

- (1) Take out the kit and put it at room temperature for 20~30 min;
- (2) Dispense 1 drop of Wash Buffer to the test window, waiting for the liquid to wet the membrane well;
- (3) Add 150µl of serum (4 drops if with a sample pipet) into the test window, waiting for the liquid to be absorbed completely;
- (4) Add 3 drops of Colloidal Gold Conjugate into the test window, waiting for the liquid to be absorbed enough;
- (5) Add 3 drops of Wash Buffer into the test window, and interpret the result within 3 minutes immediately after the liquid is absorbed adequately.

## RESULT JUDGMENT

Negative— Only the quality control area(C) shows a red dot;

Positive— Both the quality control area(C) and the test area(T) show red dots;

Invalid— that a red dot does not present in the quality control area(C) indicates operation faults or reagents invalidation.

## LIMITATIONS

1. This kit is only applied to qualitative screening tests.
2. For samples infected by HPV recently or in window phase, the result may be negative as the concentration of anti-HPV antibody in the specimen is very low or even zero.
3. This kind kit can't determine exact content of anti-HPV antibody.
4. This assay is a qualitative screening test, so it should be connected with other clinical methods and clinical symptoms to determine whether a patient is infected by HPV.

## PRECAUTIONS

1. For detection, fresh and clear serum or serum stored at 2~8°C for less than 3 days should be used. A few samples (hyperlipidemia blood, hyperbilirubinemia, hemolysis, etc.) could deepen the background color, but this generally will not affect the results.
2. For specimen with anticoagulant or coagulant, the filtration speed is slow, the background is red color, and the result judgment will be interrupted. Recommended not to use.
3. There must not be time intervals between steps of test; the liquid during one step should be added at one time quickly and adsorbed completely.
4. The result observed exceeding stated time is invalid.
5. The depth of the dot color in quality control area(C) does not indicate the quality of reagents. Reagents are valid as long as the dots are just clear to identify.
6. Colloidal Gold Conjugate Liquid of different products and different lots of one product mustn't be cross-used.
7. Ureaplasma urealyticum antibody, mycoplasma hominis antibody, neisseria gonorrhoea antibody and rheumatoid factor generally do not affect test result.
8. If the filtration speed is very slow or evens no filtration, please retreat the specimen and test again. Only for research, not for clinical diagnosis.

## STORAGE AND EXPIRY

1. Store at 2~8°C; The expiry is 10 months.
2. The kit could be transported at normal temperature for short term. Take protective measures in winter and summer, and avoid freeze-thawing or high temperature for a long term.

## MANUFACTURER

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