ASO Latex
Insert

Ref.: **157**

Intended use . System for qualitative and semi-qualitative determination of Anti-Streptolysin O (ASO) on glass slide.

Professional use.

[For in vitro diagnostic use].

Test principle . Latex particles stabilized and coated with purified Streptolysin O are agglutinated macroscopically when ASO is present in the sample in concentration more than 200 IU/mL.

Summary . Antibodies ASO are produced during Group A streptococci beta-hemolytic by a Streptolysin stimulus delivered by the bacteria. In this way, recent infection caused by this bacterium may be proved by measuring the level of these antibodies.

ASO Latex - Labtest has sensibility for detecting ASO concentrations of at least 200 IU/mL, using polystyrene particles, stabilized in Buffer pH 8.2 and coated with purified Streptolysin O.

The sensibility 200 IU/mL is established with the international is established with the international standard of the World Health Organization NIBSC 97/662.

The test is simple and fast, without dilution of the sample and presents proper reactions that are not sensible to the prozone effect up to values of 1500 IU/mL.

Methodology Latex agglutination.

Reagents

1. R 1 **- ASO Latex - Store at 2 - 8 ºC. Store the bottle well capped in the upright position.**
Do not freeze. Contains buffered aqueous suspension of polystyrene particles sensitized with streptolysin O and sodium azide < 0.1 %.

P. CONTROL + **- Positive control - Store at 2 - 8 ºC.**
Contains human serum stabilized, with AEO concentration higher than 200 IU/mL and preservative. Handle with care. Potentially infectious.

N. CONTROL − **- Negative control - Store at 2 - 8 ºC.**
Contains stabilized animal serum and preservative. Handle with care. Potentially infectious.

Stability . Unopened reagents, when stored under the indicated conditions, are stable until the expiration date printed on the label. After open the product is stable for 7 months. During handling, the reagents are subject to chemical and microbiological contamination that may lead to reduced stability time.

Auxiliary materials

1. Small glass slides.

Positive control, negative control and auxiliary materials are only part of the products ASO Latex, Ref. 157/2.5 and 157/5. The products Ref. 157K/2.5 and 157K/5 have only the ASO Latex reagent.

Precautions and warnings

The usual security cares should be applied on the reagent and patient samples handling. Avoid bacterial contamination.

Read the result 2 minutes after mixing the reagents. Readings after the recommended time may yield false positive results.

Positive and negative controls are prepared from human blood derivatives which have been tested and found to be negative for HIV, HCV and HbsAg. Nonetheless the reagent must be treated as potentially infectious and appropriate precautions should be taken when handling and on disposal.

The Reagent 1 contain sodium azide as preservative. Avoid ingestion. In case of eyes contact, immediately flush eyes with plenty of water and get medical assistance. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide accumulation.

Wash the glass slides used for testing with plenty of deionized water and let it dry at room temperature. The use of material contaminated with traces of detergent yields incorrect results and deteriorates the reagents.

The system is standardized for getting the proposed sensibility and appropriated performance in accordance to the indicated volumes in the methodology. Modification of recommended volumes and the introduction of contaminated pipettes may affect the test performance and the ASO Latex stability.

Disposal of all waste material should be in accordance with local guidelines.

Materials required and not provided

1. Pipettes for measure the samples and perform dilutions.
2. NaCl 150 mmol/L (0.85%).
3. Timer.

Sample

Fresh serum. Do not use plasma. Serum samples may be stored for up to 2 days at 2 to 8 ºC. Samples may be frozen at or below 20 ºC for up to three months[8], provided that the freezing is performed within 24 hours of collection.

Labtest

A Standard Operating Procedure (POP) should be established to establish appropriate procedures for sample collection, preparation and storage. We emphasize that the errors due to the sample may be much larger than the errors occurred in the analytical procedure.

As the samples used are potentially infectious, we suggest handling them according to the biosafety standards.

Interference

Bilirubin concentrations up to 20 mg/dL, hemoglobin up to 1000 mg/dL, lipids up to 1000 mg/dL and rheumatoid factor up to 300 IU/mL do not produce significant interferences.

