



REF 3003

April 01, 2014

# Antistreptolysin O Latex

- 100 determinations -



IVD *In vitro* diagnostic device

Latex agglutination test for the detection of anti-streptolysin O (ASO) in human serum

<b>REF</b>	Catalogue number	<b>LOT</b>	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk



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## INTENDED USE

Antistreptolysin O Latex is used for the qualitative and semi-quantitative determination of anti-streptolysin O (ASO) in human serum.

The group A  $\beta$ -hemolytic streptococci produces various toxins that can act as antigens. One of these exotoxins streptolysin O, was discovered by Todd in 1932 (1). A person infected with group A  $\beta$ -hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the  $\beta$ -hemolytic streptococcal (2). The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pretitrated and reduced streptolysin O (2-6). However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin O by agglutination of latex particles on slide (2).

1. Todd, E.W., J. Exp. Med. 55:267-280, (1932).
2. Klein, G.C. Manual of Clinical Immunology, Am. Soc. Microbiol., (1974).
3. Kalbak, K., The State Serum Institute, Denmark, (1947).
4. Klein, G.C. et al., Applied Microbiology, 19:60 (1970).
5. Klein, G.C. et al. Applied Microbiology, 21:999 (1971).
6. Rantz, L.A. et al. Proc. Soc. Exp. Biol. and Med. 59:22 (1945).
7. Hodge, B.K., Exp. Med. 58:277 (1933).

## PRINCIPLE OF THE TEST

Antistreptolysin O Latex is used for the determination of anti-streptolysin O (ASO) in human serum.

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level, are present in the test specimen.

## TEST COMPONENTS for 100 determinations

<b>A</b>	<b>Latex reagent,</b>	4.0 ml
<b>LATEX</b>	Latex particles coated with streptolysin O antigen	ready for use dropper bottle
<b>P</b>	<b>Positive control</b>	1.0 ml
<b>CONTROL</b>	ASO positive human serum concentration on the label	ready for use dropper bottle
		<b>+</b>
<b>N</b>	<b>Negative control</b>	1.0 ml
<b>CONTROL</b>	ASO negative human serum	ready for use dropper bottle
		<b>-</b>
	<b>Agglutination slide</b>	1 ready for use
	<b>Disposable stirring sticks</b>	50 ready for use

## Materials required but not provided

- timer
- test Tubes and rack.
- serological pipettes
- high intensity light
- glycine or phosphate buffered saline solution, 0.9%
- rocking shaker (optional)

## Size and storage

Antistreptolysin O Latex has been designed for 100 determinations.

The expiry date of each component is reported on its respective label that of the complete kit on the box labels.

Upon receipt, all components of the Antistreptolysin O Latex have to be stored at 2 - 8 °C, preferably in the original kit box. The Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal. **Do not freeze!**

Do not use the latex reagents if it is marked with turbidity as this may indicate reagent deterioration or contamination.

After opening all kit components are stable for at least 3 months, provided proper storage.

Agglutination slide should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

## PATIENT SAMPLES

Use fresh serum collected by centrifuging clotted blood.

If the test cannot be carried out on the same day, the serum may be stored between 2 - 8°C for no longer than 72 hours after collection. For longer periods the sample must be frozen.

As in all serological tests, hemolytic or contaminated serum must not be used. **Do not use plasma!**

## ASSAY PROCEDURE

### Qualitative evaluation

1. Allow all reagents and samples to reach room temperature prior to testing. Shake well all reagents before use.
2. Place **1 drop** (appr. 40 µl) of the positive control (P) on field no. 1 of the agglutination slide.
3. Place **1 drop** (appr. 40 µl) of the negative control (N) on field no. 2 of the agglutination slide.
4. Place **40 µl** of each undiluted patient sample to the following fields of the agglutination slide using different serological pipettes.
5. Gently resuspend the Latex reagent (A) and add **1 drop** (40 µl) to each test field.
6. Mix well using separate stirring sticks.
7. Gently rock the slide for **3 minutes** by hand or use a rocking shaker (80-100 rpm).
8. Read immediately under direct light.

