respons®920

Glucose Hexokinase FS*

Diagnostic reagent for quantitative in vitro determination of glucose in serum, plasma or urine on DiaSys respons®920

Order Information

Cat. No. 1 2511 99 10 920
4 twin containers for 200 determinations 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [6].
5. 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.
6. 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 the 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 and P or 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 1000 mg/dL glucose in serum and 920 mg/dL in urine (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.3 mg/dL glucose
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences (serum/plasma) < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 1000 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [4].

Precision in serum/plasma			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	92.9	132	291
Coefficient of variance [%]	0.85	1.25	1.95
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	89.8	127	284
Coefficient of variance [%]	1.62	1.61	1.41

Method comparison in serum/plasma (n=99)	
Test x	DiaSys Glucose HK FS (Hitachi 917)
Test y	DiaSys Glucose HK FS (respons®920)
Slope	1.018
Intercept	0.321 mg/dL
Coefficient of correlation	0.999

Precision in urine			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	9.94	26.4	284
Coefficient of variance [%]	0.97	0.61	0.97
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	9.87	25.0	270
Coefficient of variance [%]	5.16	1.74	1.71

Method comparison in urine (n=98)	
Test x	DiaSys Glucose HK FS (BioMajesty 6010)
Test y	DiaSys Glucose HK FS (respons®920)
Slope	0.999
Intercept	-0.191 mg/dL
Coefficient of correlation	0.998

** 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]

* fluid stable

Reference Range [5]

	[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.
1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 30-1, 50-3.
2. 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.
3. 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.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.
5. 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®920

Glucose Hexokinase FS

Application for serum, plasma or urine

Test Details			Test Volumes			Reference Ranges		
Test	:	GLUHK				Auto Rerun	☐	
Report Name	:	Glucose Hexokinase				Online Calibration	☐	
Unit	:	mg/dL	Decimal Places	:	1	Cuvette Wash	☐	
Wavelength-Primary	:	340	Secondary	:	405	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	GLUHK R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	GLUHK R2
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.3000	Technical Maximum	:	1000.0000			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	GLUHK		
Sample Type	:	Plasma/serum/ urine		

Sample Volumes

Normal	:	4.00	µL	Dilution Ratio	:	1 X
Increase	:	6.00	µL	Dilution Ratio	:	1 X
Decrease	:	2.00	µL	Dilution Ratio	:	1 X
Standard Volume	:	4.00	µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	45 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☑ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	GLUHK		
Sample Type	:	Plasma		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	70.00	115.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☑ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other