

Glucose Hexokinase FS*

Diagnostic reagent for quantitative in vitro determination of glucose in serum, plasma or urine on Sysmex BX-Series

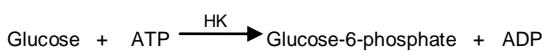
Order information

Cat. No.	Kit size	Number of tests
1 2511 99 10 973	R1 2 x 35.2 mL	BX-3010 2 x 250 tests BX-4000 2 x 192 tests
	R2 2 x 12.7 mL	BX-3010 2 x 250 tests BX-4000 2 x 192 tests

Method

Enzymatic UV test using hexokinase

Principle



Reagents

Components and Concentrations

R1:	TRIS buffer	pH 7.8	100 mmol/L
	Mg ²⁺		4 mmol/L
	ATP		2.1 mmol/L
	NAD		2.1 mmol/L
R2:	Mg ²⁺		4 mmol/L
	Hexokinase (HK)		≥ 7.5 kU/L
	Glucose-6-phosphatedehydrogenase (G6P-DH)		≥ 7.5 kU/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give false results [6].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma, urine

Separate at the latest 1h after blood collection from cellular contents.

Stability in plasma after addition of a glycolytic inhibitor (Fluoride, monoiodacetate, mannose) [1]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
1 day	at	-20°C

Only freeze once. Discard contaminated specimens.

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [2,3]:

8 h	at	25°C
72 h	at	4°C

Stability in urine [1]:

2 h	at	20 - 25°C
2 h	at	4 – 8°C

Discard contaminated specimens.

Calibrators and Controls

For calibration DiaSys TruCal U calibrator is recommended. The assigned values of this calibrator have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N, TruLab P and TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 850 mg/dL (47.2 mmol/L) glucose (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function)..	
Limit of detection**	1 mg/dL (0.056 mmol/L)
On-board stability	6 weeks
Calibration stability	6 weeks

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	69.9 mg/dL (3.88 mmol/L)
Hemoglobin	up to 500 mg/dL	70.1 mg/dL (3.89 mmol/L)
Bilirubin, conjugated	up to 60 mg/dL	111 mg/dL (6.15 mmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	67.4 mg/dL (3.74 mmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	80.6 mg/dL (4.48 mmol/L)
	up to 2000 mg/dL	110 mg/dL (6.08 mmol/L)

For further information on interfering substances refer to Young DS [5].

Precision (serum) BX-3010			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	90.1	192	283
Mean [mmol/L]	5.00	10.7	15.7
Coefficient of variation [%]	1.63	1.44	1.56
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	70.8	119	269
Mean [mmol/L]	3.93	6.63	14.9
Coefficient of variation [%]	1.44	1.54	1.73

Precision (urine) BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	7.23	24.9	286
Mean [mmol/L]	0.401	1.38	15.9
Coefficient of variation [%]	1.09	0.577	0.535
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	6.65	25.0	291
Mean [mmol/L]	0.369	1.39	16.2
Coefficient of variation [%]	1.69	2.09	1.43

Method comparison (serum) (n=111)	
Test x	Glucose Hexokinase FS (BioMajesty 6010C)
Test y	Glucose Hexokinase FS (BX 3010)
Slope	1.03
Intercept	-5.1 mg/dL (-0.285 mmol/L)
Coefficient of correlation	0.999

Conversion factor

Glucose [mg/dL] x 0.05551 = Glucose [mmol/L]

Reference Range [4]

	[mg/dL]	[mmol/L]
Newborns:		
Cord blood	63 - 158	3.5 - 8.8
1 h	36 - 99	2.0 - 5.5
2 h	36 - 89	2.2 - 4.9
5 - 14 h	34 - 77	1.9 - 4.3
10 - 28 h	46 - 81	2.6 - 4.5
44 - 52 h	48 - 79	2.7 - 4.4
Children (fasting):		
1 - 6 years	74 - 127	4.1 - 7.0
7 - 19 years	70 - 106	3.9 - 5.9
Adults (fasting):		
Venous plasma	70 - 115	3.9 - 6.4

Urine: ≤ 15 mg/dL (0.84 mmol/L)

