Cat. No 4–270 and 4-489

Prestige 24i

CE CORMAY

PRESTIGE 24i ASO

DIAGNOSTIC KIT FOR DETERMINATION OF ANTI-STREPTOLYSIN O LEVELS

INTRODUCTION

Most people infected with hemolytic streptococcus produce anti-streptolysin 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

	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 SLO (pH 8.2)	0.17 w/v%
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 VALUES [3]

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) n = 20	Mean [IU/ml]	SD [IU/ml]	CV [%]
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

1. Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983).
2. 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

Units	**IU/ml**
Decimals	**0**

Analysis

Type	**END**
Main W.Length1	**570**
Sub W.Length2	**800**
Method	**Immuno**

Corr

Slope		Inter
Y= **1.000**	X+	**0.000**

Calibration

Type	**Linear**		
Standard			
#1	*	#4	
#2		#5	
#3		#6	

Normal Range

	Male		Female	
	Low	High	Low	High
Serum	**0**	**160**	**0**	**160**
Urine				
Plasma	**0**	**160**	**0**	**160**
CSF				
Dialysis				
Other				

Item name	51	ASO

Aspiration

Kind	**Double**

	Volume	
Sample	**3**	µl
Reagent1	**100**	
Reagent2	**170**	

Third Mix.	**ON**
R1 Blank	**Water-Blank**

Monitor

0 Level Point	**1**
Span	**3.000**

Data Process

Read

	Start	End
Main	**52**	**54**
Sub	**37**	**38**

Absorbance Limit

Low	**-3.000**
High	**3.000**

Factor

Blank correction		Endpoint Limit	**2.000**
		Linear Check (%)	**0**

Dilution

Diluent	**99:Dil1**

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**
Third				**Low**

Item name	51	ASO

Auto Rerun SW

OFF

Auto Rerun Range (Result)

	OFF	OFF
	Lower	Higher
Serum		
Urine		
Plasma		
CSF		
Dialysis		
Other		

Auto Rerun Condition (Absorbance)

Absorbance Range	
Lower	**OFF**
Higher	**OFF**

Prozone Range	**OFF**

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

Item No.	51	Item Name	ASO	Optical

Data information

Units	**IU/ml**
Decimals	**0**

Analysis

Type	**END method**
Main Wave Length	**570 nm**
Sub Wave Length	**800 nm**
Method	**Immuno**

Correlation

Slope		Intercept
Y= **1**	X+	**0**

Calibration

Type	**Linear1**				
Std sample conc.					
Blank	**0**	#1	*	#2	
#3		#4		#5	
#6					

Item No.	51	Item Name	ASO	Optical

Aspiration

Kind	**Double**
Vol.	

Kind	Vol.	Add	Units
Sample	**3**	**5**	µl
Reagent 1	**160**	**10**	µl
Reagent 2	**110**	**10**	µl

Blank value

Water Blank

Reaction Monitor

0 Level Point	**1**
Span	**3**

Third mixing

ON

Data Process

Read	Start	End
Main	**50**	**52**
Sub	**37**	**38**

Abs.Limit Low **-3** ~ High **3**

Correction value

Blank correction	**1**
End Point Limit	**2**
Linear Check (%)	

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**

Item No.	51	Item Name	ASO	Optical

Normal Range

	Male		Female	
	Low	High	Low	High
Serum	**0**	**160**	**0**	**160**
Urine				
Plasma	**0**	**160**	**0**	**160**
CSF				
Dialysis				
Other				

Panic Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item No.	51	Item Name	ASO	Optical

Auto Rerun SW

ON

Auto Rerun Range (Conc.)

	First Dil	Low			High		
		Re	Value	Dil	Re	Value	Dil
Serum			**38**			**1100**	
Urine							
Plasma							
CSF							
Dialysis							
Other							

Auto Rerun Condition (Absorbance)

Lower	**OFF**
Higher	**OFF**

Auto Rerun Condition (Prozone)

OFF

Dilution

99:Dil1

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MANUFACTURER

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