GLUCOSE SYSTEM PACK

(GOD/POD METHOD)
B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI19	Glucose System Pack	4x50 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.

$$\text{Glucose} + H_2O + O_2 \xrightarrow{\text{Glucose oxidase}} \text{Gluconic acid} + H_2O_2$$

$$H_2O_2 + \text{phenol} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Quinonemine} + H_2O$$

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.

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
7days 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/dLx 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	116.05	1.43	1.23
Sample 2	284	3.13	1.10

Inter-assay precision Run to run (n=20)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	170.20	2.04	1.20

COMPARISON

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

y = 1.0161x - 3.223 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 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic chem 400
(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	33
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 to has been validate based 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,1 sted. Frankfurt: TH-Books Verlagsgesellschaft; 1998, p.131-7.
2. N.W., (Ed.) Textbook of Clinical Chemistry. Burtis CAand 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. 1 sted. Darmstadt: GIT verlag; 2001;p.30-1.
5. Snacks DB, Bruns DE, Goldstein DE, Mac Laren NK, Mc Donald 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

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

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