Glucose Gluc-DH FS*

In hemolysate

Diagnostic reagent for in vitro determination of glucose with the glucose dehydrogenase method (Gluc-DH) in hemolysate 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 2531 99 90 335	10 x 80 mL Reagent 1 2 x 100 mL Reagent 2
1 2500 99 10 030	6 x 3 mL Glucose Standard 100 mg/dL
1 2580 99 90 338	500 mL Hemolyzing Solution

Principle

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

β-D-Glucose + NAD <—Gluc-DH—> D-gluconolactone + NADH + H^+

The quantity of NADH is proportional to the glucose concentration.

Methode

Enzymatic UV test using glucose dehydrogenase
The assigned values of the standard are traceable to a primary standard.

Reagents

Components and Concentrations

R1:	HEPES	pH 7.6	≥ 180 mmol/L
	Potassium chloride		≥ 900 mmol/L
	Glucose dehydrogenase		≥ 990 U/L
R2:	NAD		≥ 18 mmol/L
Hemolyzing solution:		pH 7.6	
Phosphate buffer			≥ 50 mmol/L
NaCl			< 200 mmol/L
EDTA			< 3 mmol/L
Tensides			≥ 2 g/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 and contamination is avoided. The standard is stable up to the indicated month of expiry, if stored at 2 – 8°C. The hemolyzing solution is stable up to the indicated month of expiry, if stored at 15 – 25°C.

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. Reagent 2: P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
3. Hemolyzing solution contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
4. In very rare cases, samples of patients with gammopathy might give falsified results [7].
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 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

Whole blood

Prepare the hemolysate by introducing 40 µL of blood or standard into 1.0 mL (end-to–end capillary) hemolyzing solution and mix. The stability in whole blood, which has been hemolyzed immediately after withdrawal, is 7 days at 15 – 25°C and 2 weeks at 2 – 8°C [5]. Discard contaminated specimens!

Assay Procedure

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

Reagent Start

	Sample	Standard
Hemolysate	50 µL	50 µL
Reagent 1	400 µL	400 µL
Mix and add after 1 min.:		
Reagent 2	100 µL	100 µL
Mix, incubate for 1 min. and start stop watch. Read absorbance after 1, 2 and 3 min.		

Sample Start

	Sample	Standard
Hemolysate	50 µL	50 µL
Monoreagent	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]

* fluid stable

Controls

DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
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

Performance Characteristics

Measuring Range

The test has been developed to determine the glucose concentration up to 1000 mg/dL (55.5 mmol/L).

Specificity/Interferences

No interference was observed by bilirubin up to 30 mg/dL and lipemia up to 800 mg/dL triglycerides. For further information on interfering substances refer to Young DS [6].

Limit of Detection

The lower limit of detection is 4 mg/dL.

Precision (37°C)

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	72	0.96	1.34
Sample 2	246	1.54	0.62
Sample 3	98	1.16	1.19

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	550	20.6	3.74
Sample 2	409	15.8	3.85

Method Comparison

A comparison of DiaSys Glucose Gluc-DH FS (y) with a commercially available test (x) using 100 hemolyzed whole blood samples gave following results:
y = 1.056 x - 1.806 mg/dL; r = 0.993

Reference Range [1]

Whole blood 70 – 100 mg/dL (3.9 – 5.6 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

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.
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3. Banauch D, Brümmer W, Ebeling W, Metz H. Eine Glucose-Dehydrogenase für die Glucose-Bestimmung in Körperflüssigkeiten. Z Klin Chem Klin Biochem 1975;13:101-7.
4. Vormbrock R. UV method with Glucose dehydrogenase. In: Bergmeyer HU, Bergmeyer J, Graßl M, editors. Methods of enzymatic analysis. 3rd ed. Weinheim: Verlag Chemie; 1974. p.172-8
5. Data on file at DiaSys Diagnostic Systems GmbH.
6. 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.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

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