Turbid sera may be cleared by centrifugation at 19000g for 30 minutes.

ASO Latex and glass slide contamination with detergent modifies the colloidal structure of the reagent leading to irreversible deterioration and inconsistent results.

Procedure

Qualitative method . See notes.

1. Before performing the tests let the reagents and samples reach room temperature to use them.

2. Add 0.04 mL of the serum sample on the glass slide and 0.04 mL of each control in different areas of the glass slide.

3. Add 0.04 mL of ASO latex (previously homogenized) next to the sample and to the controls. Mix in a circle shape.

4. Tilt the slide back and forth, making oscillatory movements in several planes, for two minutes and immediately check, under a good light source, the presence or absence of macroscopic agglutination, comparing the result of the sample with the patterns obtained with the controls. Excess time may produce false positive results.

Interpretation of results

Negative . Homogeneous suspension similar to the pattern of the negative control.

Positive . Macroscopic agglutination that varies from traces to thick agglutination, characterizing a concentration of more than 200 IU/mL. Agglutination characteristics should not be used as indicator of ASO concentration in the sample.

Titre using semi-quantitative method.

Semi-quantitative method . See notes.

1. Add to 4 different tubes 0.2 mL of 0.85% NaCl. Transfer to the first tube 0.2 mL of the sample that was positive for qualitative test. Mix, transfer 0.2 mL of the 1º tube to 2º tube. Mix, transfer 0.2 mL of the 2º tube to the 3º tube and successively until the 4º tube. Obtaining the following dilutions: 1/2, 1/4, 1/8, 1/16, respectively.

2. In each area of the glass slide place 0.04 mL of the dilutions and beside them place 0.04 mL of ASO Latex (previously homogenized). Mix in a circle shape.

3. Tilt the slide back and forth, making oscillatory movements in several planes, for two minutes and immediately check, under a good light source, the presence or absence of macroscopic agglutination, comparing the result of the sample with the patterns obtained with the controls. Excess time may produce false positive results.

4. Consider as titer the highest dilution showing macroscopic agglutination. If the agglutination occurs at the dilution 1/16, keeping diluting the sample from the 4th tube on and perform the test with the other dilutions.

Sensibility . ASO Latex Labtest sensibility is 200 IU/mL (150 - 250 IU/mL).

Results

Negative test
Express the result as < 200 IU/mL.

Positive test
Express the result in IU/mL.
IU/mL = sensibility x titer found in the semi-quantitative method.

Example

If the titer is 1/4, IU/mL = 200 x 4 = 800 IU/mL

Expected values . Lower than 200 IU/mL This value should only be used as a guideline. Each laboratory should evaluate the transferability of the expected values to its own patient population and, if necessary, estimate its own reference interval.

Internal Quality Control . The laboratory should maintain an internal quality control program that clearly defines the objectives, procedures, standards, tolerance limits, corrective actions and activity records.

At the same time, it is necessary to monitor the analytical variability that occurs throughout the measurement system. Therefore, the use of negative and positive controls in all analytical runs is critical to verifying test performance. Records of the results obtained in permanent and easily located recording systems should also be recorded.

Performance characteristics[9] . Reagent calibration and detection limit 200 IU/mL are traceable to the international standard of the World Health Organization, NIBSC 97/662.

Diagnostic efficiency . One hundred and eighteen serum samples with values smaller than 200 IU/mL were tested using ASO Latex and a similar product as a comparative method.

The following results were obtained with statistical analysis:

Sensibility: 98%
Specificity: 97%
Efficiency: 97.5%

Predictive positive value: 96%
Predictive negative value: 98.5%

	ASO Latex	
Comparative method	Positive	Negative
Positive	48	1
Negative	2	67

Dilution studies . The studies were performed by diluting a sample containing 1096 IU/mL.

Sample (IU/mL)	Result
1096	SR
548	SR
274	R
219	R
183	R
157	N
137	N

SR: strongly reactive; R: reagent; N: negative

Results obtained are representative for demonstrating that the sample dilutions yield appropriated recoveries of the expected results.

