Antistreptolysin O Assay Kit (ASO)

Method: Immunoturbidimetric

Cat .No.	Size	Instrument
GB600M	R1:2×15 ml R2:1×50 ml	For Hitachi 7060/7150 &Shimadzu CL7200/8000
GS601M	R1:2×15 ml R2:1×50 ml	For Hitach i7170 & OlympusAU640/400/600
GT601M	R1:2×15 ml R2:1×50 ml	For TOSHIBA

INTENDED USE

For the quantitative in vitro determination of Antistreptolysin O (ASO) in human serum.

CLINICAL SIGNIFICANCE

Streptolysin O (SLO) is a lethal, exocellular protein produced by Group A streptococci bacteria. It is so named because it is reversibly inactivated by atmospheric oxygen. The binding of active SLO to the surface of erythrocytes causes disruption of the cytoplasmic membrane resulting in cell lysis. Anti-streptolysin O antibodies (ASO) are produced by the host to neutralise the haemolytic action of the SLO. Measurement of ASO in serum is used for the diagnosis ofstreptococcol infections such as rheumatic fever and glomerulonephritis. The ASO level can be used as a measure of the extent and degree of infection. Elevated ASO levels may also be present in other conditions such as scarlet fever, acute rheumatoid arthritis, tonsillitis and various other streptococcal infections and in healthy carriers.

ASSAY PRINCIPLE

In those infections promoted by acute streptococcal infection, antibodies to the exotoxin of streptococcus are usually produced. By reacting suspended uniform polystyrene particles coated with Streptolysin O together with serum containing antibodies, an increase in turbidity occurs. By comparing with a standard, a quantitative value for the concentration of Anti Streptolysin O (ASO) present in serum can be obtained.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Glycine buffer	83mmol/L
Reagent 2 (R2)	
Particle suspension containing latex with streptolysin O antigen	0.12%

SAMPLE COLLECTION AND PREPARATION

Serum samples.
Use fresh patient serum samples.
ASO is stable for 2 days at 2-8℃ or 6 months at - 20℃.
Discard contaminated samples.

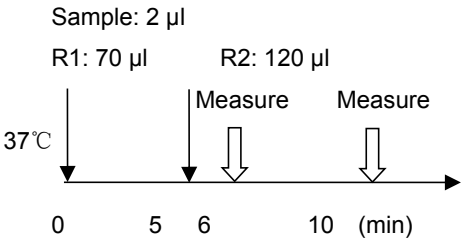
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to expiry date when stored at 2 -8℃, protected from light. The latex reagent (R2) must be carefully mixed before use, avoiding the formation of foam.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7180)

Wave Length (main/sub): 570 nm/800 nm



CALIBRATION

For the calibration of automated photometric systems the Gcell Liquid ASO calibrator is recommended.

QUALITY CONTROL

For quality control, use Gcell Specific Protein Controls as daily quality controls and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Normal range: < 166 IU/ml
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

The range of this assay is approximately 38 - 1300 IU/ml. If the concentration in sample exceeds the upper limit, please dilute the sample with 0.9% NaCl solution and re-assay it.

PRECISION

The CV of the test should be CV<8%.

Intar assay precision		
N=20	level 1	level 2
Mean(IU/ml)	142	279
SD	0.67	0.72
CV(%)	0.47	0.26

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CE version 2014

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(IU/ml)	141	138	138
$\bar{x}$	139		
(Xmax-Xmin)/$\bar{x}$	(141-138)/139*100=1.92%		

INTERFERENCE

The following analytes were tested up to the following levels and found not to interfere:

Vitamin C: up to 50 mg/dl
Bilirubin: up to 50 mg/dl
Hemoglobin: up to 500 mg/dl
Intralipid: up to 600 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Spaun, J., Bentzon, M.W., Larson, S.O., Hewitt, L.F., Bull. Wld. Hlth. Org. 24: 271-279 (1961).
2. Galvin, J.P. et al., Clin. Lab. Assays 4: 73-95 (1983).
3. Mc Cusker, M.D., Lamont , J.V. & Fitzgerald, S.P.,Proc.XVI International Congress Clin. Chem.: 468(1996).

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

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