(Value is based on an average quantity of urine of 1350 mL/day)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1, 50-1.
- Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 750-808.
- Sacks DB, Bruns DE, Goldstein DE, Mac Laren NK, Mc Donald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 2002; 48: 436-72.
- Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7, 1368.
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																						
Method No.	*	Method Name	GLUHK	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	Glucose	MethodColor		R1	GLUHK	120																				
Sample Type	Serum/Urine			R2	GLUHK	30																				
Unit	mg/dL			Diluent	Disable																					
Assay Type	End			Sample Ppt. Wash	Disable																					
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle																				
		1	22 - 23																							
		2	45 - 46																							
Wave Length	Prim. 340	Sec. 415		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>			No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
No.	Normal Range Name	Min	Max																							
1	Male-G1	*	*																							
2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																						
	Low Normal High			(Conc)	1 - 850																					
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			(mAbs/10)	* - *																					
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	* - *	%																				
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			Abnormal Range	* - *																					
<input type="checkbox"/> Rerun (Low)				Panic Range																						
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			Decimal Point	0	Profile SI Disable																				

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	GLUHK	Sample	Serum	
Limit Checks <input checked="" type="checkbox"/> Duplicate Limit 200 mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit 4000 mAbs/10 <input checked="" type="checkbox"/> Linearity Limit % (mAbs/10)/min <input type="checkbox"/> Prozone Limit Higher % SL1-S - SL1-F SL2-S - SL2-F Sensitivity mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Abs. in reaction Increase Limit 25000 mAbs/10				Blank measurement Blank measurement: Disable reagent blank and C1 blank Measurement of Reagent Blank during Run: None Reagent blank measurement at calibration: Reagent blank (No sample) The number of measurement: Duplicate Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit 50 mAbs/10		
Instrument Factor a 1.00 b 0.00						

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

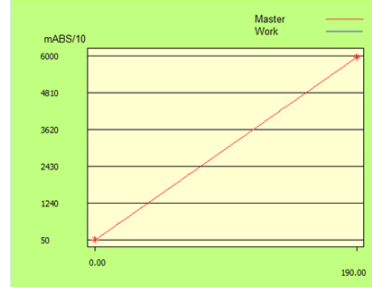
	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

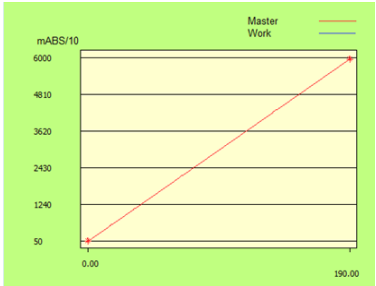
Absorbance mAbs/10

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																									
Method	* <input type="text"/>	Name	<input type="text" value="GLUHK"/>		Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	<input type="text" value="Glucose"/>		R1	<input type="text" value="GLUHK"/>	<input type="text" value="160"/>																						
Sample	<input type="text" value="Serum/Urine"/>		R2	<input checked="" type="checkbox"/> Enable	<input type="text" value="GLUHK"/>	<input type="text" value="40"/>																					
Unit	<input type="text" value="mg/dL"/>																										
Assay Type	<input type="text" value="End"/>		Diluent	<input type="checkbox"/> Enable	<input type="text"/>	<input type="text"/>																					
Measuring points	Start	End	Decimal Points	<input type="text" value="0"/>																							
	1	<input type="text" value="33"/>	-	<input type="text" value="34"/>																							
<input type="checkbox"/> Enable	2	<input type="text" value="67"/>	-	<input type="text" value="68"/>																							
Wave Length	Prim.	<input type="text" value="340"/>	Sec	<input type="checkbox"/> Disable	<input type="text" value="415"/>																						
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>								No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
No.	Normal Range Name	Min	Max																								
1	Male-G1	*	*																								
2	Male-G2	*	*																								
3	Male-G3	*	*																								
4	Female-G1	*	*																								
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text"/>	<input type="text"/>	Technical Range	(Conc)	<input type="text" value="1"/>	-	<input type="text" value="850"/>																			
	Rerun (High/Prozone)			(mAbs/10)			-																				
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text"/>	<input type="text"/>																								
	Rerun (Low)																										
<input type="checkbox"/> Dilution	<input type="text" value="2.0"/>	<input type="text"/>	<input type="text"/>																								
				SPT Wash	<input type="checkbox"/> Enable	<input type="text"/>		Reagent Name																			
				Stirring Speed	R1	<input type="text" value="Middle"/>	R2	<input type="text" value="Middle"/>																			

