Instructions for Use
For *in vitro* diagnostic use

GLICOSE WS

Glucose WS

Anvisa 80115310204

ORDER INFORMATION

Cat. No.	Kit size
1040500KWS	R 2x250mL
1040180MWS	R 6x30mL
1040174.4RWS	R 4x43,6mL
1040120MKWS	R 3x40mL
1040250KWS	R 1x250mL

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Glucose in serum or plasma on photometric systems.

SUMMARY

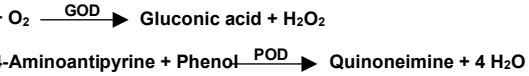
Glucose is a monosaccharide and one of the most important carbohydrates for the human organism, as it is a metabolic substrate and a source of energy. The glucose concentration in blood is kept constant by several regulatory mechanisms. The main regulation occurs via secretion of insulin and glucagon. Primarily for the organism, the coverage of the steady glucose demand of the central nervous system with only minimal glucose reserves and the demand of erythrocytes is of major importance [1]. Glucose concentration in blood depends on nutritional status of an individual. Three conditions can be distinguished: Fasting status (8-10 h after the last nutritional intake), postprandial status (2-3 h after beginning of food intake) and postabsorptive status (6-12 h after beginning of food intake) [2]. Glucose measurement is recommended, whenever hypo- or hyperglycemia is suspected. Altered glucose can be the cause of many medical conditions. The main diseases causing elevated blood glucose levels are the different types of diabetes mellitus (DM). The primary purpose of glucose measurement is to diagnose DM respectively to define and monitor therapeutic interventions [2].

METHOD

"GOD-PAP": enzymatic photometric test

PRINCIPLE

Determination of glucose after enzymatic oxidation by Glucose oxidase. The colorimetric indicator is Quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder's reaction) [3].



REAGENTS

Components and Concentrations

Monoreagent	
Potassium Dihydrogen Phosphate	0.25 mol/L
Phenol	<10 mmol/L
4–Aminoantipyrine	<5 mmol/L
Glucoseoxidase (GOD)	<50 kU/L
Peroxidase (POD)	<5 kU/L

STORAGE AND STABILITY

The reagent is stable until the expiration date, if stored at a temperature of 2 to 8 °C, protected from light and contamination is avoided. Do not freeze the reagent! Stability in use/on board: 30 days

Note: The measurement is not influenced by occasional changes in color if the absorbance of the reagent is < 0.3 to 546 nm.

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. The reagent contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [4].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) 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.
8. For professional use only.

WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

REAGENT PREPARATION

The reagent is ready to use.

MATERIALS REQUIRED, BUT NOT PROVIDED

1. NaCl solution 9 g/L.
2. General laboratory equipment.

SPECIMEN

Human serum or heparin plasma/ fluoridated plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Separate at the latest 1h after blood collection from cellular contents.

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

1 day	at	-20 ºC
2 days	at	20 - 25 ºC
7 days	at	4 - 8 ºC

Only freeze once. Discard contaminated specimens.

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor [6,7]:

8 hours	at	25 ºC
72 hours	at	4 ºC

Discard contaminated specimens.

ASSAY PROCEDURE

Applications for automatic systems are available upon request or on our website: www.kovalent.com.br

Wavelength	500 nm, Hg 546nm
Optical path	1 cm
Temperature	20 - 25 °C / 37 ºC
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	10 µL
Distilled water	10 µL	-
Reagent	1000 µL	1000 µL
Mix, incubate for 5 minutes at 37°C or 10 minutes at 20-25°C. Read the absorbance against the blank within 60 minutes.		

CALCULATION

With calibrator

$$\text{Glucose}\ \left[\frac{\text{mg}}{\text{dL}}\right] = \frac{\text{A Sample}}{\text{ACal.}} \text{x Conc. Cal.}\ \left[\frac{\text{mg}}{\text{dL}}\right]$$

Conversion factor

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

Instructions for Use

For *in vitro* diagnostic use

CALIBRATORS AND CONTROLS

For calibration in automated photometric systems, Kovalent Topkal U calibrator is recommended. Use Kovalent Topkon N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

WARRANTY

These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.

PERFORMANCE CHARACTERISTICS

Measuring range

The assay is designed to determine glucose concentrations within a measurement range of 1 - 400 mg/dL (0.06 – 22.2 mmol/L). When the values exceed this range, the samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Specificity / Interferences

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	18 mg/dL	183
Bilirubin (conjugated)	15 mg/dL	75.8
	20 mg/dL	115
Bilirubin (unconjugated)	30 mg/dL	82.1
	30 mg/dL	131
Hemolysis	200 mg/dL	87.4
	200 mg/dL	119
Lipemia (triglycerides)	1500 mg/dL	42.1
	1500 mg/dL	126

For further information on interfering substances, refer to the literature [8-10].

Sensitivity / Limit of Detection

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

PRECISION (AT 37°C)

Intra-assay precision = 10	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal control	98.06	0.77	0.78
Pathological control	257.1	4.74	1.85

Inter-assay precision n = 9	Mean [mg/dL]	SD [mg/dL]	CV [%]
Normal control	98.2	2.12	2.16
Pathological control	257.2	3.90	1.52

Method comparison

Method comparison between Kovalent Glicose WS (y) and a commercial available test (x) using 30 samples demonstrated the following results:
y = 0.9859 x + 1.1097 mg/dL; r = 0.9948.

REFERENCE RANGE [2]

	[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
20 – 28 h	46 – 81	2.6 – 4.5
44 – 52 h	48 – 79	2.7 – 4.4
Children (fasting)	60 – 99	3.3 – 5.5
Adults (fasting)	60 – 95	3.3 – 5.3

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

LITERATURE

1. Hallbach J. Klinische Chemie und Hämatologie – Biomedizinische Analytik für MTLA und Studium. 3rd ed. Stuttgart: Georg Thieme Verlag KG; 2011. p. 170-171.
2. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2023 Nov 21]. Available from: https://www.clinical-laboratory-diagnostics.com/
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
5. Guder WG et al. Die Qualität diagnostischer Proben – Empfehlung der Arbeitsgruppe Präanalytik der Deutschen Vereinten Gesellschaft für Klinische Chemie und Laboratoriumsmedizin. 7th ed. Heidelberg: BD Diagnostics Preanalytical Systems; 2012. p. 46-47, p. 68-69.
6. Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. 4th ed. St. Louis, Missouri: Elsevier Saunders Company; 2006. p. 837-901.
7. Sacks DB, Bruns DE, Goldstein DE, MacLaren NK, McDonald JM, Parrott M. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. ClinChem 2002; 48: 436-472.
8. 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.
9. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in February 2024. Published by AACC Press and John Wiley and Sons, Inc.
10. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	In vitro diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Instructions for Use

For *in vitro* diagnostic use

Manufacturer:

Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
São Gonçalo – RJ – CEP 24722-414 - Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Kit sizes variations on demand:

Anvisa No.	Kit size
80115310204	R 4x50mL
80115310204	R 2x20mL
80115310204	R 5x40mL

Costumer service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label