Shigella Polyvalent Agglutinating Sera

1. INTENDED USE

Shigella Polyvalent Agglutinating Sera are suitable for use in slide agglutination tests to identify Shigella cultures presumptively for epidemiological and diagnostic purposes. Antisera provide serological identification only; full identification of an organism must be made in conjunction with biochemical testing.

2. SUMMARY AND EXPLANATION OF THE TEST

Shigella dysenteriae, S. boydii, S. flexneri and S. sonneli can be differentiated on the basis of their reactions with specific antisera. The Remel range of polyvalent antisera covers S. dysenteriae types 1 to 10 (ZE02/R30163701), S. flexneri types 1 to 6, X and Y (ZF01/R30163801), S. boydii types 1 to 15 (ZG01/R30163901, ZG02/R30164001 and ZG03/R30164101) and S. sonnei phases 1 and 2 (ZH01/R30164201). As Shigella can be confused with some non-motile serotypes of E. coli (Alkaecens-Dispar group) an additional serum ZH05/R30164301 is available for differentiation.

3. PRINCIPLE OF THE PROCEDURE

Serological tests are based on the fact that antibodies in serum, produced in response to exposure to bacterial antigens, will react with their specific components. Serological tests based on the fact that antibodies in serum, produced in response to exposure to bacterial antigens, will remain their potency at least until the date shown on the bottle label.

4. REAGENTS

KIT CONTENTS

Shigella Polyvalent Agglutinating Sera  1 dropper bottle (2 ml)

ZE02/R30163701  Shigella dysenteriae  1-10
ZF01/R30163801  Shigella flexneri 1-6, x, y
ZG01/R30163901  Shigella boydii 1-6
ZG02/R30164001  Shigella boydii 7-11
ZG03/R30164101  Shigella boydii 12-15
ZH01/R30164201  Shigella sonnei 1 and 2

5. WARNINGS AND PRECAUTIONS

For in vitro diagnostic use only.

For professional use only. Please refer to the manufacturer’s safety data sheet and the product labelling for information on potentially hazardous components.

6. TEST PROCEDURE

Slide Agglutination Test

Step 1  Put two separate drops (40 µl) of saline on a glass slide. Emulsify portions of the culture under test with a loop in each drop of saline to give a smooth, fairly dense suspension.

Step 2  To one suspension add one drop (40 µl) of saline as a control and mix. To the other suspension add one drop (40 µl) of undiluted antiserum and mix.

Step 3  Rock the slide for one minute and observe for agglutination, which can be more easily seen by viewing against a dark background using indirect lighting. Discard the used slide for safe disinfection and disposal.

6. RESULTS

Agglutination should be strong and clearly visible within one minute.

There should be no visible agglutination in the control suspension; if agglutination is seen in the control, the suspension is not suitable for testing by this method.

8. QUALITY CONTROL

It is recommended to test the product, throughout its use, with known positive and negative cultures.