

*quantex* DIGITOXIN**Kit Configuration**

P/N 3000-2276	2 x 10.5 mL DIGI R1
	2 x 6.5 mL DIGI 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* DIGITOXIN standard multipoint Cat. No 3000-2284. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 90 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* DIGITOXIN control I/II Cat. No 3000-2291.

**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 10 - 25 ng/mL (13 - 33 nmol/L) and the toxic range is > 45 ng/mL (> 59 nmol/L). To convert results to nmol/L multiply by 1.31.

**References / Literatur / Bibliografía / Bibliographie / Bibliografia /**

See package insert enclosed in the kit

<b>Performance Characteristics</b>
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**Limitation/Interfering Substances**

No significant interference from bilirubin up to concentrations of 20 mg/dL (340 µmol/L), hemoglobin up to concentrations of 1000 mg/dL (0.6 mmol/L) and lipemia up to concentrations of 20 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	27.6	1.6	71.2	8.3
Total	4/10	27.6	0.7	71.2	8.4

**Linearity**

no rerun 19 to 80 ng/mL  
 With rerun 19 to 120 ng/mL

### Instrument Settings

<b>Chemistry Parameters</b>				<b>R1</b>			
Method	<input type="text"/>	Reagent Name	<input type="text" value="DIGI"/>	Volume	<input type="text" value="110 μL"/>		
Name	<input type="text" value="DIGI"/>	R2	<input type="text" value="enable"/>				
Unit	<input type="text" value="ng/mL"/>	Reagent Name	<input type="text" value="DIGI"/>	Volume	<input type="text" value="70 μL"/>		
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/>	Reagent Name	<input type="text"/>		
				Diluent	<input type="text" value="enable"/>	Reagent Type	<input type="text" value="Saline"/>
Measuring Points	1 enable	start	<input type="text" value="14"/>	Decimal Points	<input type="text" value="1"/>		
		end	<input type="text" value="15"/>	Normal Range	<input type="text" value="20"/>	<input type="text" value="35"/>	
	2 enable	start	<input type="text" value="25"/>				
		end	<input type="text" value="26"/>				
Wave Length							
Prim	<input type="text" value="700"/>	Sec	<input type="text"/>	Technical Range (Conc)	<input type="text" value="0.0"/>	<input type="text" value="80"/>	
				mAbs/10	<input type="text" value="-30000 / 30000"/>		
Sampling Volume	<input type="text" value="3 μL"/>						
Dilution	<input type="text" value="disable"/>	RPT Wash	(R1)	<input type="text" value="Sys Water"/>			
	<input type="text" value="μL"/>		(R2)	<input type="text" value="Sys Water"/>			
Rerun ( High)	<input type="text" value="2 μL"/>						
Dilution	<input type="text" value="enable"/>	Instrument Factor a	<input type="text" value="1"/>	b	<input type="text" value="0"/>		
	<input type="text" value="35 μL"/>	<input type="text" value="105 μL"/>	Stirring Speed	R1	<input type="text" value="high"/>	R2	<input type="text" value="high"/>
Rerun ( Low)	<input type="text" value="6 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"/>	upper	<b>Blank measurement</b>				
SL1-S	**	SL1-F **	<input checked="" type="checkbox"/>	Enable Reagent blank			
SL2-S	**	SL2-F **	<input type="text" value="None"/>				
Sens	<input type="text"/>		<b>Reagent blank measurement at calibration</b>				
	mAbs/10		<input checked="" type="checkbox"/>	Reagent blank (system water)			
<input checked="" type="checkbox"/> Absorbance Limit			<b>Multiplex measurement is the same as standards</b>				
Reaction Limit	<input type="text" value="Increase"/>			<b>Reagent Blank Limit Checks</b>			
Limit	<input type="text" value="25000"/>	mAbs/10		**	Duplicate limit		
				<input type="text" value="50"/>	mAbs/10		

### Calibration

Method	<input type="text"/>	Name	<input type="text" value="DIGI"/>	Interval	<input type="text" value="90"/>	days
Calculation	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="121"/>	<input type="text"/>	<input type="text"/>	K	<input type="text" value="N/A"/>
S2	<input type="text" value="9"/>	<input type="text" value="-305"/>	<input type="text"/>	<input type="text"/>		
S3	<input type="text" value="10"/>	<input type="text" value="-856"/>	<input type="text"/>	<input type="text"/>		
S4	<input type="text" value="20"/>	<input type="text" value="-1644"/>	<input type="text"/>	<input type="text"/>		
S5	<input type="text" value="40"/>	<input type="text" value="-2515"/>	<input type="text"/>	<input type="text"/>		
S6	<input type="text" value="80"/>	<input type="text" value="-3229"/>	<input type="text"/>	<input type="text"/>		

### Reagent Registration

Reagent Code	<input type="text" value="0164"/>													
Reagent Name	<input type="text" value="DIGI"/>													
R1	<input checked="" type="checkbox"/>	enable	Volume (L)	<input type="text"/>	mL	Volume (S)	<input type="text"/>	mL	Stability Check	<input checked="" type="checkbox"/>	enable	Term	<input type="text"/>	days
R2	<input checked="" type="checkbox"/>	enable	Volume (L)	<input type="text"/>	mL	Volume (S)	<input type="text"/>	mL	Stability Check	<input checked="" type="checkbox"/>	enable	Term	<input type="text"/>	days
**	Operator definable		N/A		not applicable to this test			Calibration curve is only as example						