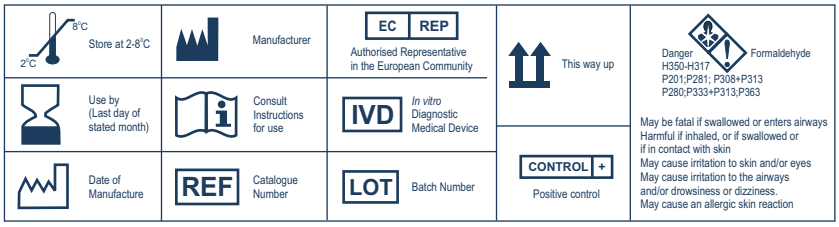
SBio Widal Positive Control

Polyspecific serum control reactive with *S. typhi* and *S. paratyphi* antigens

REF	90520001
	1 ml



INTENDED USE

SBIO WIDAL POSITIVE CONTROL can be used to validate the performance of WIDAL antigen suspensions (*S.typhi* and *S.paratyphi*).

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

SBIO 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.

ADDITIONAL MATERIAL REQUIRED

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

PRINCIPLE

SBIO 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). **SBIO 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 **SBIO WIDAL POSITIVE CONTROL** well before dispensing.

Slide Screen Method

1. Place one drop of **SBIO 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**.

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.

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^{0}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.

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot No. Utility VIII, Phase III B, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:

Singapore Biosciences PTE Ltd.
11 Yishun Street 51, #04-23,The Criterion,
Singapore 767971

EC REP

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

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