



DIAGNOSTIC KIT FOR DETERMINATION OF ANTI-STREPTOLYSIN O LEVELS

INTRODUCTION

Most people infected with hemolytic streptococcus produce antistreptolysin O (ASO), antibodies against streptolysin O (SLO), an exotoxin of Streptococcus. Measuring the level of ASO is effective for diagnosing, judging the progress of medical treatment, and assessing recovery from diseases caused by hemolytic streptococcus such as rheumatic fever, acute glomerulonephritis, scarlatina and tonsillitis.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between ASO in a sample and SLO which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of ASO in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS Package

8	Cat. No 4-270 (24-TRAY)	Cat. No 4-489 (36-TRAY)
1-Reagent	2 x 14 ml	3 x 10 ml
2-Reagent	2 x 20 ml	3 x 13 ml

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. Stability on board of the analyser at 2-10°C: Prestige 24i - 12 weeks, Biolis 24i Premium – 12 weeks. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with	0.17 w/v%
SLO (pH 8.2)	
glycine buffer solution (pH 8.3)	

Warnings and notes

- Product for in vitro diagnostic use only.
- Reagent bottles should be shaken before use by gently inverting several times.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citric acid). After blood has clotted thoroughly, the sample is centrifuged and the serum is separated from blood cells and fibrins. If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Prestige 24i, Biolis 24i, Sapphire 400 and Prestige 24i Premium, Biolis 24i Premium, Sapphire 400 Premium.

- 1-Reagent and 2-Reagent are ready to use.
- 1-Reagent put on basic position in reagent tray.

2-Reagent put on start position in reagent tray.

For reagent blank 0.9% NaCl is recommended.

REFERENCE VALUES³

serum, plasma < 160 IU/ml It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL I (Cat. No 4-288) with each batch of samples. For the calibration of automatic analysers systems the CORMAY ASO CALIBRATOR kit (Cat. No 4-278) is recommended.

The calibration curve should be prepared every 12 weeks (Prestige 24i, Biolis 24i Premium), with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Biolis 24i Premium and Hitachi 917. Results may vary if a different instrument is used.

- Sensitivity: 38 IU/ml.
- **Linearity:** up to 1100 IU/ml. For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- Specificity / Interferences

Haemoglobin up to 0.5 g/dl, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

Precision Repeatability (run to run)

Repeatability (run to run)	Mean	SD	CV
n = 20	[IU/ml]	[IU/ml]	[%]
level 1	46.8	1.07	2.29
level 2	80.2	1.31	1.63
level 3	221.7	2.62	1.18

Reproducibility (day to day) n = 12	Mean [IU/ml]	SD [IU/ml]	CV [%]
level 1	48.8	2.83	5.81
level 2	78.8	2.60	3.30
level 3	219.8	5.24	2.38

Method comparison

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 50 samples gave following results:

y = 1.11 x - 44 IU/ml;

R = 0.945

(R - correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983).
- Singer J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 21, 888 (1956).
- 3. Shojiro Kano: antistreptolysin O (ASO), Nippon Rinsho, 57, 108 (1999).

APPLICATION for Prestige 24i, Biolis 24i and Sapphire 400

Item name 51	ASO					
Data information	1 1	Calibrati	-			
Units	IU/ml	Туре	Li	near		
Decimals	0	Standard				
		#1	*	#4		
Analysis		#2		#5		
Туре	END	#3		#6		
Main W.Length1	570					
Sub W.Length2	800	Normal F	lange			
Method	Immuno		M	ale	Fer	nale
			Low	High	Low	High
Corr		Serum	0	160	0	160
Slope	Inter	Urine				
Y= 1.000	X+ 0.000	Plasma	0	160	0	160
		CSF				
		Dialysis				
		Other				

Aspiration Kind		Double		Data P Read	100033		Abcor	bance Li	mit
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		lume		Main	52	54	High	ı 3.)00
Sample	3			Sub	37	38			
Reagent1	100)	μl						
Reagent2	170)		Factor			Endpoint I	Limit	2.000
				Blank co	prrection		Linear Che	eck (%)	0
Third Mix	. (DN		Dilutio	n				
R1 Blank	V	Vater-l	Blank	Diluent	t	99:Di	11		
Monitor				Prozor	ne Check				
0 Level Po	int	1				Start	End	Limit	(%)
Span		3.00)	First					
				Second	l				Low
				Third					Low

Auto Rer	un SW		Auto Rerun	Condition (A	bsorbance)
OFF			Absorbance F	Range	
				Lower	OFF
Auto Rer	un Range (H	Result)		Higher	OFF
	OFF	OFF			
	Lower	Higher	Prozone Rang	ge	OFF
Serum					
Urine					
Plasma					
CSF					
Dialysis					
Other					

APPLICATION for Prestige 24i Premium, Biolis 24i Premium and Sapphire 400 Premium

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						Blank	l)	#1	*	#2	
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Type			END m	ethod		#6						
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Sub Wa	ve Leng	gth	800 nm									
Method			Immun	0								
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	gent 1	16			μl	AU	s.LII	m		/		High
Rea	gent 2	11	0 1	0	μl				-3		~	3
Blank v	alue					Co	rrec	tion	value			
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