

## Anti cardiolipin antibody (ACA) Dot Filtration Rapid Assay Kit

### (Colloidal Gold Immuno-filtration Assay)

(For all isotypes ACA antibodies of IgG/IgM/IgA)

#### PRINCIPLE

Anti cardiolipin antibody (ACA) in specimen combines with the solid-phase cardiolipin antigen in the reaction plate and forms antibody-antigen complexes. Then, the complexes combine with colloidal gold marked anti-human IgG, IgM, or IgA antibodies, if present in the specimen, thus a red visible dot will emerge.

#### INTENDED USE

This kind kit is used to detect qualitatively ACA in human serum.

#### SPECIMEN COLLECTION

(1) Take venous blood 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; centrifugate it at the speed of 4000r/min for at least 5 minutes, and take the serum for detection.

(2) In case of not being detected in time, the specimen should be stored at -20°C or lower. Dissolve it, centrifugate 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 centrifugated well immediately prior to use and take the clear serum for detection.**

#### TEST STEPS

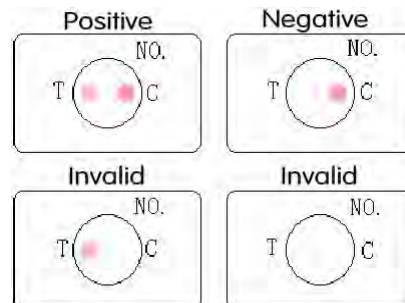
- 1). Take out the kit and put it at room temperature for 20~30 min;
- 2). Dispense 1 drop of Wash Buffer to the test window, waiting for the liquid to wet the membrane well;
- 3). Add 150µl of serum (4 drops if with a sample dropper) into the test window, waiting for the liquid to be absorbed completely;
- 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) There will be differences in results for some immune suppressive individuals or immune hyperthyroidism individuals.
- (3) This kind kit can't determine exact content of ACA.
- (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 cardiolipin antigen.

#### ATTENTIONS

1. **It must be fresh, clear serum not plasma for detection.** A few samples (hyperlipidemia blood, high hemoglobin, hyperbilirubinemia, hemolysis, etc.) could deepen the background color, but this generally will not affect the results.
2. 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.
3. The result observed exceeding stated time is invalid. In the detection of IgM, even if the prints are mere, the result should be determined as positive.
4. Dilute the positive serum specimen times by normal salt solution to test its titre;
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 dot is just clear to identify.
6. Colloidal Gold Conjugate Liquid and Wash Buffer of different products and different lots of one product mustn't be cross-used.
7. If the filtration speed is very slow or even no filtration, please retreat the specimen and test again.

#### STORAGE AND TRANSPORTATION

The kit should be stored at 2~8°C.

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.

**EXPIRY** 12 months

#### MANUFACTURER

**ATLAS LINK TECHNOLOGY CO., LTD**

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

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