

## ACCENT-300 DIGOXIN

### DIAGNOSTIC KIT FOR DETERMINATION OF DIGOXIN CONCENTRATION

#### 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 conduction 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 conduction. 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  $\lambda = 700$  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 polystyrene latex particles coated with digoxin, agglutination is inhibited in proportion to digoxin concentration in the sample.

#### REAGENTS

<b>Package</b>	
1-Reagent	2 x 12.5 ml
2-Reagent	2 x 8.5 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, polystyrene 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 copper. 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

This reagent may be used in automatic analyser ACCENT-300

1-Reagent and 2-Reagent are ready to use.  
For reagent blank deionized water is recommended.

#### APPLICATION

##### Parameters

No.	72	Prim.Wave.	700
Test	DIGO	Sec.Wave.	
Method	Endpoint	Sample Vol.	3
Direction	Ascend	R1 Vol.	180
Unit	ng/ml	R2 Vol.	120
Decimals	2	Line. Limit	20
Incubation	10	Antigen Check	
Reaction	-2   30	Substrat	0
<b>R1 Blank</b>		<b>Mix. R Blank</b>	
Lower	0	Lower	0
Upper	0	Upper	0
<b>Response</b>		<b>Linearity</b>	
Lower	-2.5	Lower	
Upper	2.5	Upper	
S. volume	45	Full Name	Digoxin
Ratio	5	Print No.	72

##### Calibration

Method	Spline
K Factor	
Replicates	1
Interval	0
Sensitivity	0
Coefficient	0
Rerun Error Limit	0 2.5
Blank Response	0   2.5
Difference Limit	0
SD	0

#### 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:

$$y = 0.949x - 0.081 \text{ ng/ml};$$

$$R = 0.9893 \quad (R - \text{correlation coefficient})$$

**WASTE MANAGEMENT**

Please refer to local legal requirements.

**LITERATURE**

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