Imprecision With run . Imprecision within run was verified by evaluating 10 replicates of 2 samples with values of 28 and 300 IU/mL; Negative and positive results showed perfect accordance to the expected results.

Imprecision - Run-to-run . Run-to-run imprecision was verified in 5 independent evaluations, using 2 samples, with values of 0,2 and 529 IU/mL. Negative and positive results obtained shows perfect accordance to the expected results.

Prozone effect . A serum sample with ASO value of 1500 IU/mL was tested with ASO Latex and repetitively positive results were obtained confirming that there was no prozone effect up to the evaluated concentration.

Notes

1. The material cleaning and drying are fundamental factors to the reagent stability and to obtain correct results. Contamination of ASO Latex with detergents modifies the colloidal structure of the reagent leading to irreversible deterioration.

2. The water in the laboratory to prepare reagents and use in the measurements, must have resistivity ≥1 megaohm.cm, or conductivity ≤1 microsiemens/cm and silicates concentration must be < 0.1mg/L.

3. Consider the sensibility of the methods when comparing methods for ASO determination. Obtained results with products presenting different sensibility can only be compared if expressed in IU/mL.

4. The system is standardized for obtaining the proposed sensibility and proper performance according to the volumes indicated in the methodology. Modifications of the recommended volumes and introduction of contaminated pipettes may affect the test performance and the stability of ASO latex.

References

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6. Parri F, Majo E. J Automatic Chem 1985;7:99-101.
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9. Labtest: data on file.

Presentation

Product	Reference	Contents	
ASO Latex	157-1/2.5	R 1	1 X 2.5 mL
		CONTROL +	1 X 0.5 mL
		CONTROL −	1 X 0.5 mL
	157-1/5	R 1	1 X 5 mL
		CONTROL +	1 X 0.5 mL
		CONTROL −	1 X 0.5 mL
	157K-1/2.5	R 1	1 X 2.5 mL
	157K-1/5	R 1	1 X 5 mL

Customer information

[Warranty conditions]

Labtest Diagnóstica warrants the performance of this product under the specifications until the expiration date shown in the label since the application procedures and storage conditions, indicated on the label and in this insert, have been followed correctly.

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Símbolos utilizados com produtos diagnósticos in vitro

Símbolos usados con productos diagnósticos in vitro

Symbols used with ivd devices

 **Conteúdo suficiente para < n > testes** Contenido suficiente para < n > tests Contains sufficient for < n > tests	 **Risco biológico** Riesgo biológico Biological risk
 **Data limite de utilização (aaaa-mm-dd ou mm/aaaa)** Estable hasta (aaaa-mm-dd o mm/aaaa) Use by (yyyy-mm-dd or mm/yyyy)	 **Marca CE** Marcado CE CE Mark
 **Material Calibrador** Material Calibrador Calibrator Material	 **Tóxico** Tóxico Poison
 **Material Calibrador** Material Calibrador Calibrator Material	 **Reagente** Reactivo Reagent
 **Limite de temperatura (conservar a)** Temperatura limite (conservar a) Temperature limitation (store at)	 **Fabricado por** Elaborado por Manufactured by
 **Representante Autorizado na Comunidade Europeia** Representante autorizado en la Comunidad Europea Authorized Representative in the European Community	 **Número do lote** Denominación de lote Batch code
 **Consultar instruções de uso** Consultar instrucciones de uso Consult instructions for use	 **Controle** Control Control
 **Número do catálogo** Número de catálogo Catalog Number	 **Controle negativo** Control negativo Negative control
 **Adições ou alterações significativas** Cambios o suplementos significativos Significant additions or changes	 **Controle positivo** Control positivo Positive control
 **Produto diagnóstico in vitro** Dispositivo de diagnóstico in vitro In vitro diagnostic device	 **Controle** Control Control
 **Liofilizado** Liofilizado Lyophilized	 **Corrosivo** Corrosivo Corrosive
 **Período após abertura** Período post-abertura Period after-opening	 **Uso veterinário** Uso veterinario Veterinary use
 **Instalar até** Instalar hasta Install before	

Ref.: 140214

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