ASO SLIDE

Latex agglutination

REF. 7701 100 tests with controls and accessories
REF. 7702 100 tests without controls and accessories
REF. 7786 50 tests with controls and accessories
REF. 7787 300 tests without controls and accessories

CE IVD

DNV CERTIFIED COMPANY
UNI EN ISO 9001:2008
UN EN ISO 13485:2012

GIESSE DIAGNOSTICS

INTENDED USE

Qualitative determination of anti-streptolysin O (ASO).

PRINCIPLE

The ASO SLIDE is a slide agglutination test for the qualitative and semi-quantitative detection of anti-streptolysin O (ASO) antibodies.
Latex particles coated with streptolysin O are agglutinate when mixed with samples containing ASO.

SAMPLE

Fresh Serum. Stable 7 days at 2-8°C or 3 months at -20°C.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.

KIT COMPONENTS

Reagent (A) ASO Latex Volume = 2.5/5.0 ml	Latex particles coated with Streptolysin O, pH 8.2 Sodium azide 0.95 g/l
Control (+) ASO Volume = 0.5 ml	Human serum with an ASO concentration > 200 U/ml Sodium azide 0.95 g/l
Control (-) ASO Volume = 0.5 ml	Animal serum Sodium azide 0.95 g/l
Stirrer	1 o 2 pz
Reaction slide	1 o 2 pz

The Reagents are stable until the expiration date printed on the label, when stored tightly closed at 2-8°C. Once opened, the reagents are stable one month at 2-8°C if contamination is avoided. Do not freeze.
Keep bottles closed when not in use.

REAGENT PREPARATION

All the kit components are ready to use.

PRECAUTIONS AND WARNINGS

Biological risk for Control (+)

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Use the normal precautions required in the laboratory.
Components from human origin have been tested and found to be negative for the presence of HbsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.
Dispose of waste according to local laws.

PROCEDURE

Qualitative method:

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Gently mix the latex.
Dispense 50 µl of serum upon a selected spot of the reaction slide, add one drop of latex and accurately mix with a stirrer paying attention to uniformly distribute the liquid on the selected spot. Rotate the slide and observe within 2 minutes possible agglutination. False positive results could appear if test is read later than 2 minutes.

Semi-quantitative method:

Make serial two fold dilutions of the sample in saline solution.
Proceed for each dilution as in the quantitative method.

READING AND INTERPRETATION

Examine the presence or absence of visible agglutination.
The presence of agglutination indicates an ASO concentration equal or greater than 200 U/ml.
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATION

The approximate ASO concentration in the sample is calculated as follow:

200 x ASO Titer = U/ml

EXPECTED VALUES

Adults:	**< 200**	**U/ml**
Children < 5 years old:	**< 100**	**U/ml**

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

Positive and Negative Controls are recommended to monitor the performance of the reagent and to have a better results interpretation.

PERFORMANCE

Sensitivity: 200 U/ml (± 50) U/ml
Prozone effect: No prozone effect up to 1500 U/ml.
Diagnostic sensitivity: 98%
Diagnostic specificity: 97%
Interferences: bilirubin does not interfere up to 20 mg/dl. Lipemia and hemoglobin do not interfere up to 10 g/l. Rheumatoid factors up to 300 U/ml do not interfere.

LIMITATIONS OF THE PROCEDURE

False positive Results may be obtained in conditions such as rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections.
Early infections and children from 6 months to 2 years may cause false negative results.
A single ASO determination does not produce much information during 4 or 6 weeks are advisable to follow the disease evolution.
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

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