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Glucose

Hexokinase

REF	Kit Size	Content
D03114B	1 x 1.25 L	1 x 1 L R1 + 1 x 0.25 L R2
D96226	5 x 100 mL	4 x 100 mL R1 + 1 x 100 mL R2
D96227	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
D00632	5 x 25 mL	4 x 25 mL R1 + 1 x 25 mL R2
D00637	5 x 10 mL	4 x 10 mL R1 + 1 x 10 mL R2
D71911	5 x 50 mL	5 x 40 mL R1 + 2 x 25 mL R2
D0426917	5 x 62.5 mL	4 x 62.5 mL + 1 x 62.5 mL R2
DA0828	5 x 50 mL	5 x 40 mL R1 + 5 x 10 mL R2
DT1028	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5 mL R2
DK0727	5 x 50 mL	4 x 50 mL R1 + 1 x 50 mL R2
DE1828	8 x 62.5 mL	8 x 50 mL R1 + 8 x 12.5 mL R2
DB20321	4 x 62.5 mL	4 x 50 mL R1 + 4 x 12.5 mL R2

Additionally available:

D95223	1 x 3 mL	Glucose Standard	
D98485	5 x 3 mL	Calibrator	Diacal Auto
D98485SV	1 x 3 mL	Calibrator	Diacal Auto
D98481	12 x 5 mL	Control normal	Diacon N
D14481	5 x 5 mL	Control normal	Diacon N
D98481SV	1 x 5 mL	Control normal	Diacon N
D98482	12 x 5 mL	Control abnormal	Diacon P
D14482	5 x 5 mL	Control abnormal	Diacon P
D98482SV	1 x 5 mL	Control abnormal	Diacon P
D08581	12 x 5 mL	Urine control normal	Diacon Urine Level 1
D08581SV	1 x 5 mL	Urine control normal	Diacon Urine Level 1
D08582	12 x 5 mL	Urine control abnormal	Diacon Urine Level 2
D08582SV	1 x 5 mL	Urine control abnormal	Diacon Urine Level 2

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	UV, endpoint, increasing reaction, Hexokinase
Shelf life	24 months
Storage	2 – 8 °C
Wavelength	340 nm, Hg 334 nm, Hg 365 nm
Temperature	20 – 25 °C, 37 °C
Sample	Serum, plasma, urine

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

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

Glucose-6-Phosphate + NAD+ $\xrightarrow{G6P\text{-}DH}$ 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

- NaCl solution (9 g/dL)

REAGENT PREPARATION

Substrate Start:
Reagents are ready to use.
Sample Start:
Mix 4 parts of Reagent 1 with 1 part of Reagent 2.
(= Working Reagent)

STORAGE AND STABILITY

Conditions: Protect from light
Close immediately after use
Avoid contamination
Do not freeze the reagent

Substrate Start:

Storage:	at 2 – 8 °C	
Stability:	up to the indicated expiry date	

Sample Start (Working Reagent):

Storage:	at 2 – 8 °C	3 months
Stability:	at 15 – 25 °C	3 weeks

The working reagent must be protected from light!

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.
5. 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!

SPECIMEN COLLECTION AND STORAGE

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!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate Start

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 Start

Pipette into test tubes	Blank	Std./Cal.	Sample
Working reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µL
Standard / Calibrator	-	10 µL	-
Dist. water	10 µL	-	-
Mix. Incubate 5 min. at 37 °C or 10 min. at 20 – 25 °C. Read absorbance against reagent blank within 30 minutes.			

Automation

Special adaptations for automated analysers can be made on request.

INTERPRETATION OF RESULTS

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
Factors:

Substrate start:	**[mg/dL]**	**[mmol/L]**
Factor at 340 nm	361	20.0
Factor at 334 nm	367	20.5
Factor at 365 nm	667	37.1
Sample start:		
Factor at 340 nm	289	16.0
Factor at 334 nm	294	16.4
Factor at 365 nm	535	29.7

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

STANDARD

(has to be ordered separately)
Concentration: 100 mg/dL (5.55 mmol/L)
Storage: 2 – 25 °C
Stability: up to the indicated expiry date
Close immediately after use!
Protect from light.

PERFORMANCE CHARACTERISTICS

LINEARITY, 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 – 500 mg/dL) 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.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 1 mg/dL (0.06 mmol/L).

PRECISION (at 37 °C)

Intra-assay,n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	65.7	1.35	2.11
Sample 2	121	2.54	2.11
Sample 3	298	6.57	2.21

Inter-assay, n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	91.0	0.86	0.94
Sample 2	117	1.07	0.91
Sample 3	290	2.28	0.79

SPECIFICITY/INTERFERENCES

No interference up to:
Ascorbic acid 30 mg/dL
Bilirubin 40 mg/dL
Hemoglobin 500 mg/dL
Triglycerides 2000 mg/dL
when working with substrate start.

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

METHOD COMPARISON

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.

TRACEABILITY

This method is traceable to ID-MS.

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.

LIMITATIONS

- Sample start is recommended only for analyzers with correction of sample blank (e.g. by bichromatic measurement). Samples often show relatively high absorbances at the measurement wavelengths which tend to show falsely high glucose values when working with sample start.
- The given calculation factors cannot be used for bichromatic measurements.

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.

CE IVD 2°C 8°C