

Alkalescens-Dispar Antisera

INTENDED USE

Serotyping of Alkalescens-Dispar.

SUMMARY AND EXPLANATION

A certain biotype of *Escherichia coli* that gas non-ferment, non-motile is called Alkalescens-Dispar.

Alkalescens-Dispar Antisera is liquid product which contain specific antibodies against Alkalescens-Dipar intended for O (somatic) grouping and K (capsular) typing. The antisera are prepared from healthy rabbits immunized with reference strains. After bleeding, the antisera are heated at 56°C for 30 minutes and cross-reactions with heterologous serotypes are removed by absorption. The antisera contain 0.08w/v% sodium azide as a preservative. Certain *Shigella* stains have the same antigen as Alkalescens-Dispar, and may cause a positive reaction.

PRINCIPLE

When the reagent is mixed with Alkalescens-Dispar cells, which have antigens corresponding to the reagent, an antigen-antibody reaction occurs to produce agglutination. The reaction is macroscopically observed to determine each serotype.

PRODUCT

Alkalescens-Dispar Antisera are produced from rabbits and contain 0.08 w/v% sodium azide as a preservative. The following sera are provided in 2 mL vials with pipette and are ready to use.

Set: 5 vials/set

Polyvalent OK (mixture of O1: K1, O2: K1, O3: K2 and O4: K3 sera)

O1: K1

O2: K1

O3: K2

O4: K3

PRECAUTIONS

1. General precautions

- 1) For *in vitro* diagnostic use only.
- 2) Only bacteriological trained laboratory staff should handle the reagents.
- 3) Reagents should only be used for the intended use.
- 4) Reagents should be used according to the described procedures.
- 5) Antigenic factors of Alkalescens-Dispar are shared widely throughout enterobacterium.

It is important to confirm that an organism used as a specimen is Alkalescens-Dispar by biochemical properties.

2. Handling precautions

- 1) All specimens, samples and containers coming into contact with samples should be treated as infectious substance.
- 2) If reagent comes into contact with skin, eyes, or mouth wash immediately with copious amounts of water, seek medical attention if necessary.
- 3) Do not freeze the reagents or use past the expiration date as this may result in poor reagent performance.
- 4) Reagents should be allowed to stand at 15°C-25°C for at least 30 minutes before use.
- 5) Used containers should not be used for other purposes.

6) Sera with different lot numbers should not be mixed.

7) Special precautions should be taken to ensure that the reagent caps are not exchanged.

8) Avoid microbial contamination of opened reagent bottles. Do not use reagents if they are contaminated or cloudy.

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 copious amounts of water.

2) All specimens, spills, inoculated products and equipment used in this test should be treated by one of the following methods.

[1] Soaking in 0.1 w/v% hypochlorite for 1 hour or more.

[2] Autoclave at 121°C for 20 minutes or more.

TEST PROCEDURE

1. Material required but not provided

Small test tubes, physiological saline, pipettes, micropipettes and tips, fluorescent light, bacteriological loops, autoclave (121°C) or boiling water bath, glass slides, glass pencil

2. Preparation of reagents

Ready to use.

3. Specimens

Pure culture of Alkalescens-Dispar identified by biochemical properties should be tested. If the specimen consists of multiple strains or is contaminated, it may not show correct results.

4. Method

The specimen derived from an axenic culture is suspended in physiological saline. The bacterial suspension is divided in two portions. One portion to be used as the live-cells (K) suspension, and the other portion for the heat-treated cells (O) suspension (heated at 100°C for one hour or at 121°C for 15 minutes). These 2 test suspensions are used in the following agglutination tests.

A) Agglutination test using live-cell suspension

- 1) Place a drop on Polyvalent OK serum and physiological saline (30 μ L) another section of the partitioned slide.
- 2) Place a live-cell suspension (5-10 μ L) on the area above each drop of serum or physiological saline, and mix well using the loop.
- 3) Tilt the glass slide back and forth for one minute and observe for agglutination.
- 4) Check whether spontaneous agglutination occurs with the physiological saline.
- 5) When Polyvalent OK serum gives a positive result, place a drop of each monovalent OK serum on a glass slide, and repeat the procedures above to determine the result.

B) Agglutination test using Heat-treated suspension

When agglutination observed between live-cell suspension and monovalent OK sera, the OK sera for those in which agglutination was observed in the live-cell suspension are reacted with heat-treated organisms using the same procedure as above and observed for agglutination. However, microorganisms belonging to O1 and O2 groups have the same type of K antigen.

INTERPRETATION OF RESULTS

The results are interpreted as follows.

Reaction between physiological saline and antigen suspension	Reaction between serum and antigen suspension	Determination
No spontaneous agglutination is observed	Strong agglutination is observed within a minute	Positive (+)
	Agglutination is not observed within a minute	Negative (-)
Spontaneous agglutination is observed	Determination is suspended.	

1. Slight agglutination after a minute or more with sera is regarded as negative.
2. When positive agglutination is observed with the live and heated cell suspensions, the specimen is determined as Alkaescens-Dispar. When the live-cell suspension is positive and the heated suspension is negative, the results is not interpreted as negative.
3. If agglutination is observed in the control reaction with physiological saline, another colony should be selected and the test repeated.

Symbols



Batch code



Use by



In Vitro Diagnostic Medical Device



Temperature limitation (Store at)



Catalogue number



Consult Instruction for use



Contents of kit

PERFORMANCE CHARACTERISTICS

1. Sensitivity

When a drop of the product is reacted on a glass slide with a reference strain of a known serotype, granular agglutination is observed.

2. Specificity

When the product is tested according to the similar manner to the sensitivity test, agglutination is observed in the reaction with a reference strain of corresponding serotype, but not observed in the reaction with a reference strain of a different serotype.

STORAGE / SHELF LIFE

Storage : 2°C-10°C.

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

PACKAGE

Alkaescens-Dispar Antisera: 2 mL serum vial with pipette.

- Set: 5 vials/set

Each serum is individually available.

REFERENCE

- 1) Supervised by the Ministry of Health, Labour and Welfare: Diarrhea/food-poisoning pathogenic *E. coli*, Microbiological test manual, Bacterial and fungi tests, Second edition, Japan Public Health Association, 219 (1978).

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

TEL : +81-3-3669-9421 FAX : +81-3-3669-9390



DENKA SEIKEN CO., LTD.

3-4-2 Nihonbashikayaba-cho, Chuo-ku, Tokyo, Japan

TEL : +81-3-3669-9421 FAX : +81-3-3669-9390

DENKA SEIKEN UK Ltd.

2 Coronation Lane
Oakthorpe, Swadlincote,
Derbyshire DE12 7QY
United Kingdom

TEL : +44 1530 270010 FAX : +44 1530 272009

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