DebenDiagnosticsLtd



# YERSINIA ENTEROCOLITICA ANTISERA

Yersinia enterocolitica (Y. enterocolitica) is a Gram-negative shortform bacillus belonging to family Enterobacteriaceae.

The Y. *enterocolitica* antisera are 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 are liquid products that contain agglutinins specific to each group shown on the vial label. Each antiserum is prepared by hyperimmunising healthy rabbits with Wauters' reference strains, and inactivating the serum at 56°C for 30 minutes. After removing the cross agglutinins by absorption, the serum is sterilised by filtration and sodium azide added at 0.08% w/v as a preservative.

### PRODUCTS

The following sera are provided as 2mL volumes in vials with a dropper attachment and are ready to use:

The complete set consists of 5 vials of the individual antisera: Polyvalent group O1 and O2

Group O3, group O5, group O8, and group O9 Each antisera is also available separately.

### INTENDED USE

The Yersinia enterocolitica Antisera are intended for the qualitative serological identification and screening of prepared Yersinia enterocolitica serotype bacterial cultures, using slide agglutination to detect the presence of bacterial antigens. Yersinia enterocolitica Antisera are intended for use by trained laboratory personnel.

### PRINCIPLE OF MEASUREMENT

When this reagent is mixed with a 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. Materials 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 are 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

- Suspend an amount of bacterial growth (3-5 times the amount of a match head) in 0.5mL physiological saline and use as antigenic suspension.
- Place a drop each of group O3, O5, O8, and O9 antiserum and physiological saline (30µL) as a control onto a cleaned glass slide partitioned into several parts with a glass pencil.
- 3) Place an antigenic suspension (5-10 $\mu$ L) onto the serum and physiological saline on the glass slide.
- 4) Mix the reagents by 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 with the reaction between antigenic suspension and physiological saline. Only strong agglutination observed within 1 minute 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 is 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 recognised as being pathogenic in humans, assessment of the

pathogenicity of the test organism should not depend solely on the O-grouping result, but 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.

#### Biotypes of Yersinia enterocolitica

Biochemical Property		Biotype						
		1B	2	3	4	5	6	
Lipase (Tween-esterase)	+	+	-	-	-	-		
Esculin / Slicin (24h)	±	-	-	-	-	-	-	
Indole	+	+	(+)	-	-	-	-	
Xylose	+	+	+	+	-	V	+	
Trehalose/No3	+	+	+	+	+	-	+	
Pyrazinamidase	+	-	-	-	-	-	+	
ß-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 tests 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 noncorresponding reference strains, macroscopic agglutination is not observed.

# PRECAUTIONS FOR USE AND HANDLING

# . General precautions

- 1) This test is for in vitro diagnostic use only.
- This kit should only be used by sufficiently trained lab staff.
  Handling precautions
  - All specimens, samples and containers coming into contact with samples should be treated as infectious.
  - If reagents come into contact with skin, mucous membranes or eyes, wash immediately with plenty of water.
  - Do not freeze the reagents nor use past the expiration date as this may result in poor reagent performance.
  - The reagent should be allowed to stand at 15-25°C for at least 30 minutes before use.
  - Used containers should not be used for other purposes.
  - 6) Sera with different production numbers should not be mixed.
  - 7) The reagents should be used according to the described procedures.
  - 8) The reagents 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

- The reagent contains 0.08% w/v sodium azide. Sodium azide may react with lead or copper pipes to form explosive heavy metal azides. The reagent should be disposed with a large amount of water.
- All specimens, 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.

### REFERENCES

- 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).

	Manufacturer
i	Consult instruction for use
IVD	For in vitro diagnostic use only
REF	Catalogue number
LOT	Batch code
X	Storage temperature limitation
52	Use by
LATEX	Contains or presence of natural rubber latex



# DebenDiagnosticsLtd

Unit 4, West Road, Ransomes Europark, Ipswich Suffolk, IP3 9FD, United Kingdom Tel. +44 (0) 1473 720869

Kingdom Tel. +44 (0) 1473 720869 Email: Info@debendiagnostics.co.uk Web: www.debendiagnostics.co.uk