

quantex Theophylline



**Kit Configuration**

P/N 3000-2282	2 x 15 mL THEO R1
	2 x 2.5 mL THEO R2

**Reagent Preparation**

P/N 3000-2278: THEO R1: Ready to use.  
 THEO 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 THEOPHYLLINE standard multipoint Cat. No 3000-2290. 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 8 - 20 µg/mL (44 - 111 µmol/L) and the toxic range is > 20 µg/mL (> 111 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 5.55.

**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.*<sup>1</sup>

**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

<b>Chemistry Parameters</b>				<b>R1</b>			
Method Name	<input type="text" value="THEO"/>	Reagent Name	<input type="text" value="THEO"/>	Volume	<input type="text" value="300 μL"/>		
Unit	<input type="text" value="μg/mL"/>	Reagent Name	<input type="text" value="THEO"/>	Volume	<input type="text" value="50 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="8.0"/>	<input type="text" value="20.0"/>	
	2 enable	start	<input type="text" value="25"/>				
		end	<input type="text" value="26"/>				
Wave Length Prim	<input type="text" value="600"/>	Sec	<input type="text" value=""/>	Technical Range (Conc) mAbs/10	<input type="text" value="0.0"/>	<input type="text" value="40"/>	
Sampling Volume	<input type="text" value="2 μL"/>	RPT Wash (R1)	<input type="text" value="Sys Water"/>				
Dilution	<input type="text" value="disable"/>	RPT Wash (R2)	<input type="text" value="Sys Water"/>				
Rerun ( High) Dilution	<input type="text" value="2 μL"/>	Instrument Factor a	<input type="text" value="1"/>	b	<input type="text" value="0"/>		
Rerun ( Low) Dilution	<input type="text" value="35 μL"/>	Stirring Speed R1	<input type="text" value="high"/>	R2	<input type="text" value="high"/>		
	<input type="text" value="4 μL"/>						

### Calibration Checks

** Duplicate Limit	<input type="text" value="**"/>	mAbs/10	<b>Sampling Method for Standards</b>				
** Sensitivity Limit	<input type="text" value="**"/>	mAbs/10	<input checked="" type="checkbox"/> Duplicate				
** Linearity Limit	<input type="text" value="**"/>	%	<input type="checkbox"/> Triplicate				
** 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" value="**"/>	mAbs/10	<b>Reagent blank measurement at calibration</b>				
<input checked="" type="checkbox"/> Absorbance Limit	<input type="text" value="**"/>		<input checked="" type="checkbox"/> Reagent blank (system water)				
Reaction Limit	<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>				
			<input type="text" value="**"/>	Duplicate limit	<input type="text" value="50"/>	mAbs/10	

### Calibration

Method	<input type="text" value=""/>	Name	<input type="text" value="THEO"/>	Interval	<input type="text" value="26"/>	days
Calculation	<input type="text" value="Point to Point"/>					
	Conc	WORK	MASTER	Lot No		
S1	<input type="text" value="0"/>	<input type="text" value="-27"/>			K	<input type="text" value="N/A"/>
S2	<input type="text" value="2.5"/>	<input type="text" value="-2803"/>				
S3	<input type="text" value="5"/>	<input type="text" value="-4893"/>				
S4	<input type="text" value="10"/>	<input type="text" value="-6821"/>				
S5	<input type="text" value="20"/>	<input type="text" value="-8146"/>				
S6	<input type="text" value="40"/>	<input type="text" value="-8846"/>				

### Reagent Registration

Reagent Code	<input type="text" value="0170"/>					
Reagent Name	<input type="text" value="THEO"/>					
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="**"/>	days
		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