ISE S.r.l. **Glucose** – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CE IVD

R1: 4x 17,5 mL **R3330000003** REF

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

TEST PARAMETERS

Method:	Colorimetric, enzymatic, GOD-PAP, endpoint, increasing reaction
Wavelength	500 nm, Hg 546 nm
Temperature:	20 – 25 °C or 37 °C
Sample:	Serum, heparinized or EDTA-plasma,
Linearity:	up to 400 mg/dL (22.2 mmol/L)
Sensitivity:	The lower limit of detection is 1 mg/dL (0.06 mmol/L).

SUMMARY [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 hypoglycaemia, the exclusion of pancreatic islet cell carcinoma as well as the evaluation of carbohydrate metabolism in various diseases.

TEST PRINCIPLE

In the presence of glucose oxidase, glucose is oxidized to gluconic acid and hydrogen peroxide.
Hydrogen peroxide reacts, in the presence of peroxidase, with phenol and 4-aminoantipyrine to form a quinoneimine dye (Trinder's reaction) [3].

$$\text{Glucose} + O_2 \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2$$

$$2\,H_2O_2 + \text{Phenol} + 4\,\text{Aminoantipyrine} \xrightarrow{\text{POD}} \text{Quinonimine} + 4\,H_2O$$

The intensity of the pink colour formed is proportional to the glucose concentration.

REAGENT COMPOSITION

COMPONENTS	CONCENTRATIONS
Phosphate Buffer, pH 7.5	250 mmol/L
Phenol	5 mmol/L
4-Aminoantipyrine	0.5 mmol/L
Glucose Oxidase (GOD)	≥ 10 KU/L
Peroxidase (POD)	≥ 1 KU/L

REAGENT PREPARATION

The reagent is ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light
Close immediately after use
Avoid contamination
Do not freeze the reagent!
Storage: at 2 – 8 °C
Stability: up to the indicated expiration date

Note: The measurement is not influenced by occasionally occurring color changes, as long as the absorbance of the reagent is < 0.3 at 546 nm.

SAMPLE STABILITY AND STORAGE

Separate at the latest 1h after blood collection from cellular contents.
Stability in plasma after addition of a glycolytic inhibitor (Fluoride, monoiodacetate, mannose) [4]:
Stability: 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 [2,5]:
Stability: at 25 °C 8 hours
at 4 °C 72 hours
Freeze only once!
Discard contaminated specimens.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kit – has to be ordered separately)
Concentration: 100 mg/dL (5.55 mmol/L)
Storage: 2 – 25 °C
Stability: up to the expiration date
Close immediately after use! Avoid contamination! Protect from light!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal.	Sample
Reagent	1000 µL	1000 µL	1000 µL
Sample	-	-	10 µL
Standard/Calibrator	-	10 µL	-
Dist water	10 µL	-	-
Mix. Incubate 10 minutes at 37 °C or 20 minutes at 20 – 25 °C. Read absorbance of sample and Std./Cal. within 60 minutes against reagent blank.			

CALCULATION

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

UNIT CONVERSION

mg/dL x 0.05551 = mmol/L

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

	[mg/dL]	[mmol/L]
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

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

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PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine glucose concentrations within a measuring range from 1 – 400 mg/dL (0.06 – 22.2 mmol/L). If values exceed this range, samples should be diluted 1+4 with NaCl solution (9 g/L) and the result multiplied by 5.

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	64.2	1.12	1.74
Sample 2	122	1.57	1.28
Sample 3	296	4.41	1.49

from day to day n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	92.5	1.10	1.19
Sample 2	121	1.02	2.01
Sample 3	292	2.01	0.69

SPECIFICITY/INTERFERENCES

no interference up to:

ascorbic acid	15 mg/dL
bilirubin	40 mg/dL
hemoglobin	200 mg/dL
triglycerides	2000 mg/dL

For further information on interfering substances refer to Young DS [6].

METHOD COMPARISON

A comparison between this Glucose (y) and a commercially available test (x) using 78 samples gave following results: y = 1.00 x + 1.00 mg/dL; r= 0.996.

CALIBRATION

The assay requires the use of a Glucose Standard or a Calibrator.

QUALITY CONTROL

All control sera with Glucose values determined by this method can be used.
Each laboratory should establish corrective action in case of deviations in control recovery.

WARNINGS AND PRECAUTIONS

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. Please refer to the safety data sheet 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!

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 131-7.
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. Barham D, Trinder P. An improved color reagent for the determination of blood glucose by the oxidase system. Analyst 1972;97:142-5.
4. Guder WG, Zawta B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: GIT verlag; 2001;p.30-1.
5. 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 Chemi 2002; 48:436-72.
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.

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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