CE

TYPHOCHEK®

WIDAL ANTIGEN SET / ANTIGENS FOR TUBE TESTS

INTENDED USE

TYPHOCHEK® is a Widal tube agglutination test that detects the presence the serum agglutinins (O, H) found in the serum of patients with typhoid and paratyphoid fever.

SUMMARY

Enteric fever occurs when pathogenic microorganisms like *S. typhi, S. paratyphi A, S. paratyphi B* and *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 TYPHOCHEK® antigen suspensions. Usually tube titres of 1:80 and above are taken as diagnostically significant, however for endemic areas higher cut-offs may need to be established.

REAGENT

TYPHOCHEK® contains ready to use coloured, smooth antigen suspensions of the bacilli; *S. typhi 'O', S. typhi 'H', S. paratyphi 'AO', S. paratyphi 'BO', S. paratyphi 'AH', S. paratyphi 'BH', S. paratyphi 'CH' and* S. *paratyphi 'CO'*. TYPHOCHEK® reagents are versatile and standardized for use in a standard tube test procedure for the detection of *S. typhi* and S. *paratyphi* antibodies in the patient's serum.
Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

REAGENT STORAGE AND STABILITY

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

PRESENTATION

Σ	4 x 50 ml	50 ml	50 ml	50 ml	50 ml	50 ml	50 ml	50 ml	50 ml
REF	105310450	105320050	105330050	105340050	105350050	105380050	105360050	105370050	105390050
Antigens	O, H, AH, BH	O	H	AO	BO	CO	AH	BH	CH
PACKAGE INSERT	1	1	1	1	1	1	1	1	1

ADDITIONAL MATERIAL REQUIRED

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

PRINCIPLE

When the coloured, smooth suspension of attenuated TYPHOCHEK® antigen suspensions are incubated with the patient serum, anti-S*almonella* antibodies present in the patient's serum react with the antigen suspensions to produce agglutination.
Agglutination is a positive test result, indicating presence of *Salmonella* antibodies in the patient's serum. No agglutination is a negative test result indicating absence of *Salmonella* antibodies in the patient's serum.

NOTE

(1). In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use. (2). The *S. typhi 'O', S. paratyphi 'CO'* reagents contains 0.5% Phenol, *S typhi 'H', S. paratyphi 'AH', S. paratyphi 'BH', S. paratyphi 'CH'* reagents contain 0.3% Formaldehyde and *S. paratyphi 'AO', S. paratyphi 'BO'* reagents contain 0.7% Ethanol along with 0.1% Sodium azide as preservative. Avoid contact with skin and mucosa. Do not breathe vapour. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Sodium azide may react with lead and copper in plumbing and form highly explosive metal oxides, on disposal flush with large quantities of water. (3).The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls. (4). Shake the reagent vials well before use to disperse the antigen suspension uniformly and improve test readability. (5). It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop. (6). Only a clean and dry glass tubes must be used. Clean the glass tubes with distilled water and dry. (7). TYPHOCHEK® antigen suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded. (8). Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

(1).No special preparation of the patient is required prior to sample collection by approved techniques. Do not use haemolysed and turbid samples. (2). Clean and dry glassware free from detergents must be used for sample collection. (3). Do not heat inactivate the serum. (4).Though freshly collected serum is preferable, store samples at 2-8°C in case of delay in testing, for upto 72 hours.

TEST PROCEDURE

1. Bring reagents to room temperature before testing.
2. Shake and mix antigens well before dispensing.
3. Carefully label test tubes for sample and reagent identity when more than one antigens is used during test procedure.

STANDARD TUBE TEST METHOD

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 0.9 ml of isotonic saline.
3. To each of the remaining tubes (2 to 8 of each set) add 0.5 ml of isotonic saline.

