respons®910

Glucose Hexokinase FS*

Diagnostic reagent for quantitative in vitro determination of glucose in serum, plasma or urine on DiaSys respons®910

Order Information

Cat. No. 1 2511 99 10 920
4 twin containers for 200 tests each

Method

Enzymatic UV test using hexokinase

Principle

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NAD}^+ \xrightarrow{\text{G6P-DH}} \text{Gluconate-6-P} + \text{NADH} + \text{H}^+$$

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. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. 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.
5. 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 rotor.

Specimen

Serum, heparin plasma or urine

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

Stability in plasma after addition of a glycolytic inhibitor (Fluoride, monoiodacetate, mannose) [2]:

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

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [1,3]:

8 h	at	25 °C
72 h	at	4 °C

Stability in urine [2]:

2 hours	at	20 - 25 °C
2 hours	at	4 - 8 °C
2 days	at	-20 °C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration the 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 and P controls or TruLab Urine control 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 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**	2 mg/dL glucose
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	**Interferences in serum < 10%**	**Glucose [mg/dL]**
Ascorbate	up to 30 mg/dL	179
Hemoglobin	up to 500 mg/dL	80.1
	up to 500 mg/dL	139
Bilirubin, conjugated	up to 60 mg/dL	82.3
	up to 60 mg/dL	106
Bilirubin, unconjugated	up to 60 mg/dL	85.2
	up to 60 mg/dL	109
Lipemia (triglycerides)	up to 1800 mg/dL	82.1
	up to 2000 mg/dL	98.8
For further information on interfering substances refer to Young DS [4].		

Precision in serum			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	95.1	135	302
Coefficient of variance [%]	1.82	1.23	2.31
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	93.0	128	296
Coefficient of variance [%]	1.83	1.46	2.24

Method comparison in serum (n=107)	
Test x	DiaSys Glucose HK FS (Hitachi 911)
Test y	DiaSys Glucose HK FS (respons®910)
Slope	1.051
Intercept	0.680 mg/dL
Coefficient of correlation	0.999

Precision in urine			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	9.60	25.7	280
Coefficient of variance [%]	2.08	1.40	0.88
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	9.61	25.3	274
Coefficient of variance [%]	2.19	1.62	2.04

Method comparison in urine (n=100)	
Test x	DiaSys Glucose HK FS (BioMajesty 6010)
Test y	DiaSys Glucose HK FS (respons®910)
Slope	0.964
Intercept	-0.332 mg/dL
Coefficient of correlation	0.999

** according to NCCLS document EP17-A, vol. 24, no. 34

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Conversion factor

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

Reference Range [5]

Serum/plasma	[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. 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.
2. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1, 50-3.
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. 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.
5. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.

Manufacturer

IVD CE

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respons®910

Glucose HK FS

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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	GLUC HK
Shortcut:	
Reagent barcode reference:	037
Host reference:	037

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	405
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	08:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	500.0000
SERUM	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	4.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	4.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	4.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	4.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	4.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	4.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=70.00 <=115.00
URINE	>= <=15.00
PLASMA	>=70.00 <=115.00
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.006
Cal. 2	0.040
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value