



## WIDAL POSITIVE CONTROL

### INTENDED USE

**WIDAL POSITIVE CONTROL** can be used to validate the performance of WIDAL antigen suspensions (such as TYDAL® / TYPHOCHEK®/VITAL WIDAL®).

### SUMMARY

Enteric fever occurs when pathogenic microorganisms like *S. typhi*, *S. paratyphi A*, *S. paratyphi B*, *S. paratyphi C* infect the human body. During the course of disease, the body responds to this antigenic stimulus by producing antibodies whose titre rises slowly in early stages, to a maxima and then slowly falls till it is undetectable. Antibodies to *Salmonella* organisms may be detected in the patient serum from the second week after onset of infection. Information regarding the titres and whether or not they are rising or falling can be obtained by performing serological tests using WIDAL antigen suspensions.

### REAGENT


The **WIDAL POSITIVE CONTROL** contains ready to use standardized Goat antiserum with polyspecific antibodies having specific reactivity towards *S. typhi* 'O' and 'H' antigens, *S. paratyphi* 'AH' and 'BH', *S. paratyphi* 'AO' and 'BO', *S. paratyphi* 'CO' and 'CH' antigens and is useful in the validation of the performance of Widal reagents.

Each batch of controls undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance.

### REAGENT STORAGE AND STABILITY

1. Store the control reagent at 2-8°C. DO NOT FREEZE. Keep the control reagent away from direct sunlight.
2. The shelf life of the control reagent is as per the expiry date mentioned on the control vial label. Do not use beyond expiry date.
3. Once opened the shelf life of the control reagent is as described on its vial label, provided it is not contaminated.

### PRESENTATION

|   |   |           |
|---|---|-----------|
| REF   |   | 1 ml      |
|  |   | 110100001 |
| Control   | + | 1 ml      |
| PACKAGE INSERT  |   | 1 No.     |

### ADDITIONAL MATERIAL REQUIRED

Stop-watch, Isotonic saline, Glass slide with clear/white background, appropriate Pipettes/Micropipettes, Mixing sticks & a High intensity direct light source.

Quantitative method: Timer, Kahn tubes / test tubes, Pipettes (0.1ml, 1ml), Physiological saline, Incubator (37°C), Test tube rack.

### PRINCIPLE

The **WIDAL POSITIVE CONTROL** is mixed with the WIDAL antigen suspensions to be tested and allowed to react. Specific reactivity of *Salmonella* antigens if present in the antigen suspensions will produce an agglutination reaction. No agglutination indicates the deterioration of the antigen suspensions used for analysis.

### NOTE

- (1). In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- (2). The control reagent contains 0.1 % sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
- (3). The Positive control can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the Positive control be verified with the known WIDAL antigen suspensions.
- (4). Only a clean and dry glass slides / tubes must be used. Clean the glass slides / tubes with distilled water and dry.
- (5). **WIDAL POSITIVE CONTROL** is not from human source hence contamination due to HBsAg and HIV is practically excluded.
- (6). Do not use damaged or leaking reagents.

### TEST PROCEDURE

Bring all reagents to room temperature before testing.

Shake and mix **WIDAL POSITIVE CONTROL** well before dispensing.

#### Slide Screen Method

1. Place one drop of **WIDAL POSITIVE CONTROL** onto a reaction circle of the glass slide.
2. Place 50 µl of physiological saline onto the next reaction circle of the glass slide.
3. Add one drop of appropriate test reagent (appropriate WIDAL antigen suspensions) to the reaction circles containing Positive control & physiological saline.

4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Rock the slide gently back and forth, and observe for agglutination **macroscopically at one minute.**

**Tube Test Procedure**

1. Take appropriate number of sets (as required; one set for each antigen suspension) of 8 Kahn tubes / test tubes and label them 1 to 8.
2. Pipette into tube No. 1 of all sets 1.9 ml of physiological saline.
3. To each of the remaining tubes (2 to 8) add 1 ml of physiological saline.
4. To tube No. 1 of all sets add 0.1 ml of Positive control to be tested and mix well.
5. Transfer 1.0 ml of the diluted Positive control from tube No. 1 to tube No.2 and mix well.
6. Transfer 1.0 ml of the diluted Positive control from tube No. 2 to tube No.3 and mix well. Continue this serial dilution till tube No. 7 in each set.
7. Discard 1.0 ml of the diluted Positive control from tube No.7 of each set.
8. Now the dilutions of the serum sample achieved from tube No. 1 to 7 respectively in each set is as follows: 1:20, 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280. Tube No. 8 in all the sets, serves as a negative control.
9. To all the tubes (1 to 8) of each set add one drop of the respective well mixed WIDAL antigen suspensions from the reagent vials and mix well.
10. Cover the tubes and incubate at 37°C (approximately 18 hours).
11. Dislodge the sedimented button gently and observe for agglutination.

**INTERPRETATION OF RESULTS**

**Slide Screen Method**

Agglutination is a positive test result and indicates that the WIDAL antigen reagents are working as per specifications. No agglutination is a negative test result and indicates deterioration of the WIDAL antigen suspension.

**Quantitative Method**

The titre of the patient serum using WIDAL antigen suspensions is the highest dilution of the Positive control that gives a visible agglutination.

**REMARKS**

(1). Turbid and contaminated controls should not be used for testing. (3). After usage the control should be immediately recapped and replaced at 2-8°C. (2). Control vials that have leakage/ breakage problem should be discarded. (3). Only qualified and well trained staff should use the reagents. (4). The performance of the positive control should be validated periodically using WIDAL antigen suspensions.

**PERFORMANCE CHARACTERISTICS**

The positive control antisera should produce 1+ or greater agglutination in the slide test at one minute when tested with the WIDAL antigen suspensions.








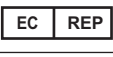




**WARRANTY**

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

**BIBLIOGRAPHY**

(1). Cruickshank R., (1982), Medical Microbiology, 12th Edition, 403. (2). Felix A., (1942), Brit. Med. J., 11, 597-600. (3). Data on file: Tulip Diagnostics (P) Ltd.

**SYMBOL KEYS**

|  |  |  |  |
|--|--|--|--|
|  Temperature limitation |  Manufacturer                 |  Contains sufficient for <n> tests  |  Batch Number/Lot Number                              |
|  Use by                 |  Consult Instructions for use |  This way up                        |  Authorised Representative in the European Community |
|  Date of Manufacture    |  Catalogue Number             |  In vitro Diagnostic Medical Device |  Positive control                                    |

  
Manufactured by  
**T TULIP DIAGNOSTICS (P) LTD.**

**Registered Office**  
GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO  
SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA.  
Website: www.tulipgroup.com E-mail: sales@tulipgroup.com

**Manufacturing Unit**  
PLOT NO. UTILITY VIII, PHASE III B, VERNA IND.  
ESTATE, VERNA, GOA - 403 722, INDIA.



CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

WPC/0323/VER-04