GENESIS

Instructions For Use

ASOT Latex (Agglutination Method)

Cat no.	size
3101 101	100 Test
3101 201	50 Test
3101 301	100 Test + Controls
3101 401	50 Test + Controls

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

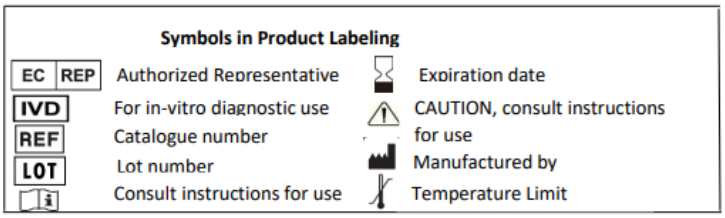
DIAGNOSTIC CHARACTERISTICS
Streptococcus belongs to the family of lactobacillacae and the majority is facultative anaerobes. The facultative anaerobic streptococci are divided into two categories:
1. those which produce soluble hemolysin.
2. those which do not produce soluble hemolysin.
The first group of streptococci are called b-hemolytic streptococci, which can be further subdivided into;
group (a) group (b) group (c) group (d)
It includes most of the species associated with primary streptococcal infections in humans.
The group (a) b-hemolytic streptococci produce various exotoxins such as streptolysin O and streptolysin S that can act as antigens. The affected individuals produce specific antibodies against streptolysin O, namely Anti-streptolysin O.
Determination of these antibodies is very useful for the diagnosis of streptococcal infections and their relative effects such as rheumatic fever and acute glomerulonephritis. An elevated ASO titre of more than 200 IU/ml may indicate an acute streptococcal infection.

PRINCIPLE OF THE METHOD
GENESIS ASO slide test for detection of antibodies to streptolysin O is based on the principle of agglutination. The test specimen (serum) is mixed with GENESIS ASO latex reagent and allowed to react. If antibodies to streptolysin O are present in concentrations more than 200 IU/ml but less than 4000 IU/ml then a visible agglutination is observed. If antibodies to streptolysin O are not present or are in concentrations less than 200 IU/ml then no agglutination will be observed.

COMPOSITION

Latex Reagent
-Latex particles coated with streptolysin(O) -pH 8.2 -Sodium azide 0.95 g/L
Positive Control
-Human serum with an ASO concentration > 200 IU/mL -Sodium azide 0.95 g/L
Negative Control
-Animal serum,Sodium azide 0.95 g/L

STORAGE.
Store at 2-8ºC.
Reagent and Controls are stable until the expiry date shown on the vial label when stored tightly closed and if contaminations are prevented during their use.



REAGENT PREPARATION
Reagent and Controls are provided ready to use.

ADDITIONAL EQUIPMENT
Stop watch, Test tubes, A high intensity direct light source, physiological saline.
sample dispensing pipette and mixing sticks would be required additionally.

SPECIMEN
1.Fresh serum. Stable 7 days at 2-8ºC or 3 months at < –20ºC.
2.Samples with presence of fibrin should be centrifuged before testing.
3.Do not use highly hemolysed or lipemic samples.

PRECAUTIONS AND WARNING
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.

PROCEDURE
Bring reagent and samples to room temperature before testing.
Qualitative Method
1. Pipette one drop (40 µl) of test specimen (serum) on the latex slide using disposable pipette.
2. Add one drop of GENESIS-ASO latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the test specimen and latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at two minutes.
Semi Quantitative Method
1. Using physiological saline prepare serial dilutions of the test specimen positive in the qualitative method 1:2, 1:4, 1:8,1:16, 1:32, 1:64 and so on.
2. Pipette one drop (40 µl) of each dilution of the test specimen into separate reaction circles.
3. Add one drop of GENESIS-ASO latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the test specimen and the latex reagent uniformly over the entire circle.
5. Immediately start a stopwatch. Rock the slide gently, back and forth, observing for agglutination macroscopically at two minutes.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates presence of detectable levels of ASO in the test specimen.

No agglutination is a negative test result and indicates absence of detectable levels of ASO in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the approximate amount of ASO in IU/ml present in the test specimen.

Concentration of ASO can be calculated as follows:

ASO (mg/dl) = S x D

Where, S = Sensitivity of the reagent i.e. 200 IU/ml.

D = Highest dilution of serum showing agglutination

REFERENCE VALUES

Up to 200 IU/ml

METROLOGICAL CHARACTERISTICS

	Total	+Ve	-Ve
ASO (Positive) samples	25	25	0
ASO (Negative) samples	75	0	75
Total	100	25	75

* Sensitivity: 100%

* Specificity: 100%.

INTERFERENCES

Hemoglobin (up to 10 g/L), bilirubin (up to 20 mg/dL) and lipemia (up to 10 g/L) do not interfere. Rheumatoid factors (>100IU/mL) interfere.Other substances may interfere

BIBLIOGRAPHY

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.

2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.