

quantex HbA<sub>1c</sub>

**Kit Configuration**

P/N 3000-2314	1 x 50 mL HbA <sub>1c</sub> (Diluent)
	1 x 28 mL Hb R1
	1 x 14 mL HbA <sub>1c</sub> R1
	1 x 14 mL HbA <sub>1c</sub> R2

**Reagent Preparation**

P/N 3000-2314	HbA <sub>1c</sub> (Diluent) : Ready to use
	Hb R1: Ready to use. Invert to mix well before first use. Avoid foam formation.
	HbA <sub>1c</sub> R1: Ready to use. Invert to mix well before first use. Avoid foam formation.
	mL HbA <sub>1c</sub> R2: Ready to use. Invert to mix well before first use. Avoid foam formation.

Place the bottles into reagent tray.

**In Use Stability**

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

**Specimen**

Whole blood or capillary blood samples.

**Calibration**

Use quantex HbA<sub>1c</sub> standard multipoint Cat. No 3000-2315.

Calibration of the quantex Hb hemoglobin reagent is performed with quantex HbA<sub>1c</sub> standard level 1 only.

Calibration of the quantex HbA<sub>1c</sub> reagents R1 and R2 is performed with quantex HbA<sub>1c</sub> standards levels 1 to 6.

The concentrations are indicated in the insert sheet. A reagent blank should be run daily before sample analysis. Recalibrate every 20 days or when a new lot of reagent is used.

**Quality Control**

Use quantex HbA<sub>1c</sub> Control I/II Cat. No.3000-2316.

**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.

**Reference Interval**

Depending on the assay used, HbA<sub>1c</sub> is approximately 4-6% in non diabetics, 6-8% in controlled diabetics, and can be as much as 20% in uncontrolled diabetics. 124 apparently normal healthy donors undergoing physical examination were tested for HbA<sub>1c</sub> using the quantex HbA<sub>1c</sub> reagents. The range of results of HbA<sub>1c</sub> was of 4.5-6.2% and a mean of 5.4% resulted.

In any case, it is recommended that each laboratory established its own expected range.

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

See package insert enclosed in the kit

**Performance Characteristics**

**Limitation/Interfering Substances**

No significant interference from triglycerides up to concentrations of 1600 mg/dL (18 mmol/L), bilirubin up to concentrations of 30 mg/dL (513 μmol/L) and rheumatoid factor up to 2000 IU/mL. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*<sup>1</sup>

**Precision**

	Samples/Runs	Mean (%HbA <sub>1c</sub> )	CV(%)	Mean(%HbA <sub>1c</sub> )	CV(%)
Within run	4/10	4.9	1.5	9.9	8.0
Total	4/10	4.9	2.0	9.9	4.0

**Method Comparison**

Comparison Method (x)	turbidimetric assay
Slope	0.96
y intercept	0.0
Range %HbA <sub>1c</sub>	6.16 – 13.03
r	0.98
n	40

**Linearity**

Total Hb : 7 to 23 g/dL

% HbA<sub>1c</sub> : 1.8% to 17.2% (for total Hb of 14 g/dL)

Samples with values above 17.2% of HbA<sub>1c</sub> should not be diluted and results should be reported as > 17.2% HbA<sub>1c</sub>.

### Instrument Settings

<b>Chemistry Parameters</b>				<b>R1</b>			
<b>Method</b>	<input type="text"/>	<b>Reagent Name</b>	<input type="text" value="HbA1c"/>	<b>Volume</b>	<input type="text" value="95 μL"/>		
<b>Name</b>	<input type="text" value="HbA1c"/>	<b>R2</b>	<input type="text" value="enable"/>	<b>Reagent Name</b>	<input type="text" value="HbA1c"/>	<b>Volume</b>	<input type="text" value="95 μL"/>
<b>Unit</b>	<input type="text" value="g/dL"/>	<b>Wash</b>	<input type="text" value="disable"/>	<b>Reagent Name</b>	<input type="text"/>		
<b>Assay Type</b>	<input type="text" value="End"/>	<b>Diluent</b>	<input type="text" value="enable"/>	<b>Reagent Type</b>	<input type="text"/>		
<b>Assay Type</b>	<input type="text" value="End"/>	<b>Reagent Name</b>	<input type="text" value="Saline"/>				
<b>Measuring Points</b>	<input type="checkbox" value="1"/> enable	<b>start</b>	<input type="text" value="15"/>	<b>Decimal Points</b>	<input type="text" value="2"/>		
		<b>end</b>	<input type="text" value="16"/>	<b>Normal Range</b>	<input type="text" value="0.0"/>	<input type="text" value="2.1"/>	
	<input type="checkbox" value="2"/> enable	<b>start</b>	<input type="text" value="23"/>				
		<b>end</b>	<input type="text" value="24"/>				
<b>Wave Length</b>							
<b>Prim</b>	<input type="text" value="700"/>	<b>Sec</b>	<input type="text"/>	<b>Technical Range (Conc)</b>	<input type="text" value="0.0"/>	<input type="text" value="2.1"/>	
				<b>mAbs/10</b>	<input type="text" value="-30000 / 30000"/>		
<b>Sampling Volume</b>	<input type="text" value="4 μL"/>						
<b>Dilution</b>	<input type="text" value="disable"/>						
	<input type="text" value="μL"/>	<input type="text" value="μL"/>					
<b>Rerun ( High)</b>	<input type="text" value="4 μL"/>						
<b>Dilution</b>	<input type="text" value="enable"/>						
	<input type="text" value="μL"/>	<input type="text" value="μL"/>					
<b>Rerun ( Low)</b>	<input type="text" value="4 μL"/>						
	<input type="text" value="μL"/>	<input type="text" value="μL"/>					
<b>RPT Wash</b>	(R1)		<input type="text" value="Sys Water"/>				
	(R2)		<input type="text" value="Sys Water"/>				
<b>Instrument Factor a</b>	<input type="text" value="1"/>	<b>b</b>	<input type="text" value="0"/>				
<b>Stirring Speed</b>	R1	<input type="text" value="mid"/>	R2	<input type="text" value="mid"/>			

