

quantex Phenytoin

**Kit Configuration**

P/N 3000-2279	2 x 14.5 mL PHNY R1
	2 x 4 mL PHNY R2

Reagent Preparation

P/N 3000-2279: PHNY R1: Ready to use.
 PHNY 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 PHENYTOIN standard multipoint Cat. No 3000-2287. The concentrations in µg/mL are indicated on the vial labels. Recalibrate every 26 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 I Lab 350 Operator Manual.

Therapeutic Range

The typical therapeutic range is 10 - 20 µg/mL (40 - 79 µmol/L) and the toxic range is > 20 - 40 µg/mL (> 79 - 158 µmol/L). Some patients achieve the desired therapeutic response at levels outside this range; therefore, individual clinical evaluation should be considered when interpreting assay results.

To convert results to µmol/L multiply by 3.95.

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 20 g/L. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*¹

Precision

	Samples/ Runs	Mean (µg/mL)	CV (%)	Mean (µg/mL)	CV (%)
Within run	4/10	4.8	2.3	15	1.3
Total	4/10	4.8	3.9	15	4.4

Linearity

no rerun 0.88 to 40 µg/mL

With rerun 0.88 to 160 µg/mL



Instrument Settings

Chemistry Parameters				R1			
Method Name	<input type="text" value="PHN"/>	Reagent Name	<input type="text" value="PHN"/>	Volume	<input type="text" value="290 μL"/>		
Unit	<input type="text" value="μg/mL"/>	Reagent Name	<input type="text" value="PHN"/>	Volume	<input type="text" value="80 μL"/>		
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/>	Reagent Name			
		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="10.0"/>	<input type="text" value="40.0"/>	
	2 enable	start	<input type="text" value="25"/>				
		end	<input type="text" value="26"/>				
Wave Length				Technical Range (Conc)	<input type="text" value="0.0"/>	<input type="text" value="40"/>	
Prim	<input type="text" value="700"/>	Sec	<input type="text" value=""/>	mAbs/10	<input type="text" value="-30000 / 30000"/>		
Sampling Volume	<input type="text" value="2 μL"/>			RPT Wash (R1)	<input type="text" value="Sys Water"/>		
Dilution	<input type="text" value="disable"/>			(R2)	<input type="text" value="Sys Water"/>		
Rerun (High)	<input type="text" value="2 μL"/>			Instrument Factor a	<input type="text" value="1"/>	b	<input type="text" value="0"/>
Dilution	<input type="text" value="enable"/>			Stirring Speed	R1 <input type="text" value="high"/>	R2	<input type="text" value="high"/>
Rerun (Low)	<input type="text" value="35 μL"/>	<input type="text" value="105 μL"/>					
	<input type="text" value="4 μL"/>						

Calibration Checks

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

Calibration

Method	<input type="text" value=""/>	Name	<input type="text" value="PHN"/>	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="156"/>			K	<input type="text" value="N/A"/>
S2	<input type="text" value="2.5"/>	<input type="text" value="-358"/>				
S3	<input type="text" value="5"/>	<input type="text" value="-1025"/>				
S4	<input type="text" value="10"/>	<input type="text" value="-2325"/>				
S5	<input type="text" value="20"/>	<input type="text" value="-3761"/>				
S6	<input type="text" value="40"/>	<input type="text" value="-4422"/>				

Reagent Registration

Reagent Code	<input type="text" value="0169"/>											
Reagent Name	<input type="text" value="PHN"/>											
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/>	mL	Volume (S)	<input type="text" value="**"/>	mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/>	days
R2	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text" value="**"/>	mL	Volume (S)	<input type="text" value="**"/>	mL	Stability Check	<input checked="" type="checkbox"/> enable	Term	<input type="text" value="**"/>	days
**	Operator definable		N/A not applicable to this test		Calibration curve is only as example							