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WIDAL Antigen

Diagnostic reagent set (Slide tests) for the in-vitro qualitative screening and semi-quantitative determination of enteric fever antibodies present in infected human serum manually.

REF: BS.1/WDC01.100.0100	100 test/Antigen	REF: BS.1/WDC6.005.0150	150 test/Antigen
REF: BS.1/WDH01.100.0100	100 test	REF: BS.1/WDC8.005.0200	200 test/Antigen
REF: BS.1/WDC04.005.0100	100 test/Antigen		

CLINICAL SIGNIFICANCE [1-2]

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 titer rises slowly in early stages, to maximum 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 titers and whether or not they are rising or falling can be obtained by performing serological tests using WIDAL antigen suspensions.

METHOD PRINCIPLE [2]

When the colored, smooth, attenuated WIDAL antigen suspensions are mixed / incubated with patient serum, anti-salmonella antibodies present in the patient serum react with the antigen suspensions to give agglutination. Agglutination is a positive test result, indicating presence of anti-salmonella antibodies in the patient serum. No agglutination is a negative test result indicating absence of anti-salmonella antibodies.

REAGENT COMPOSITION

Reagents:	Composition
WIDAL Antigen	Concentrated, smooth antigen suspensions of: - S. typhi 'O' - S. typhi 'H' - S. paratyphi 'AH' - S. paratyphi 'BH' - S. paratyphi 'AO' - S. paratyphi 'BO' - S. paratyphi 'CH', - S. paratyphi 'CO'
Positive Control * ***** Only with REF: BS.1/WDC4.005.0100 BS.1/WDC6.005.0150 BS.1/WDC8.005.0200	Poly-specific positive control reactive with WIDAL antigens.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent (R) contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment.

For further information, refer to the WIDAL antigen reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien WIDAL antigen reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration

The ***BioScien*** WIDAL 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 controls.

SPECIMEN COLLECTION AND PRESERVATION [2]

Clean and dry glassware free from detergents must be used for sample collection, freshly collected serum is preferable. Specimen should be free of turbidity and hemolysis. Fresh, uncontaminated serum samples may be stored at 2-8°C in case of delay in testing up to 72 hours.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Physiological saline (as negative control)

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix antigens well before dispensing

Qualitative procedure

1. Identify each reaction circle of the slide test to make one positive control for each type, one negative control and the desired number of samples respectively.
2. Place one drop of positive control reagents, 50 µl of physiological saline and one drop of patient's serum to be tested onto each reaction circles.
3. Add one drop of appropriate WIDAL antigen suspension to the reaction circles containing positive controls, physiological saline and patient's serum.
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.

Semi-quantitative method

1. Dispense 80 µl, 40 µl, 20 µl, 10 µl, and 5 µl of patient serum to be tested onto 5 different reaction circles on the slide. The corresponding titers obtained will be 1:20, 1:40, 1:80, 1:160, and 1:320 respectively.
2. Continue with steps 3-5 of the qualitative procedure.

Note: This method is recommended for obtaining quick approximate titers only.

READING AND INTERPRETATION

	Qualitative procedure
Positive	Agglutination as indication for the presence of corresponding antibody in the patient's serum.
Negative	No agglutination as indication for the absence of corresponding antibody in the patient's serum.
	Semi-Quantitative procedure
Titer	The titer of the patient serum corresponds to the visible agglutination in the test circle with the smallest amount of serum sample.

QUALITY CONTROL

The positive controls have been included with the test kit to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed, the reagent should not be used. For more information please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision (reproducibility and repeatability): Precision of WIDAL antigen suspensions is 100% (+/- one double dilution).

Analytical sensitivity: Accurate titer determination of the reference material, under the described assay conditions.

Prozone effect: No prozone effect was detected up to titers 1/160.

Diagnostic sensitivity: 70 %.

Diagnostic specificity: 70 %.

LIMITATIONS OF PROCEDURE

1. The results of this test ***should not*** be used as a single diagnostic tool to make a clinical diagnosis. Instead, the test results must be evaluated together with other clinical findings and observed symptoms to aid in the final diagnosis.
2. Temperature of the reagents and specimens is critical to test outcome.
3. The negative control should show no agglutination with any of the WIDAL antigen suspensions.
4. WIDAL antigen suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded.
5. Accessories provided with the kit only must be used for optimum results.
6. Do not use damaged or leaking reagents.
7. TAB vaccinated patients may show a high titer 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.
8. Agglutinins usually appear by the end of the first week of infection, blood sample taken earlier may give a negative result.
9. A rising titer is more significant than a single high titer. It is therefore necessary to evaluate two or more serum samples taken at 4- 6 days intervals after the onset of the disease.
10. 'O' being a somatic antigen brings about a coarse, compact, granular agglutination whereas 'H' being a flagella antigen brings about larger, loose, flocculent agglutination.
11. While the 'O' antigen is species specific, the 'H' antigen is specific to the serotype.
12. False positive results are likely if the test is read more than one minute after mixing on the slide test.
13. Use a separate disposable tip for each sample to prevent cross contamination.
14. After usage the antigen suspension should be immediately recapped and replaced at 2-8 C.

REFERENCES

1. Cruickshank R., (1982), Medical Microbiology, 12th Edition, 403.
2. Felix A., (1942), BritMed.J.,11,597.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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CE