Glucose – Method Oxidase
Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182530	n° 10 vials x 60 mL
	REF B75182531	n° 12 vials x 20 mL
CHEMILAB	REF B81180131	n° 6 vials x 28 mL
	REF B81180132	n° 10 vials x 34 mL

INTENDED USE
Product for use in the quantitative determination in vitro of the concentration of the Glucose in human serum, plasma or urine. The results of the test must always be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE
Glucose is the result of the chemical decomposition of carbohydrates introduced in the diet and is the primary source of energy for the human organism. When the energetic intake is greater than the energy used, the glucose in excess is converted into fat and glycogen which will be deposited in the form of energy reserves, in the adipose tissue, in the liver and muscles. The glucose concentration in human blood is regulated, within a narrow range, by the action of regulatory hormones such as insulin, glucagon or epinephrine.

PRINCIPLE OF THE METHOD
Method Enzymatic Oxidase. In accordance with Trinder's reaction, glucose oxidase (GOD) oxidises glucose to gluconic acid with the formation of hydrogen peroxide, which in the presence of peroxidase (POD), 4-aminophenazone and phenol gives rise to a coloured compound, the intensity of which is directly proportional to the glucose concentration in the sample.

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

$$2H_2O_2 + 4-\text{Aminophenazone} + \text{Phenol} \xrightarrow{\text{POD}} \text{CouloredCompoud}$$

Storage and stability
= storage temperature 2-8°C
If stored at 2-8 ° C avoiding direct light, the reagents are stable until the expiration date printed on the label.

Concentrations

Reagents:		
	Conc.	**U.M.**
Phosphate Buffer pH 7.4	200	mmol/L
Phenol	10.0	mmol/L
4-Aminophenazone	0.28	mmol/L
Glucose Oxidase (GOD)	20.000	U/L
Peroxidase (POD)	5.000	U/L
Sodium Azide	14.6	mmol/L

The product is not classified, according to CLP regulation

Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Controls, calibrators and pipettes with adequate volume.

PRECAUTIONS and WARNINGS
1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements.
Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

PROCEDURE
Quality control
Control sera with a known titer of Glucose are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration
For calibration, utilize the kit "Calibration serum" Sclavo Code B35181702.

Traceability
The Glucose traceability is reported in the package insert supplied with the "Calibrator Serum".

SAMPLE
Type of sample and storage
Serum or EDTA-plasma samples should be used. Once the sample has been centrifuged it must be separated from the erythrocytes, thus avoiding the effect of glycolysis. If the sample is not separated or tested immediately, it is advisable to use a glycolysis inhibitor. Do not use haemolysed samples. Samples prepared as described above can be stored for 8 hours at 25°C or 3 days at 4°C. After addition of glycolysis inhibitor the sample is stable for 2 days at room temperature, one week at 2-8°C and 1 day at -20°C. Urine collected within 24 hours must be processed within four days of collection; the sample should be kept at a temperature of 4-8°C.

REAGENT PREPARATION
Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2-8°C, and protected from direct light. Do not mix different batches. Slight variations in colour among batches will not affect test results.

Automation
The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R / C. Validated applications are available for Sclavo Konelab® - Indiko® and CHEMILAB instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD
The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions

Wavelength (primary):	510
Temperature:	37°C
Reaction	End point (increasing reaction)

Technique
Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	Blank	Calibr. Serum	Sample
Reagent	µL	1000	1000	1000
Calibr. Serum	µL	-	10	-
Sample	µL	-	-	10
Blank	µL	10	-	-

Mix well and let stand for 10 minutes at 37°C. Read the absorbance of sample (O.D. sample) and calibrator serum (O.D. calib. serum) against reagent blank.
Reaction volumes may be varied proportionally without alteration of results.
Results:

Manual Method
Calculation of Glucose concentration:

$$\frac{\text{O.D. Sample}}{\text{O.D. Calibrator serum}} \times \text{Calibr.Serum Concentration} = \text{Glucose mg/dL}$$

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Automation
The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the different analyzers.

REFERENCE RANGE
Serum or plasma: 70 - 110 mg/dL (3.88 – 6.10 mmol/L).
Urine: Negative
Each laboratory should calculate its own normal values on the basis of its local population.

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The method is linear up to 538 mg/dL (29.9 mmol/L) of Glucose. If the value in the sample exceeds the linearity limit of the method, dilute the sample with saline and multiply the result for the dilution factor.
Urine: With sample diluted 1:10 reaction is linear up to about 5380 mg/dL.

Recovery
Commercial control sera were analyzed with the kit in question following the guidelines of the CLSI protocol. The data obtained are shown in the table below.
Serum – Plasma

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	59.4	0.54	0.92	93.1 %
High	5	343	6.22	1.81	93.1 %

Urine

Range	Replicates	Mean	DS	CV%	Recovery
Low	5	46.73	1.291	2.80	101.6 %
High	5	315.40	4.648	1.50	100.1 %

Interference

Interference	Limits
Lipids	**300 md/dL**
Bilirubin	**20 mg/dL**
Haemoglobin	**1200 mg/dL**

Precision

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	81.0	1.40	1.72	30
High	mg/dL	285	2.30	0.80	30
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	82.0	1.10	1.72	20
High	mg/dL	284	6.20	2.18	20

Urine

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Media	S.D.	C.V. (%)	N°
Low	mg/dL	46.73	0.60	1.30	40
High	mg/dL	315.40	1.42	0.50	40
Total precision (Within-lab precision)					
Range	U.M.	Media	S.D.	C.V. (%)	N°
Low	mg/dL	46.73	1.39	3.00	40
High	mg/dL	315.40	5.05	1.60	40

Limit of Sensitivity
The Sensitivity limit has been measured using serial dilutions of high concentrated sera. The smallest detectable concentration is of about 1.86 mg/dL (0.103 mmol/L) of glucose.

Comparison between methods
The method was compared with a similar commercially available method, analyzing 200 human samples. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	0.940
Correlation Coeff. (R)	0.990

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

REFERENCES

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REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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