SPECTRUM

The Creative Approach to Bioscience

Antistreptolysin O Titre (ASOT)

A rapid latex slide test for the detection of antistreptolysin O antibodies in serum

REF: 510 001 50 test (Complete Kit)
REF: 510 002 100 test (Complete Kit)

REF: 510 003 50 test (latex with positive control)
REF: 510 004 100 test (latex with positive control)

REF: 510 005 50 test (latex only)
REF: 510 006 100 test (latex only)

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

Intended Use

Rapid latex agglutination test for the qualitative screening and semi-quantitative determination of antistreptolysin O (ASO) antibodies in human serum.

Background

In infections caused by ß-hemolytic streptococci, Streptolysin O is liberated from the bacteria stimulating production of antistreptolysin O (ASO) antibodies. The extent and degree of the infection can be monitored by measuring the levels of these antibodies. Increase in ASO titre generally occurs one to four weeks after onset of infection with β-hemolytic streptococci Group A. As the infection subsides, the titre declines and returns to normal levels within six months. If the titre does not decrease, a recurrent or chronic infection may exist.

Test Principle

Spectrum ASO latex reagent is a suspension of polystyrene particles sensitized with streptolysin O. When the latex reagent is mixed with a serum containing antibodies to streptolysin O, visible agglutination occurs. The latex reagent has been produced so that agglutination will take place only when the level of antibodies to streptolysin O is greater than 200 IU/ml.

Reagents

Spectrum ASO latex kit contains the following reagents:

Latex Reagent
A suspension of polystyrene latex particles in glycine-saline buffer pH: 8.6 ± 0.1, coated with streptolysin O.

Positive Control Serum (bottle with red cap):
Is prepared from a stabilized human serum pool containing more than 200 IU/ml antistreptolysin O. Both reagents contain 0.9 g/L Sodium azide as a preservative.

Negative Control Serum (bottle with white cap):
Reagent contain 0.9 g/L Na azide as a preservative.

Slides

Note: Negative Control Serum and Slides are only included in Complete Kits REF: 510 001 (50 test) and REF: 510 002 (100 test).

Storage and Stability

The reagents are stable up to the expiration date specified when stored at 2 – 8 ^{o}C.Open vials are stable for 6 months if contamination is avoided.

Precautions and Warnings

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive. No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

Deterioration

Latex reagent has a white uniform appearance after shaking ,reagent should be discarded in case of visible clumping.Do not use the latex reagent or controls in case of contamination.

Specimen Collection and Preservation

Use only serum specimens , plasma samples are not suitable for the test. Serum samples can be stored for 24 hrs at 2 – 8^{o}C, for longer storage it is recommended to store the samples at -20^{o}C.

Procedure

Qualitative Test (Screening)

1. Bring all reagents and specimens to room temperature.
2. Place one drop (50 µl) of the positive control and (50 µl)of the patient serum into separate circles on the glass slide.
3. Shake the ASO latex reagent gently and add one drop (45 µl) on each circle next to the sample to be tested and control.
4. Mix well using disposable stirrer spreading the mixture over the whole test area and tilt the slide gently. Agitate for about 2 minutes with rotator or by hand and observe for the presence or abscence of agglutination.

Results and Interpretation

Negative result:
No agglutination of the latex particles suspension within two minutes.

Positive result:
An agglutination of the latex particles suspension will occur within two minutes, indicating an ASO level of more than 200 IU/ml.

Semi-Quantitative Test

1. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc) in 0.9 g/L saline solution.
2. Place one drop of positive control on slide. Do not attempt to dilute the ASO positive control serum for comparative or other purposes as no correlation exists between actual titre of the control and titre of unknown sera.
3. Place 50 µl of each serum dilution individually in successive circles on the slide and proceed as in screening methodology.

Results and Interpretation

The serum ASO titre can be defined as the highest dilution showing a positive result. The approximate ASO level (IU/ml) present in the sample can be obtained by the following formula:

ASO Titre (IU/ml) = Highest dilution with positive reaction x Reagent sensitivity (200 IU/ml)

e.g. if the agglutination is present up to a titre 1:8 , the approximate serum ASO level is 8 x 200 = 1600 IU/ml

Expected Value

Up to 200 IU/ml

Limitations of the Procedure

Occasional agglutinations observed after 4 minutes have no diagnostic significance.
Highly haemolyzed and lipemic serum as well as plasma interfere with the test.

Performance characteristics

1. Analytical sensitivity: 200 (± 50) IU/mL, under the described assay conditions
2. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
3. Diagnostic sensitivity: 98 %
4. Diagnostic specificity: 97 %

Interfering Substances

Haemolysis
No significant interference from haemoglobin up to 10 g/dL.

Icterus
No significant interference from free and conjugated bilirubin up to levels of 20 mg/dL

lipemia
No significant interference up to levels of 10 g/dL

Rheumatoid factor
No significant interference up to 300 IU/ml

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct 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. refer to special instructions/safety data sheets.

References

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4. Klein GL, Applied Microbiology, 21:999, 1971.
5. Klein GC: Manual of Clinical Immunology ASM 264-273:1976.
6. Rantz LD, DiCapri JM, Randall E. Am. J. Med. Sci., 24,1952.
7. Schmidt et al. Rheumatol. 1970 ; 29 : 29-32.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
510 001	50 test
510 002	100 test
510 003	50 test
510 004	100 test
510 005	50 test
510 006	100 test

Egyptian Co for Biotechnology - Spectrum Diagnostics (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

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