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters				
Method No.	* <input type="text"/>	Name	<input type="text" value="GLUHK"/>		Sample	<input type="text" value="Serum"/>
Limit Checks						
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="200"/>	mAbs/10				
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="4000"/>	mAbs/10				
<input checked="" type="checkbox"/> Linearity Limit	<input type="text"/>	%	<input type="text"/>	(mAbs/10)/min		
<input type="checkbox"/> Prozone Limit	<input type="text"/>	%	<input type="text" value="Upper"/>			
	SL1-S	<input type="text"/>	-	SL1-F	<input type="text"/>	
	SL2-S	<input type="text"/>	-	SL2-F	<input type="text"/>	
	Sensitivity	<input type="text"/>	mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit						
	Reaction	<input type="text" value="Increase"/>				
	Limit	<input type="text" value="25000"/>	mAbs/10			
Blank measurement						
Blank measurement:						
<input type="text" value="Disable reagent blank and S1 blank"/>						
Measurement of Reagent Blank during Run:						
<input type="text" value="None"/>						
Reagent blank measurement at calibration:						
<input type="text" value="Reagent blank (No sample)"/>						
The number of measurement:						
<input type="text" value="Duplicate"/>						
Reagent blank limit checks:						
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	mAbs/10				
Instrument Factor						
	a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>		

<u>Registration Calibration</u>		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																																																	
Method <input type="text" value="*"/> Name <input type="text" value="GLUHK"/>	R Lot No. R1 <input type="text" value="*"/> Last <input type="text"/>																																																		
Sample <input type="text" value="Serum/Urine"/>	R2 <input type="text" value="*"/>																																																		
Sampling <input type="text" value="Duplicate"/>	 <p style="font-size: small; text-align: center;">The calibration curve is lot dependent</p>																																																		
Check Interval <input type="text" value="42"/> days																																																			
Auto <input type="text" value="Change Lot"/> <input type="text" value="Full Calibration"/>																																																			
Auto Interval <input type="text"/> hours																																																			
Type <input type="text" value="Linear"/> Lot <input type="text" value="New"/>																																																			
Material Name <input type="text" value="TruCal U"/>	Reagent blank <input type="text"/> mAbs/10 Last <input type="text"/>																																																		
<table border="1" style="width:100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">Conc.</th> <th style="width: 15%;">WORK</th> <th style="width: 15%;">MASTER</th> <th style="width: 15%;">Lot No. (S)</th> <th style="width: 10%;"><input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr> <td>S1</td> <td><input type="text" value="0"/></td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S2</td> <td>*</td> <td>Automatic entry</td> <td>Automatic entry</td> <td></td> <td></td> </tr> <tr> <td>S3</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S4</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S5</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S6</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>S7</td> <td>*</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					Conc.	WORK	MASTER	Lot No. (S)	<input type="checkbox"/> All	S1	<input type="text" value="0"/>	Automatic entry	Automatic entry			S2	*	Automatic entry	Automatic entry			S3	*					S4	*					S5	*					S6	*					S7	*				
	Conc.	WORK	MASTER	Lot No. (S)	<input type="checkbox"/> All																																														
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry																																																
S2	*	Automatic entry	Automatic entry																																																
S3	*																																																		
S4	*																																																		
S5	*																																																		
S6	*																																																		
S7	*																																																		
Blank <input type="text" value="Automatic entry"/> mAbs/10 Last <input type="text"/>																																																			
Type <input type="text"/> Conc. <input type="text"/>																																																			
Absorbance <input type="text"/> mAbs/10 <input type="button" value="Recalculation"/>																																																			
K <input type="text" value="Automatic entry"/> <input type="checkbox"/> S1 Blank <input type="checkbox"/> Reagent Blank for S1																																																			
*Entered by user																																																			