BioMed-Glucose L.S

Enzymatic colorimetric method (GOD- POD)

REF:

GLU109480	(4 x 120 ml)	GLU 109130	(2 x 65 ml)
GLU1091000	(2 x 500 ml)	GLU109250	(1 x 250 ml)
GLU10910001	(4 x 250 ml)	GLU109240	(2 x 120 ml)
GLU 109100	(2 x 50 ml)		

INTENDED FOR USE:

For the quantitative determination of Glucose in serum, plasma and CSF.

PRINCIPLE:

The enzymatic method uses Glucose oxidase (GOD) to catalyze the oxidation of glucose to hydrogen peroxide and gluconic acid.
Hydrogen peroxide, when combined with 4-aminoantipyrine and aderivative from phenol , forms a red dye compound.
The intensity of the red colour produced is directly proportional to the glucose quantity in the sample.

SPECIMEN COLLECTION:

Non-hemolyzed serum or heparinized plasma and liquor (CSF).
Serum must be separated from the clot promptly . Glucose in serum is stable for 24 hours at +2/8°C., and 8 hours at room temperature.
Dilute 24h-Urine 1:10 with physiologic solution.
Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENT COMPOSITION:

READY TO USE LIQUID REAGENT:		
R1	Glucose	100mg/dL (5.56mmol/L)
R2	Phosphate Buffer Glucose oxidase Peroxidase 4-AAP Phenol	100mmol/L 10000 U/L 2000 U/L 1mmol/L 10mmol/L

PACKAGE: Collection & storage.

Store at +2/8°C.
Stable till the expiration date reported upon the package.
After the unsealing and the taking of the reagent ,it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination.

PRECAUTIONS & WARNING:

Avoid pipetting with mouth.
The preparation, according to current regulation, is classified as not dangerous.
The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.
Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle aspotentially infected from HIV or Hepatitis.

REAGENT PREPARATION & STABILITY :

Liquid reagents must be at room temperature (+15/25°C) before using.
The reagent is limpid and rose-colored.
Pale coloring of the reagent (< 0.050 O.D.) due to air-light exposure doesn't compromise the working. Stable until the expiration date reported upon the label.

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

Wavelength:	546 nm
Optical path:	1 cm light path
Temperature:	+37°C
Reading:	Against blank reagent
Assay Type:	End point
Sample/Reagent Ratio:	1/100

Pipetting in tubes :

	BLANK	**STANDARD**	**SAMPLE**
Reagent (R2)	1000 µL	1000 µL	1000 µL
Distilled water	10 µL		
Standard		10 µL	
Sample			10 µL

Mix, incubate for 10 min at 37°C and read sample and standard extinction.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.
For automated procedure, ask for specific application.

CALCULATION :

Serum, plasma and liquor:

$$\textbf{Glucose}\ \text{mg/dL} = \frac{\text{(A) Sample}}{\text{(A) Standard}} \times 100\ (\text{standard value})$$

Urine:

$$\textbf{Glucose}\ \text{mg/24h} = \frac{\text{(A) Sample}}{\text{(A) Standard}} \times 10 \times L / 24h$$

Standard 100mg/dL = 5.56mmol/L.
To convert mg/dl in mmol/L, multiply by 0.0556.

EXPECTED VALUES:

serum , plasma:	60-110 mg/dL	3.33-6.11 mmol/L
(CSF)	50- 70 mg/dL	2.78-3.89 mmol/L
Urine	< 0.5 g/24h	< 28 mmol/24h

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range.

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE

LINEARITY:	500 mg/dL
DETECTION LIMIT(2 DS):	6.97mg/dL
SENSITIVITY:	0.4 mg/dL= 0.00151A a 510 nm

PRECISION:

Within Run

Mean (mg/dl)	S.D.	C.V. (%)
83	4.7	5.6
313	18.8	6.0

Run-to-Run

Mean(mg/dl)	S.D.	C.V.(%)
83	7.0	8.4
285	24.0	8.5

CORRELATION

Comparative studies were done to compare our reagents with another commercial Glucose PAP
reagent. The results from these studies are detailed below.
Correlation coefficient: r=0.9999
Linear regression: y (mmol/l)=0.980x+0.099
(x=other commercial reagent, y=own reagent).

INTERFERING SUBSTANCES

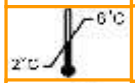
interferences are negligible up to:			
Bilirubin	50mg/dL	Hemoglobin	5g/L
Triglycerides	600mg/dL	Uric Acid	20mg/dL
Ascorbic Acid	70mg/L		

METHOD LIMITATIONS:

For concentration higher than 500 mg/dL, repeat the measure on a sample diluted 1:2 with saline solution and multiply the results by 2.
Grossly lipemic or icteric samples will cause false glucose values ,consequently a patient blank should be run.
Add distilled water to patient serum and read against a water blank.
Subtract this absorbance from the patient test absorbance to correct for the lipemia or icterus.
For a thorough evaluation of the interfering
substances , consult : Young, D.S., et al., Clin. Chem.21:1D (1975).

REFERENCES:

1. Trinder, P., Ann Clin Biochem. 6(24), 1969.
2. Henry, R.J., Clinical Chemistry, Principles and Technics. Harper and Row Publishers. New York, 1964.
3. Young D.S., et al., Clin. Chem. 18 (10), 1972

	Consult Instructions for Use
	Caution, Consult accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

EGY- CHEM for lab technology
Badr City, Industrial Area Piece 170
250 Fadan In East of Elrubaki, EGYPT
Office Tel: +202 26236727 / +202 26236598
Factory Tel: +202 23108170 / +202 23108171
Fax: +202 26240986
www.egy-chem.com

CE
EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany