Anti-HAV IgG Antibody Dot Filtration Test
（Immuno-gold Filtration Assay）

Cat. No. HAV 2622

【Introduction】

Hepatitis A is a strong infectious disease caused by HAV, it is spread generally having two means namely mouth and feces with strong infection characteristic. Hepatitis A is a prevalent disease in the human population, caused by the hepatitis A virus (HAV). Following a 14-40 day incubation period, HAV infection most commonly manifests itself by jaundice due to acute inflammation of the liver and subsequent elevated blood bilirubin concentrations. The hepatitis A virus specific immunoglobulin M (IgM) antibody is a specific serological marker for early diagnosis of hepatitis A. The dot immunogold combination assay (DIGFA), developed since 1989, is a new technique with the merit of simple and rapid immunological detection.

The HAV Antibody assay facilitates the determination of the immune status of individuals following exposure to HAV or to hepatitis A vaccine. Detection of anti-HAV antibodies in the absence of anti-HAV antibodies of type IgG, indicates either a previous infection with HAV or a successful vaccination. In general, a titer of 10 IU/L is considered to represent the minimal anti-HAV antibody concentration indicating immunization of the individual.

【Principle】

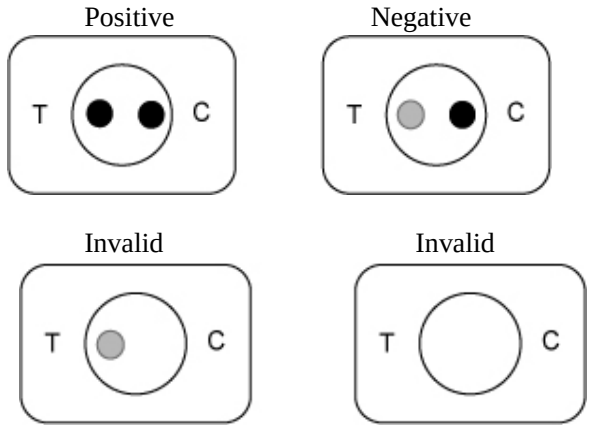
By using the red colloidal gold particles to label the antibodies as indicator, and the millipore filtering membrane coated with antigen as the carrier. Affected by filtration and condensation, the antigen antibody reaction is enabled to go on rapidly. When the serum tested is added to the Millipore membrane previously coated with HAAg, if there was HAV IgG antibody, the HAAg-anti-HAV IgG colloidal gold complex will be formed on the membrane as red dots which were visible to the naked eyes. It takes about 2 to 4 minutes for the whole reaction to be carried out.

【Test Procedure】

1. Bring sealed test cassette, diluents and the sample to room temperature prior to the testing. Do not mix the caps from different reagent vials;
2. Dilute the serum with medical physiological saline solution (salt water of 0.9%), and the proportion should be 1:200 (serum : salt water);
3. Open foil pouch and bring out the HAV test cassette.
4. Add 2 drops of wash buffer to reaction well until it is fully absorbed;
5. Collect 150ul diluted serum, and add it to testing well until it is absorbed;
6. Add 2 drops of wash buffer into the reaction well until it is absorbed;
7. Add 3 drops of colloidal gold conjugate reagent into the reaction well until it is absorbed;
8. Add 3 drops of wash buffer into the reaction well;
9. After the solution is absorbed completely, start the timer. Read the test result within 3 minutes.

【Interpretation of Results】

Negative: Control dot (C) turns red, and there is no red color appear on the test dot (T) or the color is very light.
Positive: Both control dot and test dot turn red.
Invalid: Control dot does not appear.



【Precaution】

1. For In Vitro Diagnostic Use only.
2. Use the test kit within the expiration date of 12 months.
3. The colloidal gold conjugate reagent with different lot number can not be mix-used.
4. The test should be conducted in accordance with the instruction manual strictly.

【Storage and Transportation】

1. Test kits should be stored at the temperature range of 2-8℃, and the shelf time is 12 months
2. This reagent can be transported within a short period in a normal temperature range. In summer or winter when the environment is rough, some protective measures should be taken to avoid high temperature or freeze thawing.

【Manufacturer】

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