BIOLABO
www.biolabo.fr

MANUFACTURER:
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GLUCOSE GOD-PAP

Liquid ready for use

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

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
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CE

IVD 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

Vial R1 **ENZYMES-BUFFER**

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

Vial R2 **STANDARD**

Glucose 100 mg/dL (5.55 mmol/L)

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

Reagents are ready for use.

STABILITY AND STORAGE

Store away from light, well cap in the original vial at 2-8°C.

- Reagent (vial R1) and Standard (vial R2) : Transfer requested quantity, recap and store at 2-8°C.
- Reagents are stable until expiry date stated on the label of the kit when free from contamination, stored and used as described in the insert.
- Discard reagent if cloudy or if reagent blank at 500 nm is > 0.400.

This kit should be refrigerated during transport.

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.

INTERFERENCES (3)

Ascorbic acid: No interference up to 10 mg/dL.
Total bilirubin: Negative interference above 20 mg/dL.
Direct bilirubin: No interference.
Hemolysis: No interference.
Lipemia: Positive interference above 626 mg/dL of triglycerides.

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. Normal and pathological control ser

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

CALIBRATION (7)

- Standard enclosed in the Kit (vial R2) or BIOLABO-Multicalibrator REF 95015 traceable to SRM 965a.
- Or any calibrator traceable to a reference method or material.

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

It is recommended to calibrate in the following cases:

1. When changing batch of reagent.
2. After maintenance operations on the instrument.
3. If control values are out of range, even after using a new vial of fresh control.

QUALITY CONTROL

- BIOLABO EXATROL-N (level I) REF 95010.
- BIOLABO EXATROL-P (level II) REF 95011.
- Assayed control referring to the same method.
- 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 a 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)

In 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]
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

Within run N = 30	***Normal level***	***High level***
Mean mg/dL	81	269
S.D. mg/dL	1.05	1.80
C.V. %	1.3	0.67

Between run N = 60	***Normal level***	***High level***
Mean mg/dL	81	284
S.D. mg/dL	0.97	3.01
C.V. %	1.2	1.06

Detection limit : approximately 10 mg/dL.

Sensitivity for 100 mg/dL: approximately 0.420 Abs at 500 nm.

Comparison with a commercially available reagent:

y = 0.969 x + 1.33 r = 0.9984

LINEARITY

The reaction is linear up to at least 500 mg/dL (28 mmol/L).

Above, dilute the specimen with saline solution and re-assay taking into account dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

MANUAL PROCEDURE

Let stand reagents and specimens at room temperature.

Pipette into well identified test tubes :	**Blank**	**Standard**	**Assay**
Reagent	1 mL	1 mL	1 mL
Demineralised water	10 µL		
Standard		10 µL	
Specimen			10 µL

Mix. Let stand for 10 minutes at 37°C or 20 minutes at room temperature.
Read absorbances at 500 nm (460-560) against reagent blank.
Coloration is stable for 15-20 minutes at 37°C, then slowly decreases.

Note : Specific procedures are available upon request for automated instruments. Please contact BIOLABO technical support.

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 ®*