

## quantex DIGOXIN



### Kit Configuration

P/N 3000-2275	2 x 9 mL DIGO R1
	2 x 6.5 mL DIGO R2

### Reagent Preparation

P/N 3000-2275: DIGO R1: Ready to use.  
 DIGO R2: Ready to use. Invert to mix well before first use. Avoid foam formation  
 Place the bottles into reagent tray.

### In Use Stability

Stable until the expiration date shown on the vial when stored at 2-8°C. For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

### Specimen

Serum.

### Calibration

Use quantex DIGOXIN standard multipoint Cat. No 3000-2283. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 7 days, when a new lot of reagents is used, when control recovery falls out of the expected range or when adjustments are made to the instrument. A reagent blank should be run daily before sample analysis.

### Quality Control

Use quantex TDM control I/II Cat. No 3000-2303.

### Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

### Therapeutic Range

The typical therapeutic range is 0.8 - 2.0 ng/mL (1.0 - 2.6 nmol/L) and the toxic range is > 2.5 ng/mL (> 3.2 nmol/L). To convert results to nmol/L multiply by 1.28.<sup>1,6</sup>

### References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

## Performance Characteristics

### Limitation/Interfering Substances

No significant interference from bilirubin up to concentrations of 20 mg/dL, hemoglobin up to concentrations of 1000 mg/dL and lipemia up to concentrations of 5 g/L. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*<sup>5</sup>

### Precision

	Samples/ Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	3/10	0.79	4.6	1.84	4.1
Total	3/10	0.79	7.6	1.84	2.5

### Linearity

no rerun 0.4 to 5 ng/mL

With rerun 0.4 to 40 ng/mL



### Instrument Settings

<b>Photometric Test Parameters</b>		<b>Serum</b>
Test No.		**
Test Name, Test Code		DIGO, DIGO
Sample Type		Serum
Reporting Unit, Decimal Points		ng/mL, 1
Reaction Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		End Point, 20/33
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelength		700
<b>Sampling Conditions</b>		
<i>Sampling 1</i>	Sample Vol.	7
	Sample/Diluent Vol.	0/0
<i>Sampling 2</i>	Sample Vol.	7
	Sample/Diluent Vol.	20/140
<i>Sampling 3</i>	Sample Vol.	14
	Sample/Diluent Vol.	0/0
<i>Sampling 4</i>		***
Diluent Code		Saline
Diluent Warning Limit		***
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
<b>Reagent Volumes</b>		
R1	Code	01661
	Rgt/Dil. Vol. Stirring	105/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	**
R2	Code	01662
	Rgt/Dil. Vol. Stirring	75/10, ON
	Low Vol. Warning Limit	***
	Stability (days)	**

<b>Ranges and Evaluation Criteria</b>		<b>Serum</b>
Normal Range-Male		**
Normal Range-Female		**
Normal Range-Other		**
Valid Range		0 - 5.0
Hemolysis/Icterus/Lipemia Limit		***
Reaction Slope		Positive
Absorbance Limit		Above, 3200
Prozone Limit		N/A
Non Linear Limit		N/A
Slope/Intercept Correction		1/0
Qualitative Report		OFF
<b>Calibration Conditions</b>		
Calibration		6 Points, point to point, 2 Reps
Stability (days)		7
Calibrator, Concentration		Digoxin Std, *
R-Blank Limit (mAbs)		3500
Cal. Repts Range (%)		***
Min Cal. Response (mAbs)		***
Cal. Factor Change (%)		***
M-Point Curve Fit (%)		N/A
Reagent Blank		ON
Auto R-Blank by Bottle		ON

- \* Lot dependent
- \*\* operator definable
- \*\*\* optional
- N/A not applicable to this test

