AM 5680-K

Invitro diagnostic Medical device License No. 14-2857

(in 1 vial)

ASAN Salmonella H Antigen Group d

Principle of measurement

Asan Salmonella H Antigen is a suspension that chemically deautomated and killed an internationally approved strain called Salmonella typi. This suspension is used in slide and tube agglomeration reactions that detect antibodies that mean a certain thermoactive state. The Rapid slide test is a screening test for detecting agglomerates, while the tube test is a process for quantifying agglomerates. Therefore, it is necessary to retest the sera showing a positive result in the rapid slide test as a tube test to determine its titer.

Efficacy and effectiveness

Antibodies detection of Salmonella H Antigen d in human serum

Raw materials and their quantity

Salmonella typhi About 1.8 x1010	cells/mL
Formaldehyde	5 g/L
Crystal violet	0.02g/L
NaCl·····	· 8.5g/L
Thymerosal·····	0.1g/L

Appearance

Blue bacterial suspension

Specimen collecting

Collect specimen 5~10mL of whole blood aseptically
 Coagulate the blood and collect the paste pipette serum. If red blood cells have not been removed from the serum, centrifuge them and remove them cleanly.

Usage and Capacity

1. Rapid Slide Test

- Prepare glass slides and paper slides. Clean the glass plate thoroughly and dry it before use.
- Drop 80, 40, 20, 10, and 5^{μℓ} of serum into each column of the slide using a pipette.
- Shake the antigen well and drop one drop each on each serum on the slide.
- 4) Mix them with mixers from $5\mu\ell$ side to $80\mu\ell$ side.
- 5) Hold the slide with both hands and slowly rotate it 15 to 20 times, and observe the agglomeration reaction on an appropriate light source within 1 minute.

2. Macroscopic tube test

Dilute the antigen solution by 1/20 with 0.85% NaCl and use it as an antigen for the test tube test method. Continuous dilution of serum to be tested is manufactured by the following method.

- Prepare 8 test tubes (12 mm x 75 mm) for each serum to be examined.
- Add 0.9mL of 0.85% NaCl to the first test tube in each row and 0.5mL to the remaining test tubes.
- Add 0.1 mL of serum to the first test tube containing 0.9 mL of Nacl solution.
- After mixing well with pipette, transfer 0.5mL to test tube 2 and mix thoroughly.
- 5) Continue to transfer 0.5mL of the serum dilution solution to test tube 7 and mix it sufficiently. Then, take 0.5mL of the solution from test tube 7. Test tube 8 is a control antigen test tube.
- Add 0.5mL of the required antigen to each of the eight test tubes. Shake enough to mix antigen and anti-serum.
- React in the 50°C antigen water tank for 1 hour and observe.

Reading the result

- Widal's titer as follows;
- S.typhi O is 1:160, S.typhi H is 1:320

1. Rapid Slide Test

- The degree of agglomeration is recorded as follows, and refer to Table 1.
 - 4+ : 100% agglomeration of microorganisms
 - 3+ : About 75% agglomeration
 - 2+ : About 50% agglomeration
 - 1+ : About 25% agglomeration
 - ±: Little bit agglomeration
 - : No agglomeration

- The titer of the serum is recorded as the dilution of the sample that elicits a response of at least 2+ (approximately 50% aggregation).

- In the slide test method, prozone reactions may occur in some cases, so it is recommended to test at all dilution multiples, and when it is expected to be prozone reactions, dilute serum by 1/20th with saline and retest.

<Table 1> Calculation of the dilution of serum and indication of the agglutination response

_	Dilution	Read	ction
Serum Q'ty(⊯l)	ratio of	Specimen	Specimen
	serum	1	2
80	1:20	3+	4+
40	1:40	2+	3+
20	1:80	1+	2+
10	1:160	-	1+
5	1:320	-	-
Serun	n titer	1:40	1:80

2. Macroscopic tube test

-Using a fluorescent lamp on a black background, record the degree of agglomeration reaction as follows and refer to Table 2

- 4+ : 100% agglomeration of microorganisms, and the supernatant is transparent
- 3+ : About 75% agglomeration, and supernatant is little bit cloudy
- 2+ : About 50% agglomeration, and supernatant is usually cloudy.
- 1+ : About 25% agglomeration, and supernatant is cloudy.
- No aggregation is visible and the microorganism remains a cloudy suspension, and this reaction is observed in Test Tube 8.

- The titer of the serum is recorded as the dilution of the sample that elicits a response of at least 2+ (approximately 50% accregation).

<Table 2> Calculation of dilution factor of serum and notation of agglutination reaction

Dilution ration of	Reaction		
serum	Specimen 1	Specimen 2	
1:20	3+	4+	
1:40	2+	4+	
1:80	1+	4+	
1:160	-	4+	
1:320	-	3+	
1:640	-	2+	
1:1280	-	1+	
Serum titer	1:40	1:640	

Precautions to use

- 1) Do not use it other than in vitro diagnostics purpose
- 2) Specimens should be transparent and free from fat.
- 3) Test has to be done under non-heated condition because non heat-registant agglutinin is destroyed when specimens are decomplementation by heat, 4) Shake ti well before using to maintain uniform
- suspension 5) Do not use antigens that show a positive
- b) Do not use antigens that show a positive reaction in negative serum or spontaneous aggregation in the antigen solution itself.
 6) When the antigen solution is affected by the
- b) When the antigen solution is affected by the freezing temperature during storage, it causes self-aggregation, so it should be prevented from freezing.
- Before testing, all reagents and instruments should be kept in room temperature in case of slide testing.
- 8) Please interpret the agglutination reaction within 1 minute in the case of slide test.

9) In case of tube test, avoid mixing the sample

too vigorously, as foaming during mixing will result in denaturation of the agglutinin.

- 10) In the test tube test method, it is important to keep the specified reaction time and temperature, and when using a constant temperature water bath, place it in a position where mechanical vibration does not affect the reaction.
- Evaporation of the reactants may occur upon exposure to heat and may give false positives, so it is important to ensure that the reactants do not evaporate.
- 12) Before reading in an in vitro test, read carefully while leaving the test tube unshaken.
- 13) It is necessary to observe the difference in the degree of aggregation by simultaneously testing several sera obtained at different times from the same patient.
- 14) The slide test method is used for screening purposes only, and a positive result of the slide test method must be confirmed by a tube test method.
- 15) A patient's infection diagnosis should be made comprehensively along with the patient's condition, clinical symptoms, and other diagnostic methods. Serum may show a non-specific positive reaction.
- 16) Even if the antibody test is positive, be careful as it may not reflect the current Salmonella infection status.

Storage conditions and expiry dates

Refrigerated storage (2-8°C), 12 months from the date of manufacture

Packing specifications

5mL

This product is manufactured under our strict quality control. Do not use products that have expired at the time of purchase or that have been altered, discolored or soiled.

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