

*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 97 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 350 Operator 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.

**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>1</sup>

**Precision**

	Samples/ Runs	Mean (ng/mL)	CV (%)	Mean (ng/mL)	CV (%)
Within run	4/10	0.9	4.3	2.0	3.4
Total	4/10	0.9	7.3	2.0	4.0

**Linearity**

no rerun 0.4 to 8 ng/mL

With rerun 0.4 to 28 ng/mL

Instrument Settings

<b>Chemistry Parameters</b>				<b>R1</b>			
Method	<input type="text"/>	Reagent Name	<input type="text" value="DIGO"/>	Volume	<input type="text" value="105 μL"/>		
Name	<input type="text" value="DIGO"/>	R2	<input type="text" value="enable"/>				
Unit	<input type="text" value="ng/mL"/>	Reagent Name	<input type="text" value="DIGO"/>	Volume	<input type="text" value="75 μL"/>		
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/>	Reagent Name			
		Diluent	<input type="text" value="enable"/>	Reagent Type			
				Reagent Name	<input type="text" value="Saline"/>		
<b>Measuring Points</b>	1 enable	start	<input type="text" value="14"/>	<b>Decimal Points</b>	<input type="text" value="1"/>		
		end	<input type="text" value="15"/>				
	2 enable	start	<input type="text" value="25"/>	<b>Normal Range</b>	<input type="text" value="0.8"/>	<input type="text" value="2.0"/>	
		end	<input type="text" value="26"/>				
<b>Wave Length</b>				<b>Technical Range (Conc)</b>	<input type="text" value="0.0"/>	<input type="text" value="8"/>	
Prim	<input type="text" value="700"/>	Sec	<input type="text"/>	mAbs/10	<input type="text" value="-30000 / 30000"/>		
<b>Sampling Volume</b>	<input type="text" value="7 μL"/>						
Dilution	<input type="text" value="disable"/>			<b>RPT Wash</b>	(R1) <input type="text" value="Sys Water"/>		
	<input type="text"/>	<input type="text"/>			(R2) <input type="text" value="Sys Water"/>		
<b>Rerun ( High)</b>	<input type="text" value="2 μL"/>			<b>Instrument Factor a</b>	<input type="text" value="1"/>	<b>b</b>	<input type="text" value="0"/>
Dilution	<input type="text" value="disable"/>			<b>Stirring Speed</b>	R1 <input type="text" value="high"/>	R2	<input type="text" value="high"/>
	<input type="text"/>	<input type="text"/>					
<b>Rerun ( Low)</b>	<input type="text" value="14 μL"/>						

Calibration Checks

** Duplicate Limit	<input type="text"/>	** mAbs/10	<b>Sampling Method for Standards</b>
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input checked="" type="checkbox"/> Duplicate
			<input type="checkbox"/> Triplicate
** Linearity Limit	<input type="text"/>	** %	
** Prozone Limit	<input type="text" value="upper"/>		<b>Blank measurement</b>
SL1-S	** <input type="text" value="SL1-F"/>	**	<input checked="" type="checkbox"/> Enable Reagent blank
SL2-S	** <input type="text" value="SL2-F"/>	**	<input type="text" value="None"/>
Sens	<input type="text"/>	mAbs/10	<b>Reagent blank measurement at calibration</b>
<input checked="" type="checkbox"/> Absorbance Limit			<input checked="" type="checkbox"/> Reagent blank (system water)
Reaction	<input type="text" value="Increase"/>		<b>Multiplex measurement is the same as standards</b>
Limit	<input type="text" value="25000"/>	mAbs/10	<b>Reagent Blank Limit Checks</b>
			** Duplicate limit <input type="text" value="50"/>

Calibration

<b>Method</b>	<input type="text"/>	<b>Name</b>	<input type="text" value="DIGO"/>	<b>Interval</b>	<input type="text" value="97"/>	days
<b>Calculation</b>	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="-48"/>			K	<input type="text" value="N/A"/>
S2	<input type="text" value="0.5"/>	<input type="text" value="-221"/>				
S3	<input type="text" value="1"/>	<input type="text" value="-472"/>				
S4	<input type="text" value="2"/>	<input type="text" value="-798"/>				
S5	<input type="text" value="3"/>	<input type="text" value="-1075"/>				
S6	<input type="text" value="5"/>	<input type="text" value="-1429"/>				

Reagent Registration

Reagent Code	<input type="text" value="0166"/>					
Reagent Name	<input type="text" value="DIGO"/>					
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/>	mL	Volume (S)	<input type="text" value="**"/>
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/>	mL	Volume (S)	<input type="text" value="**"/>
		Stability Check	<input checked="" type="checkbox"/> enable		Term	<input type="text" value="**"/>
			<input checked="" type="checkbox"/> enable			days
**	Operator definable	N/A	not applicable to this test		Calibration curve is only as example	