

Double-Stranded DNA (dsDNA) IgG Antibody Test Kit

(Dot Filtration Colloidal Gold Assay)

【Application】 The kit is intended for qualitative detection of anti-double-stranded DNA antibody in human serum, according to the principle of Gold Immunofiltration Assay(GIFA).

The anti-double-stranded DNA (ds-DNA) antibody is the specific autoantibody in the serum of systemic lupus erythematosus (SLE) patients, it is a main index of SLE immuno-diagnosis, There are two types of anti-ds-DNA antibody-IgM and IgG, The main type associated with disease activity index(DAI) is IgG, IgM is not clearly related to DAI, so the anti-ds-DNA antibody IgG is the main disease-causing autoantibody of SLE, and it is also a sign of DAI ,especially renal injury.

【Principle】

The kit adopts the purified double-stranded DNA antigen and combines the principle of Gold Immunofiltration Assay (GIFA) to detect the anti-ds-DNA IgG Antibody in serum indirectly.

【Major Component】

ds-DNA antigen(test spot), goat-anti-mouse antibody IgG(control spot), mouse anti-human monoclonal antibody IgG conjugated with colloidal gold (colloidal gold liquid), 1% BSA pH7.4 Tris-HCl solution (diluent), 0.5% BSA pH7.4 Tris-HCl solution and 0.25% TritonX-100 (washing buffer)

【Storage and Period of validity】

1. Store the kit at 2-8℃ and the period of validity is 12 months. The kit reagent are stable for 1 month at the condition of 2-8℃ after opening the foil bag.
2. The kit can be transported in short term at normal temperature. In summer or winter, some protective measures should be taken to avoid long-term high temperature or freezing-thawing.

【Sample Preparation】

1. **Be sure to test with fresh serum.**
2. If the specimen can not be tested in time under special circumstances, it should be kept in environment below -20℃. Any of the specimens must be fully centrifuged before testing, and take the clear liquid for test.

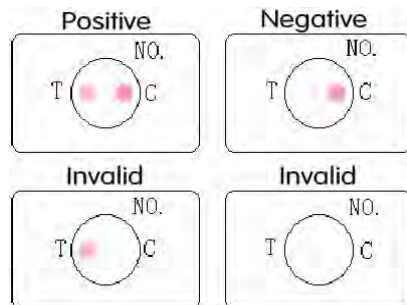
【Test Procedure】

1. Bring out the kit reagents to room temperature for about 20-30 minutes.
2. Add 1 drop of washing buffer into the test window and allow the liquid to wet the membrane completely.
3. Add 150 u l (or add 4 drops while using sample dropper) of the serum to be tested into the test window and allow it to soak into the membrane completely.
4. Add 3 drops of colloidal gold liquid into the testing window and allow it to soak into the membrane completely.
5. Add 3 drops of washing buffer into the testing window and allow it to soak into the membrane completely, and then read the results within 3 minutes.

【Interpretation of Results】

Refer to the following illustration.

- (1). **Negative** — Only the quality control area(C) shows a red dot;
- (2). **Positive** — Both the quality control area(C) and the test area (T) show red dots;
- (3). **Invalid** — No red dot present in the quality control area (C) indicates operation faults or reagents deterioration.



【Limitations】

1. Like all qualitative test reagent, the kit can be used only for screening experiment.
2. This kit can not determine the exact level of the anti-ds-DNA antibody.
3. The reagent is intended for the qualitative screening test, any positive result should be considered along with other clinical information.

【Performance Index】

1. Negative accordance: test with the quality control which is anti-ds-DNA negative, and the results must not be positive.
2. Positive accordance: test with the quality control which is anti-ds-DNA positive (strong positive, medium positive, weak positive), and the results must not be negative.
3. Minimum detection limit: test with the medium positive quality control which is serious diluted to 1:8, the result should be weak positive.
4. Repeatability: do 10 tests with repeatable quality control, the results should be identical, all results should be positive and the color is uniform.

【Precautions】

1. Be sure to test with fresh serum or the serum stored in 2-8℃ within 3 days. The background of few specimens (hyperlipemia, high bilirubin and hemolysis) may be slightly darker, but does not affect result judgment generally.
2. The specimens with anticoagulants or coagulant may infiltrate slowly, the background is too red to read the result, so anticoagulants or coagulant is not recommended.
3. Add the liquid step by step without any significant interruption, the liquid in the same step should be added quickly at once and allow fully infiltration.
4. When beyond the reading test time, the result is invalid.
5. The color intensity of control spots does not represent the quality of the reagent; the reagent is effective as long as the color of the spot is clearly visible.
6. Must not mix the colloidal gold liquid or washing buffer of different products, or of the same products which belong to different batches.
7. Rheumatoid factor in the specimens has almost no effect on the test result.

【Precautions】

ATLAS LINK TECHNOLOGY CO., LTD

Road Xing Min, Guan South Industry Zone, 065500 Langfang City, Hebei Province, CHINA

WEB: <http://www.invitro-test.com>