Anti-Streptolysin (O) 5+1
Quantitative immunturbidimetric latex-enhanced test on ASL(O)

Cat.No	Package Size
803 001	R1 = 5 x 20 ml / R2 = 1 x 20 ml
803 002 (Hit I)	R1 = 4 x 20 ml / R2 = 2 x 8 ml

Diagnostic Implications
Group A β-haemolytic streptococci produces various toxins that can act as antigens, one of these exotoxins is streptolysin O. The affected organism produces specific antibodies against streptolysin O. The concentration of ASL(O) in the patient's serum will enable to establish the degree of infection due to β-haemolytic streptococci.

Method
Measurement of antigen-antibody end-point reaction between ASL(O) and ASL-sensitized Latex .

Reagents
R1 (Buffer)
Phosphate buffered saline (pH 7.4)
Polyethylene glycol (40 g/L)
Sodium azide (0.95 g/L)
R2 (Latex)
Glycine Buffer (pH 8.2)
ASL sensitized Latex (0.17 %)
Sodium azide (0.95 g/L)

Preparation and Stability of Reagents
Reagent Preparation
Liquid reagents, ready for use.
The reagents are stable until expiry date when kept at 2-8°C.
Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied
1. 0.9 g % sodium chloride
2. Calibrators ("Cal") and Controls ("Con")

Sample collection
Use fresh serum.
If the test cannot be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours.
If stored for a longer period, the sample should be frozen.

Warnings and precautions
Reagents contain Sodiumazide (0,95 g/l) as conservative. Do not swallow! Do not touch skin and / or mucous membranes !

Assay Procedure

Wavelength	600 nm
Cuvette	1 cm lightpath
Temperature	37 °C
Measure	Against Reagent Blank (RB)

	Reagent-Blank	Sample/Cal/Contr
Sample / Cal/Contr	-	10 µl
Reagent R1	250 µl	250 µl
Mix, incubate for 3 min , read absorbance A_1 ,then add :		
Reagent R2	50 µl	50 µl
Mix, incubate for 5 min , read absorbance A_2 .		

$\Delta A = [(A_2 – A_1)$ Sample/Cal/Con]

Calculation
The concentration is calculated through a calibration curve using a suitable mathematical procedure e.g. logit/log. The calibration curve is established by 4 calibrators of different concentrations and NaCl-solution (9 g/l) for the determination of zero.
Stability of the calibration is at least 4 weeks.

Applications for automated systems are available on request

Calibration /Controls
For the calibration of automated photometric systems we recommend Greiner ASL calibrators.
The values are traceable on the WHO-reference material .

For internal QC use Greiner ASL- or Protein-controls.

Reference Values
Normal: 0 - 200 IU/mL (WHO)

(This range is given for orientation only. Each laboratory should establish its own reference values)

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Performance Data

- Range / Linearity

The test can measure ASL-concentrations up to the concentration of 400 IU/ml.
At higher concentrations dilute the samples 1+1 with NaCl-solution (9 g/l). Multiply result by 2 .

- Hookeffect

Not observed .

- Specifity / Interferences

Greiner ASL is specific on human ASL.
Rheumafactor interference is not observed, and no interference with bilirubine up to 30 mg/dl, hemoglobin up to 500 mg/dl, lipämia up to 1000 mg/dl triglycerides.
No interference from anticoagulants in the normal concentrations .

- Sensitivity / Detection Limit

Low detection limit = 12.5 IU/mL

- Precision (n = 20)

Intra run	mean (IU/mL)	CV [%]
Sample 1	low	2.9
Sample 2	medium	-
Sample 3	high	3.6

Inter run	mean (IU/mL)	CV [%]
Sample 1	low	-
Sample 2	medium	6.3
Sample 3	high	-

- **Correlation**

A comparative study has been performed between the Greiner method and another commercial reagent on 20 human serum samples. The parameters of linear regression are as follows:

y = 0.998 x - 8.115 IU/mL ; r = 0.997

Literature

1. Dillon, H. C. jr., Reeves M. A., Am. J. Med., 56, 333-346 (1974)
2. Klein, G. C., Baker, C. N., Jones, W. L., 21, 999-1001 (1971)

SYMBOLS USED

For *in vitro* diagnostic medical use

Batch Code


Use by


Temperature limitation

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