BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

GLUCOSE GOD-PAP

Liquid ready for use

Reagent for quantitative determination of glucose
in human serum and plasma, urines or cerebrospinal fluid (CSF)

REF	LP80209	**R1**	2 X 200 mL	**R2**	1 x 5 mL
REF	LP87809	**R1**	8 X 200 mL	**R2**	1 x 5 mL

TECHNICAL SUPPORT AND ORDERS
Tel : (33) 03 23 25 15 50
Fax : (33) 03 23 256 256
support@biolabo.fr

CE

IN VITRO DIAGNOSTIC USE

CLINICAL SIGNIFICANCE (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 epinephrin. 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 oxidised 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 coloured complexe, proportional to the concentration of glucose in the specimen is measured at 500 nm.

REAGENTS COMPOSITION

R1 GLUCOSE GOD PAP 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

R2 GLUCOSE GOD PAP Standard

Glucose 100 mg/dL (5.55 mmol/L)

According to 1272/2008 regulation, these reagents are not classified as dangerous

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use (do not pipette with mouth).

- 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.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

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

Unopened,

- Until the expiry date stated on the label of the Kit.

Once opened:

- Transfer requested quantity, well recap vials and store at 2-8°C,
- Reagent (R1) is stable at least 3 months without contamination.
- Discard reagent (R1) if cloudy or if reagent blank at 500 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 stabilises.

Glucose is stable in serum or heparinised 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. Spectrophotometer or Biochemistry Clinical Analyzer

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Σ sufficient for | → dilute with | H2O Demineralized water | Biological hazard

QUALITY CONTROL

- BIOLABO EXATROL-N (level I) REF 95010
- BIOLABO EXATROL-P (level II) REF 95011
- 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. Repeat the test with the same control.
2. If control is still out of range, prepare fresh control and repeat the test.
3. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (2)

GLUCOSE in serum or plasma :

Population	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]
In CSF :	**mg/dL**	**[mmol/L]**
Infant, Child	60-80	[3.3-4.4]
Adult	40-70	[2.2-3.9]

In 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 at 37°C on KENZA 240TX

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 on Spectrophotometert with commercially available reagent:

Realised on serum specimens (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 337 µmol/L
Direct bilirubin	Negative interference from 190 µmol/L
Ascorbic acid	Negative interference from 360 mg/dL
Haemoglobin	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

CALIBRATION (7)

- REF 95015 BIOLABO Multicalibrator traceable *to SRM 965b*
- Standard (vial R2)

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

PROCEDURE

Detailed Kenza 240TX procedure is available on request

Wavelength: 505 nm

Temperature: 37°C

Let stand reagents and specimens at room temperature.

	Automated analyzer	Manual procedure
Reagent	300 µL	1000 µL
Standard, Controls, Specimen	3 µL	10 µL

Mix. Let stands for 10 minutes at 37°C or 20 minutes at room temperature.

Read absorbance at 500 nm (460-560) against reagent blank.

Coloration is stable for 15-20 minutes at 37°C, and then slowly decreases.

Notes:

1- For urines, use standard of the kit to calibrate and control with REF 95012

2- Performances and stability data's have been validated with serum on KENZA 240TX and KENZA 450TX

3-With Manual Procedure on Spectrophotometer and on other automated analyzers, performances and stability should be validated by user.

4- Applications proposal are available on request

CALCULATION

Calculate the result as follows:

$$\text{Result} = \frac{\text{Abs (Assay)}}{\text{Abs (Standard)}} \times \text{Standard concentration}$$

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 ®*