Glucose Gluc-DH FS*

Diagnostic reagent for in vitro determination of Glucose with the Glucose dehydrogenase method (Gluc-DH) on photometric systems

Order Information

Cat. No.	Kit size
1 2531 99 90 314	10 x 20 mL Reagent 1 2 x 30 mL Reagent 2
1 2500 99 10 030	6 x 3 mL Glucose Standard 100 mg/dL

Principle

Glucose dehydrogenase catalyzes the oxidation of Glucose according to the following equation:

β-D-Glucose + NAD $\xleftarrow{\text{Gluc-DH}}$ D-gluconolactone + NADH + H^+

The quantity of NADH is proportional to the glucose concentration.

Reagents

Concentrations of the Reagents

R1:	HEPES	pH 7.6	≥ 180 mmol/L
	Potassium chloride		≥ 900 mmol/L
	Glucose dehydrogenase		≥ 990 U/L
R2:	NAD		≥ 18 mmol/L

Storage Instructions and Reagent Stability

Reagents and standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided.
Do not freeze the reagents! Protect the standard from light!

Warnings and Precautions

1. Reagent 1 and 2: Warning. H317 May cause an allergic skin reaction. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 If on skin: Wash with plenty of water/soap.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. 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 examen and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The standard is ready to use.

Substrate Start

The reagents are ready to use.

Sample Start

Mix 4 parts of R1 with 1 part of R2
(e.g. 20 mL R1 + 5 mL R2) = mono reagent

Stability: 12 weeks at 2 – 8°C
4 weeks at 15 – 25°C

The mono reagent must be protected from light.

Material required but not provided

NaCl-Solution 9 g/L
General laboratory equipment

Specimen

Serum, plasma, urine or cerebrospinal fluid
Separate at the latest 1h after blood collection from cellular contents.

Stability in plasma after addition of a glycolytic inhibitor (fluor, monoiodacetate, mannose) [5]:

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

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [2,6]:

8 h at 25°C
72 h at 4°C

Stability in urine [5]:
2 h at 20 – 25°C
2 h at 4 – 8°C

Stability in cerebrospinal fluid [5]:
5 h at 20 – 25°C
3 days at 4 – 8°C

Freeze only once!
Discard contaminated samples!

Assay Procedure

Wavelength	340 nm, Hg 334 nm, Hg 365 nm
Optical path	1 cm
Temperature	25°C, 30°C, 37°C
Measurement	Against air

Reagent Start

	Sample/Standard
Sample/standard	5 µL
Reagent 1	400 µL
Mix and add after 1 min.:	
Reagent 2	100 µL
Mix, incubate for 1 min. and start stop watch. Read absorbance after 1, 2 and 3 min.	

Sample Start

	Sample	Standard
Sample	5 µL	-
Standard	-	5 µL
Mono reagent	500 µL	500 µL
Mix, incubate for 1 min. and start stop watch. Read absorbance after 1, 2 and 3 min.		

Calculation

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

Conversion factor

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

Calibrators and Controls

For calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. The assigned values of the 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 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

* fluid stable

Performance Characteristics

Measuring Range

The test has been developed to determine the glucose concentrations up to 1000 mg/dL (55,5 mmol/L) in serum and plasma and up to 300 mg/dL (17 mmol/L) in urine.

Specificity/Interferences

No interference was observed by bilirubin up to 12 mg/dL, hemoglobin up to 1000 mg/dL and lipemia up to 2000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [7].

Limit of Detection

The lower limit of detection is 2 mg/dL.

Precision in serum (37°C)

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	86.6	1.02	1.19
Sample 2	248	3.02	1.22
Sample 3	116	2.17	1.88

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	86.6	1.32	1.53
Sample 2	250	3.73	1.49
Sample 3	110	1.56	1.42

Precision in urine (37°C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	4.4	0.17	3.78
Sample 2	13.6	0.18	1.34
Sample 3	188	0.90	0.48

Method Comparison

A comparison of DiaSys Glucose Gluc-DH FS (y) with a commercially available Hexokinase method (x) using 90 serum and plasma samples gave following results:
y = 0.957 x – 0.364 mg/dL; r = 0.998

Reference Range [1]

	[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
Whole blood	70 – 100	3.9 – 5.6

Urine: ≤ 15 mg/dL (0.84 mmol/L)

(Value is based on an average quantity of urine of 1350 mL/day)

Cerebrospinal fluid: 45 – 70 mg/dL (2.5 – 3.9 mmol/L)

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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Manufacturer

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