

SALMONELLA TYPHI H MACRO

Determination of antibodies associated with Salmonella Typhi H infections by coloured bacterial suspension in test-tube

TEST SUMMARY

The Antibodies associated with Salmonella Typhi H infections cause agglutination of inactive bacteria present in suspension. The intravital colouring permits an easier reading of agglutination formation.

SAMPLES

Serum. Stability 6 days at 4°C.

REAGENTS

Suspension: Coloured intravital inactive bacterial suspension; conservative and stabilizer.

REAGENTS PREPARATION

Reagents are ready for the use.

The bacterial suspension must be resuspended with much care, shaking many times by inversion. Stability: the components of this kit will remain stable until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution. Automatic micropipette. Normal laboratory equipment.

PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

PROCEDURE

In a 8 tubes serie (12 x 100 mm) dilute the serum in the first 7 with physiologic solution as indicated in the following table. Using the same pipette (inspiring and discharging many times) mix carefully content of the second tube and transfer 500 µl in the following tube etc. Discharge 500 µl from last tube (tube n°7).

Test-tubes	1	2	3		7	Susp. Contr.		
Physiologic	900 µl	500 µl	500 μl		500 µl	500 μl		
Sample	100 μΙ	500 μl from 1	500 μl from 2	•••	500 μl from 6			
Discharge 500 μl from last test-tube								
Bacterial suspension	500 μΙ	500 μl	500 μΙ		500 μΙ	500 μΙ		
Titre	1:20	1:40	1:80		1:1280			
Shake tubes by a sweet movement. Incube at 37°C for 16-18 h or at 22°C for 2 days.								

RESULTS INTERPRETATION

Being given the intravital colouring of suspension, it's possible to effect a preliminary reading without shake the tubes:

A coloured bottom with a clear point shape, on the tube bottom, indicates negativity.

An agglutinate that cover all the tube bottom indicates a clear positivity, while, a no uniform agglutinate with a bottom in the centre, on the tube bottom, indicate a feeble positivity.

The serum titre is given by a high dilution in which there is a feeble positivity.

Proceed then with a light shaking of tubes:

Shake before the 8th tube (suspension control) to can characterize the suspension, then shake tubes that contain the sample and value the precipitate's behaviour as regards that of suspension's control.

The negativity is given by absence of agglutinates (the same behaviour as regards that suspension's control), positivity shows, on the contrary, the presence of agglutinates always as bigger as the positivity is greater.

The agglutination of somatic component has an uncouther appearance and persists also after the shaking, while the ciliary component has a flaky appearance and tends to dissolve by shaking.

The serum titre is given by a higher dilution in which there is a feeble positivity.

DIAGNOSTIC VALUES

Titres until 1:40 are considered negative; from 1:80 to 1:160 are suspect, and from 1:320 are positive.

It is a distinctive sign for the infection diagnosis the significant increase of titre between examinated samples after some days.

NOTES

 If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION/QUALITY CONTROL

It's advisable the execution of a quality internal control. In order to do this, are available by request the following control sera.

BS0001

3 x 0,5 ml

Positive Control Salmonella, Brucella, Proteus

TEST PERFORMANCE

Sensitivity

In presence of high antibodies titres, phenomenon of prozone can happen, therefore positivity is absent for low dilutions also being present for higher dilutions.

Specificity

A comparison with an available commercial method gave following results on 50 samples compared, giving a specificity = 100%.

		LTA		
S		+	-	тот.
COMPETITORS	+	17	0	17
OMPE	-	0	33	33
ŏ	тот.	17	33	50

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE MA00100

S. typhi H macro suspension 1 x 20 ml

CODE MA00105

S. typhi H macro suspension 5 x 20 ml

REFERENCES

Widal F. – Bull. Men. Soc. Med. Hop de Paris – 6;

26 (1986).

Rose N.R., Friedman H. – Manual of clinical Immunology – American Society for Microbiology, II ed.

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SYMBOLS

IVD Only for IVD use

LOT Lot of manufacturing

REF Code number

Storage temperature interval

Expiration date

Warning, read enclosed documents

Read the directions

Biological risk

Mod. 01.06 (ver. 2.2 - 29/10/2007)