4. To tube No. 1 of all sets add 0.1 ml of serum sample to be tested and mix well.
5. Transfer 0.5 ml of the diluted serum sample from tube No. 1 to tube No.2 and mix well.
6. Transfer 0.5 ml of the diluted serum sample from tube No. 2 to tube No.3 and mix well. Continue this serial dilution till tube No. 7 in each set.
7. Discard 0.5 ml of the diluted serum from tube No.7 of each set.
8. Tube No. 8 in all the sets, serves as a saline control.
9. To all the tubes of the respective sets add 0.5 ml of the respective TYPHOCHEK® antigen suspensions. Mix well.
10. This will give final dilutions in tube 1 to 7 as 1:20, 1:40, 1:80, 1: 160, 1: 320, 1: 640, 1: 1280.
11. Cover and incubate at 37°C overnight (approximately 18 hours).
12. Dislodge the sedimented button gently and observe for agglutination macroscopically.

INTERPRETATION OF RESULTS

The titre of the patient serum using TYPHOCHEK® antigen suspensions is the highest dilution of the serum sample that gives a visible agglutination.

REMARKS

(1). Positive results obtained in the slide test should be confirmed with the tube test to establish whether the titres are diagnostically significant or not. (2).TAB vaccinated patients may show a high titre of antibodies to each of the antigens. Similarly, an amnestic response to other vaccines and unrelated fevers in case of patients who have had prior infection or immunization may give a false result. (3). Agglutinins usually appear by the end if the first week of infection, blood sample taken earlier may give a negative result.(4). A rising titre is more significant than a single high titre. It is therefore necessary to evaluate two or more serum samples taken at 4- to 6- day intervals after the onset of the disease.(5). 'O' being a somatic antigen brings about a coarse, compact, granular agglutination whereas 'H' being a flagellar antigen brings about larger, loose, flocculant agglutination.(6). While the 'O' antigen is species specific, the 'H' antigen is specific to the serotype. (7). Generally antibody titres of 1:80 or more are considered clinically and diagnostically significant. However the significant titre may vary from population to population and needs to be established for each area.(8). Any deviation in test procedure could result in variable results. (9). Since techniques and standardization vary from lab to lab one tube difference in tube titres can be expected. (10). Use a separate disposable tip for each sample to prevent cross contamination. (11). After usage the antigen suspension should be immediately recapped and replaced at 2-8°C. (12). Do not interchange reagent caps. (13). It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis. (14). The performance of the reagents should be validated occasionally using the positive control and negative controls.(15). Apart from the pattern of sedimented antigens in the tube test method decreases in opacity as compared to the saline control must also be considered while judging the degree of agglutination. (16). Turbid and contaminated sera should not be used for testing

PERFORMANCE CHARACTERISTICS

(1).The positive control antisera (available as WIDAL POSITIVE CONTROL, REF 110100005 and 110100001) should produce 1+ or greater agglutination at 1: 80 in the tube test when tested with the TYPHOCHEK® antigen suspensions. (2). The negative control should show no agglutination with any of the TYPHOCHEK® antigen suspensions. (3). Generally accepted performance characteristic of this type of test is 70% specificity and sensitivity. (4). Reproducibility of TYPHOCHEK® antigen suspensions is 100% (+/- one double dilution).

WARRANTY

This product is designed to perform as described on the label and 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	Σ	Contains sufficient for <n> tests
	Use By		Consult Instructions for use		This way up
	Date of Manufacture	REF	Catalogue Number	PS	Production Site
LOT	Batch Number/ Lot Number	IVD	*In vitro* Diagnostic Medical Device	EC REP	Authorised Representative in the European Community

Danger
H350-H317
P201;P281; P308+P313
P280;P333+P313;P363
Formaldehyde

May be fatal if swallowed or enters airways
Harmful if inhaled, or if swallowed or if in contact with skin
May cause irritation to skin and/or eyes
May cause irritation to the airways and/or drowsiness or dizziness.
May cause an allergic skin reaction

Manufactured by

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