respons®940

Glucose Hexokinase FS*

Order Information

Cat. No.	Kit size
1 2511 99 10 920	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of glucose in human serum, heparin plasma or urine on automated respons®940.

Summary

Glucose is a monosaccharide and one of the most important carbohydrates for the human organism, as it is a metabolic substrate and a source of energy. The glucose concentration in blood is kept constant by several regulatory mechanisms. The main regulation occurs via secretion of insulin and glucagon. Primarily for the organism, the coverage of the steady glucose demand of the central nervous system with only minimal glucose reserves and the demand of erythrocytes is of major importance [1]. Glucose concentration in blood depends on nutritional status of an individual. Three conditions can be distinguished: Fasting status (8-10 h after the last nutritional intake), postprandial status (2-3 h after beginning of food intake) and postabsorptive status (6-12 h after beginning of food intake) [2]. Glucose measurement is recommended, whenever hypo- or hyperglycemia is suspected. Altered glucose can be the cause of many medical conditions. The main diseases causing elevated blood glucose levels are the different types of diabetes mellitus (DM). The primary purpose of glucose measurement is to diagnose DM respectively to define and monitor therapeutic interventions [2].

Method

Enzymatic UV test using hexokinase

Glucose is phosphorylated by hexokinase in the presence of ATP to form glucose-6-phosphate. Glucose-6-phosphate is converted in presence of NAD^+ by glucose-6-phosphate dehydrogenase to gluconate-6-phosphate and NADH + H^+. The increase of absorbance of NADH + H^+ is determined spectrophotometrically at a wavelength of 340 nm as endpoint measurement. The increase of absorbance is proportional to the glucose concentration in the sample.

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

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

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-phosphate dehydrogenase	(G6P-DH)	≥ 7.5 kU/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 12 months until expiry date.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.
7. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum, heparin plasma or urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

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

Stability in serum/plasma after addition of a glycolytic inhibitor (fluoride, monoiodacetate, mannose) [4]:

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 [5,6]:

8 h	at	25°C
72 h	at	4°C

Discard contaminated specimens.

Stability in urine [4]:

2 h	at	20 – 25°C
2 h	at	4 – 8°C
2 days	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

Serum/Plasma

Measuring range from 2.2 mg/dL up to 500 mg/dL. Linearity < 5 mg/dL is given with ± 1.2 mg/dL, between 5 mg/dL to 20 mg/dL within ± 10%, at > 20 mg/dL within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	2.2 mg/dL
Limit of quantitation**	2.2 mg/dL
Onboard stability	16 weeks
Calibration stability	16 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	36 mg/dL	44.6
	70 mg/dL	243
Bilirubin (conjugated)	70 mg/dL	55.2
	70 mg/dL	220
Bilirubin (unconjugated)	45 mg/dL	52.1
	70 mg/dL	216
Hemolysis	700 mg/dL	46.6
	700 mg/dL	233
Lipemia (triglycerides)	1100 mg/dL	40.1
	1700 mg/dL	211
For further information on interfering substances, refer to the literature [7-9].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	71.1	113	277
CV [%]	0.884	1.27	0.677
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	74.8	121	274
CV [%]	1.65	1.13	1.32
Reproducibility (n=75, no. of instruments=3)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	45.9	122	405
CV [%]	1.27	1.31	2.45

Method comparison (n=164)	
Test x	Competitor Glucose Hexokinase (cobas c 501)
Test y	DiaSys Glucose Hexokinase FS (respons®940)
Slope	0.959
Intercept	0.075 mg/dL
Coefficient of correlation	0.999

Urine

Measuring range from 2.2 mg/dL up to 500 mg/dL. Linearity < 5 mg/dL is given with ± 1.2 mg/dL, between 5 mg/dL to 20 mg/dL within ± 10%, at > 20 mg/dL within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	2.2 mg/dL
Limit of quantitation**	2.2 mg/dL
Onboard stability	16 weeks
Calibration stability	16 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	300 mg/dL	10.3
	300 mg/dL	206
N-acetylcysteine (NAC)	18.2 mg/dL	12.5
	18.2 mg/dL	217
Protein	321 mg/dL	11.5
	321 mg/dL	200
Urobilinogen	48 mg/dL	12.0
	48 mg/dL	208
For further information on interfering substances, refer to the literature [7-9].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	6.90	26.7	281
CV [%]	1.24	0.460	0.379
Within-laboratory (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	6.84	26.2	280
CV [%]	3.37	2.17	1.32
Reproducibility (n=75, no. of instruments=3)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	7.74	13.3	276
CV [%]	2.73	1.72	1.89

Method comparison (n=55)	
Test x	DiaSys Glucose Hexokinase FS (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Glucose Hexokinase FS (respons®940)
Slope	1.02
Intercept	0.019 mg/dL
Coefficient of correlation	0.998

** according to CLSI document EP17-A2, Vol. 32, No. 8

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

Reference Range

	[mg/dL]	[mmol/L]
Newborns		
Cord blood	63 – 158	3.5 – 8.8
1 h	36 – 99	2.0 – 5.5
2 h	39 – 89	2.2 – 4.9
5 – 14 h	34 – 77	1.9 – 4.3
20 – 28 h	46 – 81	2.6 – 4.5
44 – 52 h	48 – 79	2.7 – 4.4
Children (fasting)	60 – 99	3.3 – 5.5
Adults (fasting)		
Serum/Plasma	60 – 95	3.3 – 5.3
Urine	≤ 16.5	≤ 0.91

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

Literature

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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

respons®940

Glucose Hexokinase FS

Application for serum, plasma and 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	:	415	Special Diluent	☐	
Assay Type	:	2-Point	Curve Type	:	Linear	Warn after	:	20
M1 Start	:	24	M1 End	:	24	Reagents Used	:	2
M2 Start	:	57	M2 End	:	57	Reagent R1		GLUHK R1
Sample Replicates	:	1	Standard Replicates	:	2	Reagent R2		GLUHK R2
Control Replicates	:	1	Control Interval	:	0	**Consumables/Calibrators:**		
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Blank /Level 0		0
Prozone Limit %	:	0	Prozone Check	:	Lower	Calibrator 1		*
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000	Calibrator 2		
Technical Minimum	:	2.0000	Technical Maximum	:	500.0000	Calibrator 3		
Y = aX + b a=	:	1.0000	b=	:	0.0000	Calibrator 4		
Reagent Abs Min	:	0.0000	Reagent Abs Max	:	0.0000	Calibrator 5		

Test Details			Test Volumes	Reference Ranges
Test	:	GLUHK		
Sample Type	:	Serum		

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	:	180.00	µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	45.00	µL	R2 Stirrer Speed	:	High

Sample Types

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

Test Details			Test Volumes	Reference Ranges
Test	:	GLUHK		
Sample Type	:	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	:	180.00	µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	45.00	µL	R2 Stirrer Speed	:	High

Sample Types

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

respons®940

Test Details	Test Volumes	Reference Ranges

Test : GLUHK

Sample Type : Serum** Urine**

Reference Range : DEFAULT

Category : Male

Reference Range

	Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal :	#	#
Panic :	#	#

Sample Types

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

* Enter calibrator value
** Specimen selected by user
# Editable by user