



**BIOLABO**  
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# GLUCOSE GOD-PAP

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

REF 87409	R1 4 x 250 mL	R2 4 x 250 mL	R3 1 x 5 mL
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## TECHNICAL SUPPORT AND ORDERS

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**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 hyperglycemia, 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

### Vial R2 CHROMOGEN

Chloro-4-phenol	2	mmol/L
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### Vial R3 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

Vial R1 and R2: If appropriate, use a non-sharp instrument to remove aluminium cap.

Transfer the contents of vial R1 into vial R2 and mix gently until complete dissolution (approximately 2 minutes).

Store away from light in a plastic bottle free from contamination

## STABILITY AND STORAGE

Store at 2-8°C, away from light.

- Standard (vial R3): transfer requested quantity, well recap the vial and store at 2-8°C.
- Reagent R1 (unopened) and reagents R2 and R3 are stable until expiry date stated on the label of the kit when stored and used as described.
- Once reconstituted, working reagent is stable for at least 2 years when free from contamination.
- Discard reagent if cloudy or if reagent blank at 500 nm is > 0.400.
- Don't use working reagent after expiry date stated on the label of the kit.

## 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 sera.

## CALIBRATION

- Standard enclosed in the Kit (vial R3) 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	Between run N = 60	Normal level	High level
Mean mg/dL	81	269	Mean mg/dL	81	284
S.D. mg/dL	1.05	1.80	S.D. mg/dL	0.97	3.01
C.V. %	1.3	0.67	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 :

$$y = 0.969 x + 1.33 \quad r = 0.9984$$

## 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
Deminerilised 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 absorbance at 500 nm (460-560) against reagent blank.  
Coloration is stable for 15-20 minutes at 37°C, and 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. 3<sup>rd</sup> Ed. C.A. Burtis. E.R. Ashwood. W.B. Saunders (1999) p. 750-785.
- (2) Clinical Guide to Laboratory Test, 4<sup>th</sup> Ed., N.W. Tietz (2006) p. 444-455
- (3) YOUNG D.S.. Effect of Drugs on Clinical laboratory Tests. 4<sup>th</sup> 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, 2<sup>cde</sup> éd.,Edition Maloine (1989), p.165-167
- (7) SRM : Standard Reference Material ®



Manufacturer



Use by



In vitro diagnostic



Temperature limitation



Catalogue number



See insert



Batch number



Store away from light



sufficient for



dilute with