BIOLABO
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GLUCOSE GOD-PAP

Reagent for quantitative determination of glucose in human serum and plasma, urines

I REF K1209	**R1**	5 x 17 mL
I REF K2209	**R1**	4 x 30 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of glucose in human serum and plasma, urines.

I GENERALITIES (1) (6)

The glucose level in blood is maintained within a fairly narrow range under diverse conditions (feeding, fasting, or severe exercise) by regulatory hormones such as insulin, glucagon, or epinephrine. Measurement of glucose is one of the most frequently performed procedures in clinical chemistry laboratories in conjunction with other tolerance testing (Glucose tolerance test, Glucose 2h post-prandial…).
The most frequently encountered disorder of carbohydrate metabolism in blood is hyperglycemia due to diabetes mellitus.
Hyperglycemia higher than 300 mg/dL (16.5 mmol/L) may induce keto-acidosis and hyperosmolar coma.
In prolonged hypoglycemia, lower than 30 mg/dL (1.7 mmol/L), severe irreversible encephalic damage may occurs.

PRINCIPLE (4) (5)

Trinder Method.
Glucose is oxidized by GOD to gluconic acid and hydrogen peroxide which in conjunction with POD, reacts with chloro-4-phenol and PAP to form a red quinoneimine. The absorbance of the colored complex, proportional to the concentration of glucose in the specimen is measured at 500 nm.

REAGENTS

R1 **GL1**	Reagent	
Phosphate Buffer	150	mmol/L
Glucose oxidase (GOD)	≥ 20 000	UI/L
Peroxidase (POD)	≥ 1000	UI/L
4-Amino-antipyrine (PAP)	0.8	mmol/L
Chloro-4-phenol	2	mmol/L

According to 1272/2008/EC regulation, this reagent is not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, and used as described, reagents are stable:

Unopened:
- Until the expiry date stated on the label.

Once opened:
- Reagent is stable at least 3 months.
- Discard reagent if cloudy or if absorbance at 505 nm > 0.400.

SPECIMEN COLLECTION AND HANDLING (2)

Serum or plasma:

Separate promptly from cells to prevent glycolysis. If fluoride is used as a preservative, a decrease of 9 mg/dL (0.5 mmol/L) is seen within the first 2 hours, then concentration stabilizes.

Glucose is stable in serum or heparinized plasma:
- for 8 h at 25°C
- for 72 h at 2-8°C

Glucose is stable in plasma (Sodium fluoride or iodoacetate) :
- for 24 h at room temperature.

CSF:

Process immediately to avoid falsely low results. Store at –20°C.

Urines:

Collect in dark bottle and store at 2-8°C. Preserve 24 h urines with 5 mL glacial acetic acid or 5 g sodium benzoate or sodium fluoride.

LIMITES (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (2)

Serum or plasma	mg/dL	[mmol/L]
Newborn, 1 day	40-60	[2.2-3.3]
Newborn > 1 day	50-80	[2.8-4.4]
Children	60-100	[3.3-5.6]
Adult	74-106	[4.1-5.9]
60-90 years	82-115	[4.6-6.4]
> 90 years	75-121	[4.2-6.7]
24 h urines :	1-15 mg/dL	[0.1-0.8 mmol/L]
	< 0.5 g/24 hours	[<2.78 mmol/24 hours]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza 240TX, 37°C, 505 nm

Linearity Range: between 8 and 500 mg/dL

Detection limit: approx. 2 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	36	108	300
S.D. mg/dL	0.7	1.8	3.2
C.V. %	1.9	1.7	1.1

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	36	108	291
S.D. mg/dL	0.7	2.1	4.0
C.V. %	2.0	1.9	1.4

Comparison studies with liquid available reagent:
Realized on human serum (n=61) between 24 and 357 mg/dL

y = 0.969 x + 1.33 R= 0.9984

Analytical Sensitivity: approx. 0.060 abs for 10 mg/dL

Interferences:

Turbidity	Positive interference from 0.181 OD
Total bilirubin	Negative interference from 437 µmol/L
Direct bilirubin	Negative interference from 190 µmol/L
Ascorbic acid	Negative interference from 760 mg/dL
Hemoglobin	Positive interference from 228 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 2 months

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request

CALIBRATION (7)

- REF 95015
- Multicalibrator traceable *to SRM 965*

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- REF 95012 Urinary controls
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ Textbook of clinical chemistry. 3rd Ed. C.A. Burtis. E.R. Ashwood. W.B. Saunders (1999) p. 750-785.*
(2) *Clinical Guide to Laboratory Test. 4th Ed.. N.W. TIETZ (2006) p. 444-451*
(3) *YOUNG D.S.. Effect of Drugs on Clinical laboratory Tests. 4th Ed. (1995) p. 3-274 to 3-294.*
(4) *FARRANCE I. Clin. Biochem. reviews (1987). 8. p.55 to 68.*
(5) *TRINDER P.. Ann. Clin. Biochem.(1969). 6. p.24-27.*
(6) *BERNARD S., Biochimie clinique, 2cde éd.,Edition Maloine (1989), p.165-167.*
(7) *SRM : Standard Reference Material* ®

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with