ASO (Anti Streptolysin-O) Latex

ANTI STREPTOLYSIN-O (SLIDE LATEX AGGLUTINATION TEST)

Intended Use

The reagents are for *in-vitro* diagnostic use only.

Principle

The ASO Reagent is a suspension of polystyrene latex particles coated with stabilized Streptolysin O. The reagent has been adjusted in the way that the presence of an ASO titer of 200 IU/ml or higher in the serum, gives a visible agglutination of the latex without previous sample dilution.

Reagent provided

1. Reagent 1- Latex ASO in suspension (contains Sodium Azide 0.1%).
2. Reagent 2-Positive Control containing at least 200 IU/ml of ASO.* Human Serum(Contains Sodium Azide 0.1%).
3. Reagent 3- Negative Control containing less than 200 IU/ml of ASO.* Human Serum. (Contains Sodium Azide 0.1%).

*The human sera used in the controls has been tested and found negative for HBsAg and HIV. However a careful handling is always recommended.

Reagent storage and stability

Shake the Reagent 1 (ASO Latex) before use. After that it must be uniform and without visible clumping. The test sensitivity depends on the drop volume (50 µl).Do not use droppers other than those provided in the kit and place the dropper perpendicular to the slide surface.
The Reagents, if stored at 2-8°C are stable till the expiry date stated on the label. DO NOT FREEZE.

Specimen collection and preservation

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Haematic, lipaemic or contaminated sera must be discarded.

Procedure

- Before using the kit, allow the components to reach room temperature.
- Gently shake the reagent to disperse the latex particles.

A. Qualitative Test

1. Check the reagent against the positive and negative controls (as follows).
2. Place a drop (40 µl) of UNDILUTED serum into a circle of the slide.
3. Add a drop of the Reagent 1 (ASO Latex) 40 µl next to the drop of serum.
4. Mix both drops spreading them over the full surface of the circle.
5. Rotate the slide, manually or with a mechanical rotor at 80-100 rpm for two minutes. Read the presence or absence of visible agglutination in this period of time. ***Unspecific agglutination could appear if the test is read later than two minutes.***

Reading

- Presence of agglutination indicates a content of ASO in the sample equal or greater than 200 IU/ml.
- The lack of agglutination indicates an ASO level lower than 200 IU/ml in the sample.

B. Semi-Quantitative Test

The test will be performed in the same way as qualitative test but using dilution of the serum sample in saline (NaCl 9g/l) PBS or glycine buffer.

Dilutions	1:2	1:4	1:8	1:16
Sample Serum	100 µl	-	-	-
Saline	100 µl	100 µl	100 µl	100 µl
	→	100 µl →	100 µl →	100 µl
Volume of above diluted Sample	40 µl	40 µl	40 µl	40 µl

Concentration will be the reciprocal of positive reading dilution

200 x n (Ratio of Dilution)	200x2	200x4	200x8	200x16
IU/ml	400	800	1600	3200

Normal Range

Adults: < 200 IU /ml

Elevated serum titers happen as a result of infections coming from Group A β-hemolytic Streptococci producers of Streptolysin O.

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%

INTERFERENCES:

Hemoglobin (10g/l), Bilirubin (20mg/dl)

Lipemia (10g/l), Rheumatoid Factors (300 IU/ml) do not interfere. Other substances may interfere.

LIMITATION OF THE PROCEDURE:

1. False positive result may be obtained in conditions such as rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
2. A single ASO determination does not produce much information about the actual state of the disease. Titrations at weekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

References

1. Plotz and Singer, Am.J.Med.22, (1979).
2. Adams, L.E., Hess, E.J.Amer.Technol.48 (1978).
3. Normausell, D.Immunochemistry 9, (1972).
4. Dito, W.Am.Soc.Clin.Pat. 69, (1976).

Symbols

IVD In Vitro Diagnostics. Caution. Keep away from sun light. Date of Manufacture.

LOT Batch No. Read Instructions. Fragile. Product Expiry Date.

CONT Content. Storage Temperature. Keep Dry. Manufactured By.

REF Catalogue No.

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