HumaTex ASO

Latex Agglutination Slide Test for the Qualitative and Semi-quantitative Determination of Antistreptolysin O in Non-diluted Serum

Package Sizes

REF	40062	40 Tests	Complete Test Kit
	40060	100 Tests	ASO Latex Reagent
	40063	100 Tests	Complete Test Kit
	40037	100 ml	GBS

IVD

Method

The HumaTex ASO test kit contains polystyrene latex particles, coated with stabilised streptolysin O as antigen which reacts immunologically with corresponding anti-streptolysin O (ASO) antibodies of a patient specimen or control serum.

The positive reaction is indicated by a distinctly visible agglutination of the latex particles in the test cell of the slide.

Contents

LR	▽ 40 or ▽ 100	**ASO Latex Reagent (white cap)** Yellow coloured suspension of polystyrene latex particles, coated with stabilised streptolysin-O	1.0 %
PC	1.0 ml	**Control Serum Positive (red cap)** Ready for use human serum control, containing an ASO concentration sufficient to produce a distinct agglutination	
NC	1.0 ml	**Control Serum Negative (green cap)** Ready for use control, non-reactive with LR	
	1	**Slide with 6 cells**	
REF	40037:		
GBS	100 ml	**Glycine-NaCl Buffer** Glycine NaCl	pH 8.2 ± 0.2 100 mmol/l 1 g/l

LR, PC, NC and GBS contain 0.095% sodium azide.

Stability

LR, PC and NC are stable up to the expiry date when stored at 2...8°C.

Do not freeze!

Specimen

Serum

Stability: up to 7 days at 2...8°C,
up to 3 months at -20°C.

Pipetting Scheme

A. Qualitative Determination (Screening Test)

Bring LR, PC, NC and serum samples to room temperature. Mix LR carefully prior to use to suspend the latex particles completely.	
Pipette / drop onto separate cells of the slide:	
Sample	40 µl
PC, red cap	1 drop
NC, green cap	1 drop
LR, white cap, onto all sample and control cells	1 drop **each**
Mix with **separate** sticks and spread the fluid over the entire area of the particular cell.	
Tilt the slide back and forth for **2 minutes** so that the mixture rotates slowly inside the cells or place the slide on an automated rotator at 100 r.p.m.	
At the end of the 2 min. read results under **bright** artificial light.	

(1 drop ≈ 40µl)

Interpretation of Results

Distinct agglutination indicates an ASO content of more than **200 IU/ml** in the **non-diluted** specimen. Sera with positive results in the screening test should be retested in the titration test (see part B).

B. Semi-quantitative Test

Dilute specimens with GBS (REF 40037):

Dilution	ASO (IU/ml in non-diluted specimen)
1 + 1 (1 : 2)	400
1 + 2 (1 : 3)	600
1 + 3 (1 : 4)	800
1 + 4 (1 : 5)	1000
Continue test as described in part A.	

Interpretation of Results

Read the titre in the last dilution step with visible agglutination and multiply the titre with the conversion factor 200 (see "Sensitivity") to get the results in IU/ml;

e.g. titre 1 : 5 → ASO concentration

5 x 200 [IU/ml] = 1000 [IU/ml].

Sensitivity

HumaTex ASO is standardised to detect ASO concentrations in non-diluted serum samples of approximately 200 IU/ml or higher in accordance with the "International Reference Preparation" of the WHO.

Quality Control

PC and NC are to be used with each series. Their results should be compared with those of unknown specimens to distinguish possible granularity from agglutination.

PC - distinct agglutination within 2 minutes.

NC - smooth suspension without visible agglutination after 2 minutes.

Diagnostic Value

Increased ASO titres may be associated with rheumatoid fever and glomerulonephritis. An elevated ASO titre of more then 200 IU/ml may indicate an acute streptococcal infection. The titre of ASO should be monitored every 2 weeks over a period of 4 to 6 weeks.

Performance Characteristics

Typical performance data can be found in the Verification Report, accessible via:

www.human.de/data/gb/vr/lx-aso.pdf or

www.human-de.com/data/gb/vr/lx-aso.pdf

Notes

1. Contaminated and markedly lipemic sera may cause non-specific reactions and should therefore not be tested.
2. A reaction time longer than 2 minutes may lead to false positive results due to a drying effect.
3. During dispensing hold dropper vertically!
4. As with all diagnostic methods, the final diagnosis should not be based on the result of a single test, but on a correlation of test results with other clinical findings.
5. All reagents contain sodium azide: Do not swallow. Avoid contact with skin and mucous membranes.
6. PC has been tested for HBsAg, HCV and HIV antibodies and was found to be non-reactive. However, in spite of negative results it should be treated as potentially infectious.

References

1. Klein, G.C. *et al.*, Appl. Microbiol. **21**, 999 (1979)
2. Spaun, J. *et al.*, Bull. WHO **24**, 271 (1961)
3. Klein, G.C., Manual of Clinical Immunology, Amer. Soc. Microbiol., 264 (1976)

EN-ASO INF 4006001 GB 03-2009-11

CE

Human

Human Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21 · 65205 Wiesbaden · Germany
Telefon +49 6122-9988-0 · Telefax +49 6122-9988-100 · e-Mail human@human.de