### Calibration Checks

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

### Calibration

<b>Method</b>	<input type="text"/>	<b>Name</b>	<input type="text" value="HbA1c"/>	<b>Interval</b>	<input type="text" value="20"/>	<b>days</b>
<b>Calculation</b>	<input type="text" value="Point to Point"/>					
	<b>Conc</b>	<b>WORK</b>	<b>MASTER</b>	<b>Lot No</b>		
S1	<input type="text" value="0"/>	<input type="text" value="-1124"/>	<input type="text"/>	<input type="text"/>	<b>K</b>	<input type="text" value="N/A"/>
S2	<input type="text" value="0.47"/>	<input type="text" value="-3613"/>	<input type="text"/>	<input type="text"/>		
S3	<input type="text" value="0.78"/>	<input type="text" value="-5225"/>	<input type="text"/>	<input type="text"/>		
S4	<input type="text" value="0.99"/>	<input type="text" value="-6053"/>	<input type="text"/>	<input type="text"/>		
S5	<input type="text" value="1.54"/>	<input type="text" value="-6821"/>	<input type="text"/>	<input type="text"/>		
S6	<input type="text" value="2.00"/>	<input type="text" value="-7270"/>	<input type="text"/>	<input type="text"/>		

### Reagent Registration

<b>Reagent Code</b>	<input type="text" value="0198"/>						
<b>Reagent Name</b>	<input type="text" value="HbA1c"/>						
	<b>Volume (L)</b>	<b>Volume (S)</b>	<b>Stability Check</b>	<b>Term</b>			
R1	<input checked="" type="checkbox"/> enable	<input type="text" value="**"/>	<input type="text" value="mL"/>	<input checked="" type="checkbox"/> enable	<input type="text" value="**"/>		
R2	<input checked="" type="checkbox"/> enable	<input type="text" value="**"/>	<input type="text" value="mL"/>	<input checked="" type="checkbox"/> enable	<input type="text" value="**"/>		

\*\* Operator definable      N/A not applicable to this test      Calibration curve is only as example

<b>Chemistry Parameters</b>		<b>R1</b>	
Method	<input type="text"/>	Reagent Name	<input type="text" value="HbA1c"/> Volume <input type="text" value="195 μL"/>
Name	<input type="text" value="Hb"/>	R2	<input type="text" value="disable"/>
Unit	<input type="text" value="g/dL"/>	Reagent Name	<input type="text"/> Volume <input type="text"/>
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"/>
			Reagent Name <input type="text" value="Saline"/>
Measuring Points	1 <input type="text" value="disable"/> start <input type="text"/>	Decimal Points	<input type="text" value="2"/>
	end <input type="text"/>		
	2 <input type="text" value="enable"/> start <input type="text" value="23"/>	Normal Range	<input type="text" value="0.0"/> <input type="text" value="23.0"/>
	end <input type="text" value="24"/>		
Wave Length		Technical Range (Conc)	<input type="text" value="0.0"/> <input type="text" value="23.0"/>
Prim	<input type="text" value="600"/> Sec <input type="text"/>	mAbs/10	<input type="text" value="-30000"/> <input type="text" value="30000"/>
Sampling Volume	<input type="text" value="4 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="15 μL"/>	Instrument Factor a	<input type="text" value="1"/> <input type="text" value="0"/>
Dilution	<input type="text" value="disable"/>	Stirring Speed	R1 <input type="text" value="high"/> R2 <input type="text" value="mid"/>
Rerun ( Low)	<input type="text" value="15 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"/>	%	<b>Blank measurement</b>	
** Prozone Limit	<input type="text"/>	upper	<input checked="" type="checkbox"/> Enable Reagent blank	
SL1-S	**	SL1-F **	<input type="text" value="None"/>	
SL2-S	**	SL2-F **	<b>Reagent blank measurement at calibration</b>	
Sens	<input type="text"/>	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	<input type="text" value="Increase"/>		<b>Reagent Blank Limit Checks</b>	
Limit	<input type="text" value="25000"/>	mAbs/10	<input type="text"/>	<input type="text" value="50"/> mAbs/10

Calibration

Method	<input type="text"/>	Name	<input type="text" value="Hb"/>	Interval	<input type="text" value="20"/> days
Calculation	<input type="text" value="Point to Point"/>				
	Conc	WORK	MASTER	Lot No	
S1	<input type="text" value="0"/>	<input type="text" value="8"/>			K <input type="text" value="N/A"/>
S2	<input type="text" value="18"/>	<input type="text" value="1230"/>			
S3					
S4					
S5					
S6					

Reagent Registration

Reagent Code	<input type="text" value="0197"/>				
Reagent Name	<input type="text" value="Hb"/>				
R1	<input checked="" type="checkbox"/> enable	Volume (L)	<input type="text"/>	Volume (S)	<input type="text"/>
R2	<input checked="" type="checkbox"/> enable	mL	mL	Stability Check	Term
				<input checked="" type="checkbox"/> enable	<input type="text"/>
				<input checked="" type="checkbox"/> enable	<input type="text"/>

Calculated Tests

Method (71-80)	<input type="text"/>
Name	<input type="text" value="% HbA1c"/>
Unit	<input type="text" value="%"/>
Decimal Point	<input type="text" value="**"/>
Expression	<input type="text" value="[HbA1c] / [Hb]*100"/>
Normal range Low - High	<input type="text" value="4"/> <input type="text" value="8"/>

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