GLUCOSE SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400
(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI19	Glucose System Pack	4 x 50 ml

BEACON

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
Peroxidase	>2000
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 (2-10°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
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 referance 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

COMPARISON

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

y = 0.963x + 1.487 mg/dl
r = 0.999

INTERFERENCES

Following substances do not interfere:
haemoglobin upto 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.

WASTE MENAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera 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 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSATRATE DEPLETED	-
LINEARITY	600 mg/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	2 µ l

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 glukose 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, 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

IVD

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