

# **Instruction for Use (IFU) of Diagnostic Kit**

## **for the Detection of Anti-Sperm antibodies (IgG/IgM/IgA)**

(Colloidal Gold Filtration Method)

is 10 months. The kit reagents are stable for 1

**【Product Name】** Diagnostic Kit for detection of Antisperm Antibody (Colloidal Gold)

### **【Packing Specification】**

25 Tests/Kit

**【Application】** The kit is intended for qualitative detection of anti-sperm antibody (ASA) in human serum, according to the principle of Gold Immunofiltration Assay(GIFA) . There are many ways antisperm antibody can act on conception process from many faces, its dominant mechanisms include: the antibody can obstruct sperm from penetrating cervical mucus; inhibit sperm from penetration and adhesion on zona pellucida; interfere with sperm's ability to contact and bind to zona pellucida; inhibit sperm fusion with vitelline membrane; prevent sperm penetration and sperm-egg fusion, prevent fertilization, even if the egg is fertilized, the antisperm antibody can also cause abortion by affecting embryo.

Therefore, the detection of antisperm antibody has important clinical significance for definite diagnosis of both infertility and prognosis.

### **【Fundamentals】**

The kit adopts the purified antigen and combines the principle of Gold Immunofiltration Assay (GIFA) to detect the ASA in serum indirectly.

### **【Major Component】**

Sperm 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°C and the period of validity

month at the condition of 2-8°C 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.

**【Suitable Instruments】** Not applicable

### **【Sample Requirements】**

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

### **【Test Procedure】**

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

### **【Reference Value (reference range)】**

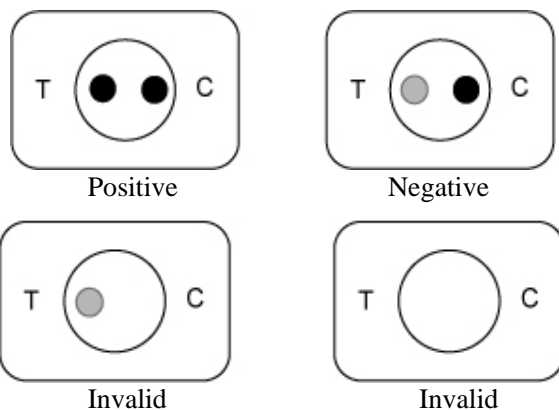
Not applicable

### **【Interpretation of Result Judgment】**

1. **Negative:** the control spot (C) shows red and no red spot appears on the test spot (T)

location.

2. **Positive:** the control spot (C) shows red and a red spot appears on the test spot (T) location.
3. **Invalid:** the control spot (C) does not show any color, indicating the error operation and/or the test reagent has deteriorated.



#### 【Limitations of Test Results】

1. Like all qualitative test reagent, the kit is only limited to the screening experiment.
2. This kit can not determine the exact level of the ASA antibody.
3. The reagent is intended for the qualitative screening test, any positive result should be diagnosed combining with the clinical information.

#### 【Performance Index】

1. Negative accordance: test with the quality control which is ASA negative, and the results must not be positive.
2. Positive accordance: test with the quality control which is ASA 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°C 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 added 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 interruption, the liquid in the same step should be added quickly at once and allow fully infiltration.
4. When beyond the given test time, the result is invalid.
5. The color depth 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 liquid 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.

#### 【References】

1. In vitro diagnostic reagent registration regulations
2. China Biologicals Regulations.
3. Guiding principles for written of in vitro diagnostic reagent instructions
4. Specifications, labels and the package label regulations for medical equipment
5. Liu Fang. The clinical value of antisperm antibodies detection[J]. Journal of practical medical techniques. 2009, 16 (6): 475-476.
6. Chen Jiajian, Jiang Bangrong. The clinical value of the detection of antisperm antibodies for diagnosis of infertility [J]. China Laboratory Diagnostics 2008, 12 (4): 545-546.

#### 【Manufacturer】

ATLAS LINK TECHNOLOGY CO., LTD

Road Xing Min, Guan South Industry Zone,

065500 Langfang City, Hebei Province, CHINA

Web: <https://www.invitro-test.com>