Glucose Test Kit

(GOD/POD Method)

Code	Product Name	Pack Size
VS231	Glucose Test Kit	10 x 32 ml
VS331	Glucose Test Kit	10 x 44 ml

IVD

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Glucose in human serum, plasma and urine.

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 recieving 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.

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

$$H_2O_2 + \text{phenol} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Red Dye} + 2H_2O$$

REAGENT COMPOSITION
Reagent 1 : Glucose Enzyme Reagent

Phosphate buffer	300 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: 30 days if refrigerated (2–10°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING
Serum or Plasma (preferably fluoride plasma) free of hemolysis.
Serum should separated from the clot as quickly as possible.
It is recommended to follow standardized procedure.

CALIBRATION
Calibration with Cfas calibrator is recommended.

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

EXPECTED VALUES
Serum:
Glucose Fasting:

Cord:	45 – 96 mg/dl
Newborn, 1 d:	40 – 60 mg/dl
Newborn, >1 d:	50 – 80 mg/dl
Child:	60 – 100 mg/dl
Adult:	74 – 100 mg/dl
>60 y:	82 – 115 mg/dl
>90 y:	75 – 121 mg/dl

Glucose 2 h Postprandial: <120 mg/dl
WB (Hep) Adult: 65 – 95 mg/dl
Urine: 1 – 15 mg/dl

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

Limit of quantification: 2.60 mg/dl
Linearity: 600 mg/dl
Measuring range: 2.60 – 600 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	284.2	2.3	0.83
Sample 2	156.1	2.0	1.28

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	279.6	1.70	0.61
Sample 2	154.5	1.96	1.27

COMPARISON
A comparison between vecsys Glucose (y) and a commercially available test (x) using 40 samples gave following results:
y = 1.000 x - 0.714 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.

WASTE MANAGEMENT
Please refer to local legal requirements.

ASSAY PARAMETERS

Parameter Screen window	VEC-150+	VEC-200+
Chemistry	Glucose	Glucose
Full Name	Glucose	Glucose
Decimal	0.000	0.000
Test Method	End Point	End Point
Direction	Increase	Increase
Unit	mg/dl	mg/dl
Primary Wavelength	510 nm	505 nm
Secindary Wavelength	630 nm	630 nm
Linearity	600 mg/dl	600 mg/dl
Calibration Method	Linear	Linear
Reagent Alarm No.	from 5 to 10	from 5 to 10
Sample Volume	3	3
R1	300	300
R2	0	0
Blank Cycle/Time (s)	7-9	7-9
Reaction Cycle/Time (s)	26-27	37-38
Substrate Depletion Limit		
Response Range		
Auto Dilution Rerun Condition		
Above Substrate Depletion Limit		
Above Linearity Limit	✓	✓
Auto Dilution Rerun Set up: Dilution Ratio	5	5
Original Sample Volume	40	40
Calibration Validity		

ASSAY PARAMETERS

Parameter Screen	VEC-300+
Item	Glucose
Full Name	Glucose
Test Method	End Point
Filter	505 nm
Decimal	0.00
Unit	mg/dl
Sub Filter	620 nm
High Poluted	No
Reagent Blank	
Blank Medium	Reagent
Blank Value	Nil
Sample	
Sample Volume	3
Dilution	
Dilution Sample	15
Dilution Rate	30
Dilution Correct	0.9
Reagent 1 Volume	300
Reagent 2 Volume	0
Assistance	
Linearity	600 mg/dl
Test Point	46-48
Dilution	0
No. of Standard	1

NOTE

The Program is only for VECSYS kits.

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

REFERENCES

1. Thomas L.: Clinical Laboratory Diagnostics, 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998, p. 131 - 7.
2. Tietz 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 ISO 9001:2015

SYMBOLS USED ON LABELS

LOT Lot Number

Manufacturer

See Instruction for Use

Expiry Date

IVD In Vitro Diagnostics

8°C 2°C Storage Temperature