## Semi-quantitative evaluation

1. Allow all reagents and samples to reach room temperature prior to testing. Shake well all reagents before use.
2. Set up at least five dilutions per patient sample: 1:2, 1:4, 1:8, 1:16, 1:32, etc. using buffered saline.
3. Place **1 drop** (appr. 40 µl) of the positive control (P) on field no. 1 of the agglutination slide.
4. Place **1 drop** (appr. 40 µl) of the negative control (N) on field no. 2 of the agglutination slide.
5. Place **40 µl** of each sample dilution (refer 2.) to the following fields of the agglutination slide using different serological pipettes.
6. Gently resuspend the Latex reagent (A) and add **1 drop** (40 µl) to each test field.
7. Mix well using separate stirring sticks.
8. Gently rock the slide for **3 minutes** by hand or use a rocking shaker (80-100 rpm).
9. Read immediately under direct light.

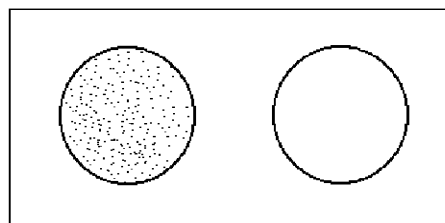
## EVALUATION OF RESULTS

### POSITIVE

A positive reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the ASO Negative Control.

### NEGATIVE

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed with the ASO Negative Control.



Positive

Negative

### Semi-quantitative test evaluation

A positive reaction is indicated by any observable agglutination in the reaction mixture. Record the last dilution showing a positive reaction. Concentration of ASO can be determined by multiplying the last positive dilution factor of the sample with the concentration of the positive control (200 IU/ml, refer to label!).

The titer of the serum is the reciprocal of the highest dilution which exhibits a positive reaction.

$$\text{IU/ml of sample} = \text{conc. of positive control (200)} \times \text{titer}$$

Example:

TITER	IU/ml
1	200
2	400
4	800
8	1600
etc.	

## Test validity

Internal procedural controls are included in the test. A green line appearing in the control region is an internal control. It confirms sufficient specimen volume and correct procedural technique.

## Expected values

Although normal values can vary with age, season of the year and geographical area (2), the "upper limit of normal" antistreptolysin O titers for preschool children is less than 100 IU/ml and in school age children or young adults is usually between 166 and 250 IU/ml. In any case, the average can be established at less than 200 IU/ml.

Because of this variation, titers above the upper limits may be indicative of a streptococcal infection, but only a two dilution rise in titer between acute and convalescent stage specimens should be considered significant (1).

Following acute streptococcal infection, the antistreptolysin O titer will usually rise after one week, increasing to a maximum level within 3 to 5 weeks and usually returning to the preinfection levels in approximately 6 to 12 months (2).

## Limitations of the method

Any clinical diagnosis should not be based on the results of in vitro diagnostic methods alone. Physicians are supposed to consider all clinical and laboratory findings possible to state a diagnosis.

## SAFETY PRECAUTIONS

- **This kit is for in vitro use only.** Follow the working instructions carefully. GA GENERIC ASSAYS GmbH and its authorized distributors shall not be liable for damages indirectly or consequentially brought about by changing or modifying the procedure indicated. The kit should be performed by trained technical staff only.
- The expiration dates stated on the respective labels are to be observed.
- Do not use or mix reagents from different lots. Do not use reagents from other manufacturers.
- All reagents should be kept at 2 - 8 °C before use in the original shipping container.
- Some of the reagents contain small amounts of Sodium azide (0.095%) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Positive and negative controls prepared using human sera found negative for hepatitis B surface antigen (HBsAg) and antibodies to HIV (Human Immunodeficiency Virus) and HCV (Hepatitis C Virus) by FDA required test. However, handle controls as if potentially infectious.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
  - Do not smoke, eat or drink while handling kit material,
  - Always use protective gloves,
  - Never pipette material by mouth,
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

Bemerkungen: