

Yersinia enterocolitica Antisera

IVD

Yersinia enterocolitica is a Gram-negative short-form bacillus belonging to family *Enterobacteriaceae*.

These are the immune sera to be used for identifying groups O3, O5, O8 and O9 of Wauters' classification of *Y. enterocolitica* by slide agglutination. These groups are considered as having conspicuous pathogenicity in humans. The antisera contain agglutinins specific to each group shown on the vial label.

Each antiserum is prepared by hyper-immunizing healthy rabbits with Wauters' reference strains provided by the National Institute of Infectious Diseases, Japan, and inactivating the serum at 56°C for 30 minutes. After removing the cross agglutinins by absorption, the serum is sterilized by filtration and sodium azide is added at 0.08 w/v% as a preservative.

PRODUCTS

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

Set : 5 vials : Polyvalent group O1 and O2, group O3, group O5, group O8, group O9

INTENDED USE

Determination of *Y. enterocolitica* serogroup

PRINCIPLE OF MEASUREMENT

When this reagent is mixed with *Y. enterocolitica* 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.

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 *Y. enterocolitica* by biochemical tests should be serotyped. If the specimen consists of multiple strains, the serotype 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 0.5 mL physiological saline and use antigenic suspension.
- 2) Place a drop each of group O3, O5, O8, O9 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.
- 5) If a specimen tests positive with group O3 antiserum, perform steps 2-4 above using polyvalent group O1 and O2 antiserum. When agglutination found with the polyvalent group O1 and O2 antiserum, the specimen does not belong to serogroup O3. *Y. enterocolitica* group O3 do not agglutinate with the polyvalent O1 and O2 antiserum.

Note:

Although group O3, O5, O8 and O9 of *Yersinia enterocolitica* are recognized as being pathogenic in humans, assessment of the pathogenicity of the test organism should not depend solely on the O-grouping result, and its biotype (refer to the table below) should also be referred to. Groups O3 and O8 mostly belong to Biotype 3 and Biotype 4 and groups O5 and O9 belong to Biotype 2.

Biotype of *Yersinia enterocolitica*

Biochemical property	Biotype						
	1A	1B	2	3	4	5	6
Lipase (Tween-esterase)	+	+	-	-	-	-	-
Esculin / Slicin (24h)	±	-	-	-	-	-	-
Indole	+	+	(+)	-	-	-	-
Xylose	+	+	+	+	-	V	+
Trehalose/No3	+	+	+	+	+	-	+
Pyrazinamidase	+	-	-	-	-	-	+
β-D-Glucosidase	+	-	-	-	-	-	-
Voges-Proskauer	+	+	+	+	+	(+)	-
Proline peptidase	V	-	-	-	-	-	+

PERFORMANCE

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

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

- Set : 5vials one package
- * Each serum is separately available.

REFERENCE

- 1) Supervised by the Ministry of Health, Labour and Welfare: *Yersinia*, Microbiological Test Manual. Bacterial and Fungi Tests, Third edition, Japan Public Health Association, D-55 (1987)
- 2) Wauters, G., et al. : Revised biogrouping scheme of *Yersinia enterocolitica*, Contr. Microbiol. Immunol., 9, 14(1987)

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

LOT

Batch code



Use by

IVD

In Vitro Diagnostic Medical Device



Temperature limitation (Store at)

REF

Catalogue number



Consult Instruction for use

Cont.

Contents of kit



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