SUMMARY
Since streptococcal infections are frequent, anti-streptolysin O (ASO) antibody is widely found in human in low titers. However, high ASO titer or increasing in ASO titer indicate recent infection produced by group A beta hemolytic Streptococci, such as tonsillitis, scarlet fever, puerperal sepsis, erysipelas, etc.

PRINCIPLE
Antistreptolysin O antibodies present in sample, are capable of agglutinating latex particles coated with streptolysin O producing a macroscopically visible agglutination.

PROVIDED REAGENTS
A. Reagent A: suspension of polystyrene latex particles coated with streptolysin O.
Positive Control: human serum containing antistreptolysin O in concentrations over 250 UI/ml.
Negative Control: non-reactive human serum to the Reagent A.

NON-PROVIDED REAGENTS
Saline solution (for the semi-quantitative technique).

INSTRUCTIONS FOR USE
Reagent A: shake well to homogenize and then replace the screw cap with the provided dropper cap.
Positive Control: ready to use.
Negative Control: ready to use.

WARNINGS
Reagents are for “in vitro” diagnostic use.
The Positive and Negative Controls have been tested for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C virus (HCV) and antibodies against Human Immunodeficiency Virus (HIV 1/2) and have been found non-reactive. However, they should be handled as capable of transmitting infection. Use the reagents according to the working procedures for clinical laboratories.
The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS
Provided Reagents are stable in refrigerator (2-10°C) until the expiration date shown on the box. Do not freeze.

INSTABILITY OR DETERIORATION OF REAGENTS
Self agglutination of the Reagent A is a sign of its deterioration. In that case, discard.

SAMPLE
Serum
a) Collection: obtain serum in the usual way.
b) Additives: not required.
c) Known interfering substances: lipemic or contaminated sera may yield false positive results.
d) Stability and storage instructions: streptolysin in serum is stable 24 hours in refrigerator (2-10°C) or frozen for long periods.

REQUIRED MATERIAL
1- Provided
- plastic or glass slides with black background.
- 1 dropper cap
2- Non-provided
- droppers or pipettes for measuring the stated volumes
- disposable mixing rods
- stopwatch
- lamp or light source
- Kahn tubes

PROCEDURE
Bring the reagents and the sample to room temperature.
Shake the Reagent A before use, after emptying the dropper pipette.

I- QUALITATIVE TECHNIQUE
In one of the circles of the provided slide, place:
Reagent A 1 drop (50 ul)
Sample 1 drop (50 ul)
Mix with a disposable rod (one for each sample) to obtain a uniform suspension all over the circle surface. Immediately, release the stopwatch, gently move the slide and observe the result macroscopically within 2 minutes.

II- SEMI-QUANTITATIVE TECHNIQUE
Positive sera can be titrated performing serial dilutions in Kahn tubes.
a) Place 0.5 ml Saline Solution in each tube.
b) Add 0.5 ml serum to tube N° 1 and mix.
Transfer 0.5 ml of this dilution to tube N° 2 and mix; continuing with the dilutions in this manner up to the last tube. The dilutions obtained in this way are 1:2, 1:4, 1:8, 1:16, etc.
c) Test each dilution following the Qualitative Technique.
INTERPRETATION OF RESULTS

Qualitative technique

Negative: homogeneous suspension.

Positive: agglutination that appears within 2 minutes. It is qualified from 1 to 4 (+):
4+: strong agglutination
3+: moderate agglutination
2+: mild agglutination
1+: slight agglutination

Semi-quantitative technique

Titer: it is the inverse of the highest dilution showing a macroscopically visible agglutination.

The approximate level of Antistreptolysin O in the sample, can be calculated with the following formula:

ASO (UI/ml)= Titer x Reaction Sensitivity (200 UI/ml)

Example: the sample has a titer of 1:2. The ASO level is: 2 x 200 = 400 UI/ml

QUALITY CONTROL METHOD

Simultaneously process the provided Positive and Negative Controls, using a drop of the corresponding control instead of the sample and a drop of Reagent A according to the qualitative technique.

REFERENCE VALUES

Up to 200 UI/ml.

It is recommended that each laboratory establishes its own reference values.

PROCEDURE LIMITATIONS

See Known interfering substances under SAMPLE.

- Reaction times longer than 2 minutes may produce false positive reactions as the reagents dry.
- In children older than 6 months and younger than 6 years or with a recent infection, false negative results may be obtained.
- In this kind of infections, an isolated result is only an additional information. Thus, it is recommended to perform serial determinations every 15-20 days for 4 or 6 weeks.

PERFORMANCE

a) Sensitivity: 200 UI/ml.

b) Specificity: in an adult healthy population, 95% of the antiestreptolysin O titers obtained are below or equal to 200 UI/ml. In an infant population (over 2 years old) titers up to 300 UI/ml may be obtained.

WIENER LAB. PROVIDES

Kit for 50 tests (Cat. N°: 1073151).

REFERENCES