BIOLABO
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GLUCOSE GOD-PAP

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

REF	80009	**R1**	1 x 500 mL	**R2**	1 x 7,5 mL	**R3** 1 x 5 mL
REF	87109	**R1**	6 x 250 mL	**R2**	6 x 3,75 mL	**R3** 1 x 5 mL
REF	16GL8	**R1**	6 x 1000 mL	**R2**	6 x 15 mL	**R3** 1 x 10 mL

SUPPORT TECHNIQUE ET COMMANDES
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Dernière révision : www.biolabo.fr

CE

IVD

Made In France

I : correspond aux modifications significatives

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 to screen its level.

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 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 GLUCOSE GOD PAP 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

R2 GLUCOSE GOD PAP Chromogen

Chloro-4-phenol	140	mmol/L

EUH210: Material safety data sheet available upon request

P302+352: IF ON SKIN: Wash with soap and water

P305+351+338: IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing

R3 GLUCOSE GOD PAP Standard

Glucose 100 mg/dL (5.55 mmol/L)

According to 1272/2008/EC regulation, these reagents are 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

Use a non-sharp instrument to remove aluminium cap.
Using a volumetric flask, measure the volume of demineralised water stated on the label of R1and transfer into the flask for reconstitution.
Add the contents of R1 and mix gently until dissolution.
Then, add the contents of vial R2 and mix gently.
Vial R3: Ready for use.

STABILITY AND STORAGE

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

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

Once opened:
- Reconstitute immediately Enzymes-buffer (vial R1)
- Vial R3: Transfer requested quantity and store the vial at 2-8°C.

Once reconstituted:
- Transfer requested quantity and store the vial at 2-8°C.
- Working reagent is stable at least for 2 years.
- Discard any reagent if cloudy or if reagent blank at 500 nm > 0.400.
- Don't use working reagent after expiry date.

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 or 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.

LIMITS (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

QUALITY CONTROL

- REF 95010 EXATROL-N Level I.
- REF 95011 EXATROL-P Level II.
- REF 95012 Urinary Controls (Level 1, Level 2)
- 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 calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat with a new vial of reagent.

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

REFERENCE INTERVAL (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.

I PERFORMANCES

On Kenza 240TX, 37°C, 505nm

Detection limit: approx. 10 mg/dL

Precision:

Within run N = 20	*Low level*	*Medium level*	*High level*	*Between run N = 20*	*Low level*	*Medium level*	*High level*
Mean mg/dL	35	130	222	Mean mg/dL	37.3	115.1	232
S.D. mg/dL	1.0	2.0	2.0	S.D. mg/dL	1.75	4.75	9.68
C.V. %	2,9	1.5	0.9	C.V. %	4.7	4.1	4.2

Measuring range:
between 25 mg/dL (1.39 mmol/L) and 500 mg/dL (28 mmol/L)

Analytical sensitivity (manual procedure):

0,420 abs for 100 mg/dL (500 nm, 1 cm pathlength)

Comparison study with commercially available reagent:

With n=61 specimens between 24 and 357 mg/dL

y = 0,969 x – 1,33 r = 0,9984

Interferences:

Ascorbic acid	Negative interference from 100 mg/L
Total bilirubin	Negative interference from 275 µmol/L
Hemoglobin	No interference up to 434 µmol/L
Turbidity	Positive interference from 0.100 abs

Other substances may interfere (see § Limits)

I CALIBRATION

- REF 95015 Multicalibrator traceable *to SRM 965b*
- Standard (vial R3): With manual procedure and urines

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

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

PROCEDURE

Manual method

Let stand reagent and specimens at room temperature.

Reagent	1000 µL
Calibrator, Control or 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.	

Notes:

1. Serum, plasma, or diluted urines with saline.
2. Performances with manual procedure should be validated by user.
3. Kenza applications and other applications proposal are available on request.

CALCULATION

Serum or plasma:

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

Diluted urines: Multiply the above result by dilution factor.

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. 444-455*
(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