Anti-streptolysin O (ASO) Diagnostic Reagent Kit (Latex Enhanced Immunoturbidimetry Method) Product Instruction

Product name
Generic Name: Anti-streptolysin O (ASO) Diagnostic Reagent Kit (Latex Enhanced Immunoturbidimetry Method)
Abbreviation: ASO

Package Specifications

R1	R2
40ml×1	10ml×1
800ml×1	200ml×1
8000ml×2	2000ml×2

Calibrator (liquid):
Specification 1 (1.0mL×1; 1 level);
Quality Control (liquid):
Specification 1 (1.0mL×1; 2 levels);

Intended use
Anti-streptolysin O (ASO) diagnostic reagent is used for quantitative in vitro determination of Anti-streptolysin O in human serum on photometric systems.

Clinical significance
Antistreptolysin O (ASO) is an antibody to SLO. The ASO test is used to provide evidence for antecedent streptococcal infection, primarily in patients suspected of having acute rheumatic fever or poststreptococcal glomerulonephrltis, and occasionally in individuals who had pharyngitis or other acute infections. The antibody response to the antigen, in general, peaks at about 3 weeks after the acute streptococcal infection, remains at the peak level for 3 to 4 months, and the declines gradually to normal levels.

Principle
ASO in the sample combines specifically with the latex sensitized with streptolysin O in the latex reagent to yield an insoluble aggregate which causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the concentration of ASO in the patient’s sample.

Main ingredients

Composition	Main ingredients
R1	Tris buffer 10mmol/L, Surfactant 1mL/L, NaCL 3g/L
R2	Latex particles labeled with streptolysin O 1.25%
Calibration	Phosphate buffer 100mM, Sucrose 7%, BSA 6%, Streptolysin O. antibody
Quality control	Phosphate buffer 100mM, Sucrose 7% BSA 6%, Streptolysin O antibody.

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum;
-20℃, stable for 7 days.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	570 nm	Sample(S)	2 μ l
Subwavelength	700nm	Reagent 1	160 μ l
Reation temperature	37℃	Reagent 2	40 μ l
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	2 μ l
R1	160 μ l
Mix well, incubate at 37° C for 5 minutes, then add	
R2	40 μ l
Mix well, incubate at 37℃for 30 seconds, absorbance A1; incubate at 37℃for 4.5 minutes, absorbance A2 △A= A2- A1	

Calculations
Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in IU/ml on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval
0 IU/ml-200 IU/ml
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective

measures to be taken if values fall outside the limits.

Performance characteristics

1. Measuring range

0IU/ml - 600IU/ml. Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

2. Sensitivity

When a control serum (75 IU/ml) is used as a sample, the absorbance change is 0.008-0.05.

3. Precision

Within-Run		
n= 20	Level 1	Level 2
Mean (IU/ml)	106.2	201.0
SD (IU/ml)	1.43	2.26
CV (%)	1.35	1.12

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	30 mg/dl
Haemoglobin	5 g/L
Intralipid	0.3 %
VC	0.5 g/L
Heparin Sodium	100U/ml

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

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

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters for analyzers

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	18-34
Wave Length Sec	700
Wave Length Prim	570
ABS. Limit	32000
Sample Volume（uL）	2
R1 Volume（uL）	160
R2 Volume（uL）	0
R3 Volume（uL）	40
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	2
Sample DIL. VOL.	/
R1 Volume（uL）	160
R2 Volume（uL）	40
Reagent DIL. VOL.	/
Measure Wave 1	570
Measure Wave 2	700
METHOD	END
SLOPE	-
Method Point	11-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	0
Dynamic Range H	600
Correlation Factor A	1.0

Correlation Factor B	0.0
Calibration Type	5AB
Formula	spline
STD(1) Conc.#	*
Unit	IU/ml

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