

Glucose Hexokinase FS*

Diagnostic reagent for quantitative in vitro determination of glucose in serum, plasma or urine on BioMajesty JCA-BM6010/C

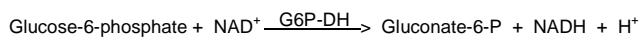
Order information

Cat. No.	Tests
1 2511 99 10 963	R1 4 x 570 tests
	R2 3 x 760 tests
1 2511 99 10 962	R1 6 x 380 tests
	R2 6 x 380 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 animal 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, moniodacetate, 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 500 mg/dL (30 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 (0.05 mmol/L) glucose
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 500 mg/dL
Conjugated bilirubin up to 60 mg/dL
Unconjugated bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [5].

Precision (Serum/plasma)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	77.5	91.9	267
Mean [mmol/L]	4.30	5.10	14.8
Coefficient of variance [%]	0.73	0.87	0.57
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	57.3	111	332
Mean [mmol/L]	3.18	6.17	18.4
Coefficient of variance [%]	1.42	1.50	1.13

Method comparison (Serum/plasma; n=124)	
Test x	Competitor Glucose HK
Test y	DiaSys Glucose HK FS
Slope	1.000
Intercept	1.80 mg/dL (0.100 mmol/L)
Coefficient of correlation	0.999

Precision (Urine)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	27.9	98.9	274
Mean [mmol/L]	1.55	5.49	15.2
Coefficient of variance [%]	0.82	1.31	0.82
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	27.9	99.4	272
Mean [mmol/L]	1.55	5.52	15.1
Coefficient of variance [%]	1.81	1.62	0.99

Method comparison (Urine; n=100)	
Test x	Competitor Glucose HK
Test y	DiaSys Glucose HK FS
Slope	0.985
Intercept	-0.38 mg/dL (-0.021 mmol/L)
Coefficient of correlation	1.000

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

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

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1, 50-1.
2. 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.
3. 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.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7, 1368.
5. 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.
6. 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
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Glucose Hexokinase FS

Chemistry code 10 251

Application for serum, plasma and urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	GLUHK
Digits	2
M-wave L.	340
S-wave.L	410
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	3
Factor	3
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999