

Legionella Antisera

Legionella is a Gram-negative bacillus having motility through flagella and is the causative of legionellosis.

These are immune sera used for serological tests of *Legionella* and are liquid products that contain group-specific agglutinins. When these products are used, the group is identified using the slide agglutination.

The antisera are prepared by hyper-immunizing rabbits with ten reference strains of ATCC. For immunization, the strains are cultured using a B-CYE (Buffered Charcoal Yeast Extract) medium and inactivated by heating at 100°C. After bleeding, the antisera are separated, heated at 56°C for 30 minutes, absorbed to remove non-specific agglutinins, and sterilized by filtration. Sodium azide is added at 0.08 w/v% as a preservative.

PRODUCTS

Legionella Antisera are produced from rabbits and contain 0.08% sodium azide as a preservative. Serum following types are provided as 2mL volumes in vials with dropper attachment and ready to use.

Set : 10 vials

- 1) *L. pneumophila* Serogroup 1
- 2) *L. pneumophila* Serogroup 2
- 3) *L. pneumophila* Serogroup 3
- 4) *L. pneumophila* Serogroup 4
- 5) *L. pneumophila* Serogroup 5
- 6) *L. pneumophila* Serogroup 6
- 7) *L. bozemanii*
- 8) *L. dumoffi*
- 9) *L. gormanii*
- 10) *L. micdadei*

INTENDED USE

Determination of the *Legionella* serogroup

PRINCIPLE OF MEASUREMENT

When this reagent is mixed with *Legionella* strain which has antigens correspondent to the reagent, the antigen antibody reaction occurs to produce agglutination. This reaction is macroscopically observed to determine each serotype.

PROCEDURES

1. Material required but not provided

Glass slide, Glass pencil, small test tubes, pipette and micropipette, Microbiological loop, physiological saline, Autoclave(121°C) or water bath(100°C), Centrifugator.

2. Preparation of reagents

The antisera are ready for use.

3. Specimen

Cultures of organisms which is derived from a pure culture and identified as *Legionella* by biochemical tests should be tested. If the specimen consists of multiple strains, the serogroup may not be correctly identified.

4. Procedures

- 1) Suspend a certain amount of bacterial growth (3-5 times the amount of a match head) in 3 mL physiological saline and heat to 121°C for 15 minutes or 100°C for 1 hour. Centrifuge the heated solution at 900 g for 20 minutes, discard the supernatant, suspend the precipitate with 0.5mL physiological saline and use as antigenic suspension.
- 2) Place a drop each of antiserum and physiological saline (30 µL) as a control onto a cleaned glass slide partitioned into several parts with a glass pencil.
- 3) Place a antigenic suspension (5-10 µL) onto the serum and physiological saline on the slide glass.
- 4) Mix the reagents with tilting the glass slide back and forth for 1 minute and the agglutination pattern is observed. Agglutination is grossly observed with light through the slide including fluorescent light. It should be first confirmed that no agglutination is found on the reaction with antigenic suspension and physiological saline. Only strong agglutination observed within 1 minutes in the reaction with each serum should be regarded as positive. Delayed or weak agglutination is regarded as negative.

PRECAUTIONS FOR INTERPRETATION OF THE RESULT

1. Slight agglutination occurring more than 1 minute after the reaction between the antiserum and antibody should be regarded as negative.
2. If positive agglutination is observed, the isolate possesses the specific antigen group.
3. If a cross-reaction occurs for a sample with two or more groups of sera, heating the bacterial suspension should be repeated before retesting the sample.
4. The complex type is rarely isolated for the *L. pneumophila* Serogroup 4 and Serogroup 5.
5. If agglutination is observed in the physiological saline control, the test should be repeated selecting another colony.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

When one drop of the antiserum is allowed to react on a slide with a known serotype of the reference strain, granular agglutination is observed macroscopically.

2. Specificity

In test performed in a similar manner to the sensitivity test, the antiserum agglutinates only with the reference strain corresponding to the serotype, while in reactions with non-corresponding reference strains, macroscopic agglutination is not observed.

PRECAUTION FOR USE AND HANDLING

1. General precautions

- 1) This test is for in vitro diagnostic use only.
- 2) This reagents should only be used from sufficiently trained lab staff.

2. Precautions of handling

- 1) All specimens, samples and containers coming into contact with samples should be treated as infectious.
- 2) If reagent come into contact with skin, mucous membranes of eyes, wash immediately with plenty of water.
- 3) Do not freeze the reagents nor use past the expiration date as this may result in poor reagent performance.
- 4) The reagent should be allowed to stand at 15-25°C for at least 30 minutes before use.
- 5) Used containers should not be used for other purposes.
- 6) Sera with different production numbers should not be mixed.
- 7) The reagent should be used according to the described procedures.
- 8) The reagent should only be used for the intended use.
- 9) Special precautions should be taken to ensure that the reagent caps are not exchanged.

3. Precautions for disposal

- 1) The reagent contains 0.08 w/v% sodium azide. Sodium azide may react with lead or copper to form explosive heavy metal azides. The reagent should be disposed with a large amount of water.
- 2) All specimen, spills, inoculated product and equipment used in this test should be treated with one of the following methods.
 - [1] Soaking in 0.1 w/v% hypochlorite for 1 hour or more.
 - [2] Autoclaving at 121°C for 20 minutes or more.

STORAGE AND SHELF LIFE

Storage : 2-10°C

Shelf life : Up to the expiry date on the label.

PACKAGE

Legionella Antisera : Each type in a 2 mL vial with a pipette.

• Set : 10vials one package

* Each serum is separately available.

REFERENCE

- 1) Saitoh, A. : Legionnaires' disease., Clin. Lab., **24**, 925(1981)

Please feel free to contact us at the following with your questions or comments:
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Symbols



Batch code



Use by



In Vitro Diagnostic Medical Device



Temperature limitation (Store at)



Catalogue number



Consult Instruction for use



Contents of kit



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