Cat. No 4-254 and 4-454

PRESTIGE 24i DIGOXIN

DIAGNOSTIC KIT FOR DETERMINATION OF DIGOXIN CONCETRATION

INTRODUCTION

Digoxin is a cardiac glycoside used to treat heart failure and atrial fibrillation with rapid ventricular rhythm. It increases the force and excitability of the heart muscle, slows down condution in atrioventricular node and also reduces heart rate. Digoxin is a glycoside obtained from *Digitalis lanata*. It is excreted mainly unchanged via the kidneys. Digoxin concentration monitoring is recommended because of a narrow therapeutic range and serious side effects: arrhythmia, disturbance of condution. Using digoxin under the control of concentration enables detection of dangerous side effects before clinical symptoms appear, also it allows to avoid underdosage - "sham therapy".

METHOD PRINCIPLE

Immunoturbidimetric method; inhibition of agglutination.
Increase of absorbance measured at λ = 700 nm is inversely proportional to the concentration of digoxin in the sample.
Digoxin which is present in the sample forms immune complexes with specific antibody contained in the first reagent. After adding a second reagent containing polistyrene latex particles coated with digoxin, agglutination is inhibited in proportion to digoxin concentration in the sample.

REAGENTS

Package

	Cat. No 4-254 (24-TRAY)	**Cat. No 4-454 (36-TRAY)**
1-Reagent	2 x 11.5 ml	2 x 10 ml
2-Reagent	2 x 7.5 ml	2 x 7 ml

Unopened reagents stored at 2-8°C are stable up to the expiry date printed on the package. After opening the reagents are stable for 21 days on board the analyser at 2-10°C. Protect from light!

Reagents composition

Bis-Tris buffer, monoclonal antibodies to digoxin, polistyrene latex particles coated with digoxin, sodium azide (< 0.1%).

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents should be used by suitably qualified laboratory personnel only in accordance with intended purpose.
- The reagents contain sodium azide as a preservative (< 0.1%). Avoid contact with skin and mucous membranes.Sodium azide can form high explosive metal azide combinations with lead and cooper. Drains should be flushed well with a large amount of water when discarding the solution.
- Mix well Reagent 2 before first use. Avoid foam formation.
- For optimal reagents stability it is recommended to remove them from the system and store in tightly closed bottles at 2-8°C.

SPECIMEN

Serum. Samples may be stored up to 3 days at 2-8 °C. or longer at -20°C. Nevertheless it is recommended to perform the assay with freshly collected samples!
Avoid repeated freezing and thawing. Mix well the samples before analysis.

PROCEDURE

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

APPLICATION

Item name	**DIGOX**

Data information

Units	**ng/ml**
Decimals	**2**

Analysis

Type	**END**
Main W.Length1	**700**
Sub W.Length2	
Method	**Immunoturbidymetric**

Corr

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

Calibration

Type	**Linear**
Factor	

Standard

#1	*	#4	*
#2	*	#5	*
#3	*	#6	*

Normal Range

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

Aspiration

Kind	**Double**

	Volume	
Sample	**10**	µl
Reagent1	**150**	
Reagent2	**100**	

Third Mix.	**OFF**
R1 Blank	**Water-B**

Monitor

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

Data Process

Read			**Absorbance Limit**	
	Start	End		
Main	**53**	**54**	Low	**0.000**
Sub	**34**	**35**	High	**3.000**

Factor		Endpoint Limit	**2.000**
Blank correction:	**1.0000**	Linear Check (%)	**90%**

Dilution

Diluent	**100 : Dil2**

Prozone Check

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

Auto Rerun SW

ON

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**

THERAPEUTIC RANGE

therapeutic concentration	0.8 – 2.0 ng/ml (1 – 2.6 nmol/l)

Some patients achieve the desired therapeutic response at levels outside this range, so it is recommended to consider the need to establish an individual therapeutic ranges for each patient.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY TDM CONTROLS (Cat. No 5-107) with each batch of samples. For the calibration of automatic analysers systems the CORMAY DIGOXIN CALIBRATORS (Cat. No 5-113) is recommended.
The calibration curve should be prepared every 7 days, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

Metrological characteristics may differ from values presented below with the instrument used.

- **Sensitivity / Limit of Detection:** 0.14 ng/ml (0.18 nmol/l).

- **Linearity:** up to 5.5 ng/ml (7.08 nmol/l). If the digoxin concentration exceeds 5.5 ng/ml, dilute the sample 1:5 with saline solution and repeat the assay. The dilution take into account when making the results.

- **Specificity / Interferences**

Haemoglobin up to 3 g/dl, bilirubin up to 60 mg/dl, total protein up to 10 g/dl, triglyceride up to 1.9 g/dl do not interfere with the test.

- **Precision**

Reproducibility (day to day) n = 80	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	1.0	0.07	7.32
level 2	1.89	0.09	4.82
level 3	2.92	0.08	2.86

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 50 samples gave following results:
y = 0.949x – 0.081 ng/ml;
R = 0.9893 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Oellerich, M. Therapeutic drug monitoring. In: Thomas L, ed. Clinical Laboratory Diagnostics. Use and Assesment of Clinical Laboratory Results. 1st Edition. TH-Books, Frankfurt/Main, Germany, 1998.
2. Ruiz R, Borque L, Soria AG, Córdova MA, Asolo B. Evaluation of an immunoturbidimetric assay of serum digoxin wilthout sample pretreatment. Eur J Clin Chem Clin Biochem 33, 171-175, 1995.
3. Scholer A, Boecker J, Engelmayer U, Feldmann K, Hannak D, Kattermann R, Oellerich M, Raith H, Schlebusch H, Wieland H, Willems D, Jarausch J, Domke I. Comparability of a new turbidimetric digoxin test with other immunochemical tests and with HPLC – a multicenter evaluation. Clin Chem 43, 92- 99, 1997.
4. Biosafety in Microbiological and Biomedical Laboratories, Richmond JY, McKinney RW, eds. US Department of Health and Human Services, 4th Edition, 1999.
5. Westgard JO, Barry PL. Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes, AACC Press, 1986.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th Edition, AACC Press, 2000.
7. Tietz NW. Clinical Guide to Laboratory Tests. WB Saunders Company, Philadelphia, 1990.
8. Alan H. B. Wu, Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Company, 4th edition, 1456 (2006).

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