Key Code TSMX7807C

www.oxoid.com/ifu

Europe +800 135 79 135 US 1 855 2360 190

CA 1 855 805 8539 ROW +31 20 794 7071

# Shigella Polyvalent EN 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.

IVD For *in vitro* diagnostic use only. For professional use only.

## 2. SUMMARY AND EXPLANATION OF THE TEST

*Shigella dysenteriae, S. boydii, S. flexneri* and *S. sonnei* 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* (Alkalescens-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 agglutinate with bacteria carrying homologous antigens.

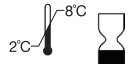
## 4. REAGENTS

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 |

### 4.1. DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also **Warnings and Precautions**




The sera should be stored at 2 to 8°C, under which condition they will retain their potency at least until the date shown on the bottle label.

AGGLUTINATING SERUM

**Shigella Polyvalent Agglutinating Sera**

Produced in rabbits and are preserved with 0.5% phenol. Each bottle, fitted with teat and dropper, contains 2 ml liquid and is supplied ready to use.

On storage some sera become slightly turbid. This does not necessarily indicate deterioration and normally it will not interfere with the results but the sera may be clarified by centrifugation or membrane filtration (0.45 µm) before use. Gross turbidity indicates contamination and such sera should be discarded.

## 5. WARNINGS AND PRECAUTIONS

Please refer to the manufacturer's safety data sheet and the product labelling for information on potentially hazardous components.

### 5.1. HEALTH AND SAFETY INFORMATION

5.1.1 Handle all bacteria according to appropriate local and statutory guidelines.

5.1.2 Non-disposable apparatus should be sterilised by any appropriate procedure after use, although the preferred method is to autoclave for at least 15 minutes at 121°C. Disposables should be autoclaved or incinerated.

5.1.3 Spillage of potentially infectious material should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a standard bacterial disinfectant or 70% alcohol. Materials used to clean spills, including gloves, should be disposed of as biohazardous waste.

5.1.4 Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

5.1.5 These reagents contain phenol. Although the concentration is low, phenol is known to be toxic by ingestion and skin contact. Avoid ingestion of the reagents. If any come in contact with skin or eyes wash the area extensively by immediately rinsing with plenty of water.

5.1.6 In accordance with the principles of Good Laboratory Practice it is strongly recommended that samples and reagents should be treated as potentially infectious and handled with all necessary precautions.

### 5.2. ANALYTICAL PRECAUTIONS

5.2.1 Do not use antisera beyond the stated expiry date. Microbiological contamination of the antisera must be avoided as this may cause erroneous results and reduce product life.

5.2.2 Do not modify the test procedure, incubation time or temperatures.

5.2.3 After use return sera to recommended storage temperature.

5.2.4 Do not use a microbiological loop to dispense the antisera.

## 6. SPECIMEN COLLECTION, TRANSPORT AND STORAGE

For details on specimen collection and preparation a standard text book should be consulted. The use of fresh cultures grown on non-selective media is recommended e.g. nutrient agar.

## 7. PROCEDURE

MATERIALS PROVIDED

See **Kit Contents**.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 0.85% saline.
2. Glass slides.
3. Microbiological loop and bunsen burner.
4. Light source over dark background.
5. Timer.

TEST PROCEDURE

**Slide Agglutination Test**

**Step 1** Put two separate drops (40 µl each) 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.

## 8. 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.

### 8.1. QUALITY CONTROL

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

| CODE / SPECIES | POSITIVE CONTROL | |
|---|---|---|
| ZE02/R30163701 *S. dysenteriae* 1-10 | N C T C 9955 | *Shigella dysenteriae* 5 |
| ZF01/R30163801 *S. flexneri* 1-6, x, y | N C T C 8522 | *Shigella flexneri* 4b |
| ZG01/R30163901 *S. boydii* 1-6 | N C T C 9771 | *Shigella boydii* 6 |
| ZG02/R30164001 *S. boydii* 7-11 | N C T C 9355 | *Shigella boydii* 9 |
| ZG03/R30164101 *S. boydii* 12-15 | N C T C 9363 | *Shigella boydii* 13 |
| ZH01/R30164201 *S. sonnei* 1,2 | N C T C 8219 | *Shigella sonnei* 2 |

If any antiserum shows agglutination with a known negative culture or shows no agglutination with a known positive culture it should be discarded.

### 8.2. INTERPRETATION OF RESULTS

Non-specific agglutination due to minor antigenic relationships or roughness may occur, the latter particularly with cultures taken from selective media. These non-specific reactions are usually slow to appear and if due to roughness will also be apparent in the control suspension.

## 9. LIMITATIONS OF THE PROCEDURE

The sera are made specific within the Shigella genus but reactions with organisms outside the Shigella genus may be found.

Serological tests used alone provide no more than presumptive identification and confirmatory biochemical identification tests must be performed[1,2].

Some isolates of Shigella and Alkalescens-Dispar possess K antigens which mask the O antigens. These capsular antigens (K) can be destroyed by heating at 100°C for two hours.

Before implementation of WGS (Whole Genome Sequencing), *Shigella flexneri* belonging to ST1753 was misidentified as *Shigella boydii*. This type of *Shigella flexneri* has a mutation which means that the *S. flexneri* O antigen is not expressed meaning the serology for *S. flexneri* in this instance is falsely negative.

## 10. EXPECTED RESULTS/PERFORMANCE CHARACTERISTICS

The ZE02/R30163701 antisera should show visible agglutination with *S. dysenteriae* types 1 to 10. The ZF01/R30163801 antisera should show visible agglutination with *S. flexneri* types 1 to 6, X and Y. The ZG01/R30163901, ZG02/R30164001 and ZG03/R30164101 antisera should show agglutination with *S. boydii* types 1 to 6, 7 to 11, and 12 to 15 respectively. The ZH01/R30164201 antisera should show agglutination with *S. sonnei* 1 and 2. See limitations of the procedure.

## 11. BIBLIOGRAPHY


1. **Edwards, P.R. and Ewing, W.H.** (1986). *Identification of Enterobacteriaceae,* 4th Ed., Elsevier Science Publishing Co. Inc., New York. Pages 135-172.
2. **Bopp, C.A.** *et al.* (1999). *Manual of Clinical Microbiology,* 7th Ed., American Society for Microbiology, Washington, D.C. Pages 459-474.

## 12. PACKAGING

REF ZE02/R30163701.....2 ml
ZF01/R30163801.....2 ml
ZG01/R30163901.....2 ml
ZG02/R30164001.....2 ml
ZG03/R30164101.....2 ml
ZH01/R30164201.....2 ml

## 13. SYMBOL LEGEND

| | |
|---|---|
| REF | Catalogue Number |
| IVD | In Vitro Diagnostic Medical Device |
|  | Consult Instructions for Use (IFU) |
|  | Temperature Limitations (Storage temp.) |
|  | Contains sufficient for <N> tests |
|  | Contains or prescence of natural rubber latex |
| TITRE | Last dilution showing positive agglutination |
| LOT | Batch Code (Lot Number) |
|  | Use By (Expiration Date) |
|  | Manufactured by |

CE

IFU X7807C Revised January 2021 Printed in the UK

Remel Europe Ltd.
Clipper Boulevard West, Crossways
Dartford, Kent, DA2 6PT
UK

For technical assistance please contact your local distributor.