

GLUCOSE SYSTEM PACK

(GOD/POD METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 ,
Beaconnic chem 200, Beaconnic B200, Beaconnic analyzer 120,
Bonavera chem 100(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA219	Glucose System Pack	5x40 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Glucose in human serum, plasma (preferably sodium fluoride).

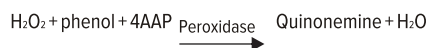
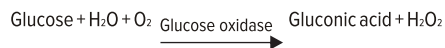
CLINICAL SIGNIFICANCE

Accurate measurement of glucose in body fluid is important in diagnosis and management of diabetes, hypoglycemia, adrenal dysfunction and various other conditions. High levels of serum glucose may be seen in case of Diabetes mellitus, in patients receiving glucose containing fluids intravenously, during severe stress and in cerebrovascular accidents.

Decreased levels of glucose can be due to insulin administration, as a result of insulinoma, inborn errors of carbohydrate metabolism or fasting.

PRINCIPLE

Glucose in the sample is oxidised to yield gluconic acid and hydrogen peroxide in the presence of Glucose oxidase. The enzyme peroxidase catalyses the oxidative coupling of 4-aminoantipyrine with phenol to yield a coloured quinonemine complex, with absorbance proportional to the concentration of glucose in sample.



REAGENT COMPOSITION

Reagent 1: Glucose Enzyme Reagent

Phosphate buffer	>75 mmol/L
Glucose oxidase	>8500 U/L
Peroxidase	>2000 U/L
Phenol	>15 mmol/L

REAGENT PREPARATION

Reagents are liquid. ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2 - +8°C.
On board stability: Min 30 days if refrigerated
(+8 - +14°C) and not contaminated.



BEACON

SPECIMEN COLLECTION AND HANDLING

Use unheamolyse serum, plasma (preference sodium fluoride).

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability after addition of a glycolytic inhibitor (Fluoride, monoiodoacetate, mannose):
2 days at +20 - +25°C
7 days at +4 - +8°C

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor:

8 Hours at +25°C
72 Hours at +4°C

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance.

UNIT CONVERSION

mg/dl x 0.056 = mmol/L.

EXPECTED VALUES

Fasting : 70 to 110 mg / dl
PPBS : Up to 130 mg / dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon system.

Data obtained in your laboratory may differ from these values.

Limit of quantification: 2.34 mg/dl
Linearity: 600 mg/dl
Measuring range: 2.34 - 600 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	115	0.82	0.71
Sample 2	277	2.83	1.02
Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	141.47	2.44	1.73

BEACON DIAGNOSTICS PVT. LTD. 424, NEW GIDC, KABILPORE, NAVSARI - 396 424. INDIA

COMPARISON

A comparison between Glucose System Pack (y) and commercially available test (x) using 20 samples gave following results:

$$y = 0.963x + 1.487 \text{ mg/dl}$$

$$r = 0.999$$

INTERFERENCES

Following substances do not interfere:

haemoglobin up to 7.5 g/L, bilirubin up to 30 mg/dL, triglycerides up to 750 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	GLUCOSE
Full Name	GLUCOSE
PRI Wave	505 nm
SEC Wave	630 nm
Assay/Point	1 POINT END
Start	1
End	34
Decimal	2
Unit	mg/dl
Linearity Range Low	2.34
Linearity Range High	600
Sample Volume	2 µl
Reagent 1 (R1) Volume	200 µl
Reagent 1 (R2) Volume	-
Substrate Depleted/Abs.limit	-
Linearity	600 mg/dl
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE









The program is made as per the in house testing, it can be modified as per requirements.

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics, 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998, p.131-7.
2. N.W., (Ed.) Textbook of Clinical Chemistry. Burtis CA and Ashwood ER, Fifth Edition, 2012.
3. Barham, D., Trinder, P: An improved color reagent for the determination of blood glucose by the oxidase system. Analyst, 1972, 97; 142-5.
4. Guder WG, Zawta B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: GIT verlag; 2001; p.30-1.
5. Snacks DB, Bruns DE, Goldstein DE, Mac Laren NK, McDonald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and Management of Diabetes mellitus. Clin Chemi 2002; 48: 436-72.

Symbols Used On Labels

	Catalogue Number		Manufacturer
	See Instruction for Use		Lot Number
	Content		Storage Temperature
	Expiry Date		In Vitro Diagnostics

BEA/24/GLU/SB/IFU Ver-02
09/05/2024

