

ANTISERUM YERSINIA ENTEROCOLITICA O:3**63501****ANTISERUM YERSINIA ENTEROCOLITICA O:9****63502****SEROTYPING OF *YERSINIA ENTEROCOLITICA* O:3 AND O:9****IVD****1- CLINICAL VALUE**

Yersinia enterocolitica responsible for gastrointestinal infections (enteritis), especially in children, and can secondarily induce complications affecting the joints (arthritis) or the skin (erythema nodosum).

2- INTENDED USE

These antisera are designed for the serological identification of *Y. enterocolitica* (O:3 and O:9) by the slide agglutination method.

3- PRINCIPLE

The test is based on agglutination, by specific sera, of bacteria possessing the corresponding antigens.

These antisera are obtained by immunizing rabbits with strains of *Y. enterocolitica* serogroups O:3 and O:9.

4- HOW SUPPLIED

- Antiserum *Yersinia enterocolitica* O:3, 2 ml dropper bottles (40 tests) code 63501
- Antiserum *Yersinia enterocolitica* O:9, 2 ml dropper bottles (40 tests) code 63502

5- STORAGE

Sera stored at +2-8°C in the absence of contamination are stable until the expiry date indicated on the kit (even when opened).

6- MATERIAL REQUIRED BUT NOT SUPPLIED

- Glass slide.
- Plastic or platinum inoculation loop.
- Physiological saline.

7- PRECAUTIONS FOR USE

- Always comply with current techniques and precautions concerning protection against microbiological hazards, for handling and elimination of material and biological products used for the agglutination reaction.
- Do not dilute reagents.

8- PROCEDURE

Serotyping is performed after identification of the species on a fresh, pure culture of *Y. enterocolitica* isolated on agar medium.

Perform a control test on the strain to be tested in physiological saline:

- Take one loop of culture.
- Suspend these bacteria in a drop of physiological saline, ensuring homogeneous suspension.

No agglutination should be observed with physiological saline. If agglutination is observed, it corresponds to a self-agglutinating strain and the test with antisera cannot be performed.

- Deposit 1 drop of immune serum on the slide.
- Take one loop of fresh, pure culture of *Y. enterocolitica*.
- Suspend these bacteria in the drop of serum, ensuring homogeneous suspension gradually adding bacteria to the serum.
- Shake the slide with a gently rotary movement.
- Examine the mixture with the naked eye over a dark surface or over a concave mirror.

9. INTERPRETATION OF THE RESULTS

A positive reaction corresponds to the appearance of agglutination in **less than one minute**.

10-TEST PERFORMANCES/QUALITY CONTROL

The activity of *Y. enterocolitica* O:3 and O:9 antisera is controlled with the following strains:

Strains	Results
<i>Yersinia enterocolitica</i> O:3 antiserum	
<i>Y. enterocolitica</i> O:3 W191	Agglutination
<i>Y. enterocolitica</i> O:3 E397/88	Agglutination
<i>Y. enterocolitica</i> O:9 W193	No agglutination
<i>Y. pseudotuberculosis</i> (pst I E620/85)	No agglutination
<i>Yersinia enterocolitica</i> O:9 antiserum	
<i>Y. enterocolitica</i> O:9 W193	Agglutination
<i>Y. enterocolitica</i> O:9 E470/89	Agglutination
<i>Y. enterocolitica</i> O:3 W191	No agglutination
<i>Y. pseudotuberculosis</i> (pst I E620/85)	No agglutination

11-MANUFACTURER'S QUALITY CONTROL

All reagents manufactured are prepared according to our Quality System, starting from reception of raw materials to final commercialization of the product. Each lot is submitted to quality control tests and is only released onto the market when it complies with predefined acceptance criteria. Records relating to production and control of each lot are kept by Bio-Rad.

12-LIMITS OF USE

- Identification of the bacterial species must be performed before determination of the serogroup, especially as *Yersinia enterocolitica* serogroup O:9 and Brucella share common antigens.
- Serotyping must be performed on colonies grown for less than 24 hours at an incubation temperature not exceeding 30°C.

13-REFERENCES

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