DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Glucose, Hexokinase

(en) English

REF	Content								
D03114B	1 x	1	L	R1	+	1 x	0.25	L	R2
D96226	4 x	100	mL	R1	+	1 x	100	mL	R2
D96227	4 x	50	mL	R1	+	1 x	50	mL	R2
D00632	4 x	25	mL	R1	+	1 x	25	mL	R2
D00637	4 x	10	mL	R1	+	1 x	10	mL	R2
D71911	4 x	50	mL	R1	+	2 x	25	mL	R2
D0426917	4 x	62.5	mL	R1	+	1 x	62.5	mL	R2
DA0828	5 x	40	mL	R1	+	5 x	10	mL	R2
DT1028	4 x	50	mL	R1	+	4 x	12.5	mL	R2
DK0727	4 x	50	mL	R1	+	1 x	50	mL	R2
DE1828	8 x	50	mL	R1	+	8 x	12.5	mL	R2
DB20321	4 x	50	mL	R1	+	4 x	12.5	mL	R2

For professional in vitro diagnostic use only.

INTENDED USE

Diagnostic reagent for quantitative in vitro determination of glucose in human serum, plasma or urine on photometric systems.

DIAGNOSTIC SIGNIFICANCE[1,2]

Measurement of glucose concentration in serum or plasma is mainly used in diagnosis and monitoring of treatment in diabetes mellitus. Other applications are the detection of neonatal hypoglycemia, the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrate metabolism in various diseases.

TEST PRINCIPLE

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

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

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
Tris Buffer, pH 7.8	100 mmol/L
Mg^{2+}	4 mmol/L
ATP	2.1 mmol/L
NAD	2.1 mmol/L
Reagent 2:	
Mg^{2+}	4 mmol/L
Hexokinase (HK)	≥ 7.5 kU/L
Glucose-6-phosphate dehydrogenase (G6P-DH)	≥ 7.5 kU/L

MATERIAL REQUIRED BUT NOT PROVIDED

Standard or Calibrator eg:

REF	Name	Content
D95223	Glucose Standard	1 x 3 mL
D98485	Diacal Auto	5 x 3 mL
D98485SV	Diacal Auto	1 x 3 mL

Controls, eg:

REF	Name	Content	Description
D98481	Diacon N	12 x 5 mL	Control normal
D14481	Diacon N	5 x 5 mL	Control normal
D98481SV	Diacon N	1 x 5 mL	Control normal
D98482	Diacon P	12 x 5 mL	Control abnormal
D14482	Diacon P	5 x 5 mL	Control abnormal
D98482SV	Diacon P	1 x 5 mL	Control abnormal
D08581	Diacon Urine Level 1	12 x 5 mL	Urine control normal
D08581SV	Diacon Urine Level 1	1 x 5 mL	Urine control normal
D08582	Diacon Urine Level 2	12 x 5 mL	Urine control abnormal
D08582SV	Diacon Urine Level 2	1 x 5 mL	Urine control abnormal

- NaCl solution (9 g/L).
- Photometric device.
- General laboratory equipment.

REAGENT PREPARATION

Reagents are ready to use.

STORAGE AND STABILITY

Conditions	Protect from light. Close immediately after use. Avoid contamination. Do not freeze the reagents!
Stability	up to the end of the indicated month of expiry

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 false 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. In the event of an incident related to the device, report it to the manufacturer and your competent authority as required.
6. For professional use only!

SPECIMEN COLLECTION AND STORAGE

Use serum, plasma or urine.

For serum/plasma: separate from cellular contents at the latest 1h after blood collection.

Stability in plasma after addition of a glycolytic inhibitor (fluoride, monoiodacetate, mannose)[3]:

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

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor[2,4].

at 25 °C	8 hours
at 4 °C	72 hours

Stability in urine[3].

at 20 – 25 °C	2 hours
at 4 – 8 °C	2 hours

Freeze only once!
Discard contaminated specimens!

STANDARD

(not included in the kit; has to be ordered separately)

Concentration:	100 mg/dL (5.55 mmol/L)
Storage:	2 – 8 °C
Stability:	up to the indicated expiration date

Close immediately after use! Avoid contamination! Protect from light!

TEST PROCEDURE

Method:	UV, endpoint, increasing reaction, Hexokinase
Wavelength:	340 nm, Hg 334 nm, Hg 365 nm
Optical path:	1 cm
Temperature:	20 – 25 °C, 37 °C

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent 1	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µL
Standard / Calibrator	-	10 µL	-
Dist. water	10 µL	-	-
Mix. Incubate for 1-5 min. at 20 – 25 °C/37 °C. Read absorbance A1, then add:			
Reagent 2	250 µL	250 µL	250 µL
Mix. Incubate 5 min. at 37 °C or 10 min. at 20 – 25 °C. Read absorbance A2 against reagent blank within 30 minutes. Calculate: ΔA = (A2 – A1) Sample / Std. or Cal.			

Automation

Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS

Calculation

With Standard or Calibrator:

$$\text{Glucose [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc Std/Cal [mg/dL]}$$

With Factor: (light path 1cm)
Glucose = ΔA Sample x Factor

Wavelength	Factors [mg/dL]	Factors [mmol/L]
340 nm	361	20.0
Hg 334 nm	367	20.5
Hg 365 nm	667	37.1

Unit Conversion

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

QUALITY CONTROL AND CALIBRATION

All control sera with glucose values determined by this method can be used.
We recommend the DIALAB serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range) as well as the DIALAB urine controls **Diacon Urine Level 1** (control urine normal) and **Level 2** (control urine abnormal).

Calibration

For calibration a glucose standard or a calibrator can be used.
We recommend the DIALAB **Glucose Standard** and the DIALAB multi calibration serum **Diacal Auto**.

PERFORMANCE CHARACTERISTICS

Accuracy and precision

CV ≤ 2.21 % for within-run precision and CV ≤ 0.94 % for between-run precision.

Analytical sensitivity

The lower limit of detection is 2 mg/dL (0.1 mmol/L).

Linearity and measuring range

The test has been developed to determine glucose concentrations within a measuring range from 2 – 900 mg/dL (0.1 – 50 mmol/L) at 365 nm, respectively within a measuring range from 2 – 500 mg/dL (0.1 – 28 mmol/L) at 334/340 nm. When values exceed these ranges serum and plasma samples should be diluted 1+2 with NaCl solution (9 g/L) and the result multiplied by 3, urine samples should be diluted 1+10 with distilled water and the results multiplied by 11.

Analytical specificity

No interference up to (when worked with substrate start):

Ascorbic acid	30 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	2000 mg/dL

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

Clinical performance

A comparison of DIALAB Glucose, Hexokinase (y) with a commercially available test (x) using 73 samples gave following results: y = 1.00 x + 0.00 mg/dl; r = 0.998.

Tests were performed on the following instrument: EPOS 5060.

TRACEABILITY

The calibrator values of Diacal Auto have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS).

EXPECTED VALUES[1]

Newborns:	[mg/dL]	[mmol/L]
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):		
Serum/plasma	70 – 115	3.9 – 6.4

Urine: ≤ 15 mg/dL (0.84 mmol/L)
(the 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.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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

USED SYMBOLS

Symbol	Description
Cont.	Content

CE IVD 2°C 8°C