SBio GLUCOSE KIT

(GOD / POD Method)

(For invitro diagnostic use only)

REF	90503150	90504250	90511000
Pack Size	3 x 150 ml	4 x 250 ml	1000 ml

CE

8°C 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	S Glucose Standard (100 mg/dl)	GOD / POD GOD / POD Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	This way up	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	L1 Glucose Reagent		

INTENDED USE

Glucose kit is used for the determination of Glucose in Serum, Plasma and CSF.

PRINCIPLE OF THE TEST

Glucose is oxidised to gluconic acid and hydrogen peroxide in the presence of glucose oxidase. Hydrogen peroxide further reacts with phenol and 4-aminoantipyrine by the catalytic action of peroxidase to form a red coloured quinoneimine dye complex. Intensity of the colour formed is directly proportional to the amount of glucose present in the sample.

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\textit{Glucose Oxidase}} \text{Gluconate} + H_2O_2$$

$$H_2O_2 + \text{4 Aminoantipyrine} + \text{Phenol} \xrightarrow{\textit{Peroxidase}} \text{Red Quinoneimine dye} + H_2O$$

CLINICAL SIGNIFICANCE

Glucose is by far the most common carbohydrate and classified as a monosaccharide, an aldose, a hexose, and is a reducing sugar. Excessively high glucose levels, called hyperglycemia, might be due to too much sugar or too little insulin. Extremely low glucose levels can result from too little food or variable insulin excretion. A common disease related to irregular management of glucose is diabetes.

PRESENTATION	3 x 150 ml	4 x 250 ml	1000 ml
L1 : Glucose Reagent	3 x 150 ml	4 x 250 ml	1000 ml
S : Glucose Standard (100 mg/dl)	5 ml	5 ml	5 ml

COMPOSITION

Phosphate Buffer 100 mM; pH 7.0; GOD ≥ 15 KU/L; POD ≥ 1000 U/L; 4-AAP 0.3 mM; Phenol 5 mM; Non-Reactive Stabilizers and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8° C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum, Plasma, CSF is required.

REAGENT PREPARATION

Reagents are ready to use.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter : 505 nm (Hg 546 nm) / Green

Temperature : 37° C / R.T.

Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Glucose Reagent (L1)	1.0	1.0	1.0
Distilled Water	0.01	--	--
Glucose Standard (S)	--	0.01	--
Sample	--	---	0.01

Mix well and incubate at 37°C for 10 min or at R.T. (25°C) for 30 mins. Measure absorbance of the Standard (Abs.S) and Test Sample (Abs.T) against the Blank within 60 mins.

CALCULATIONS

$$\text{Total Glucose in mg/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 100$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Glucose. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 500 mg/dl. If values exceed this limit, dilute the serum with normal saline (NaCl 0.9%) and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Glucose is 2 mg/dl.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	86.96	2.79	93.4	1.04	180.36	3.83
Control 2	230.95	1.71	254	1.40	484.95	3.11

Method comparison:

Comparative studies were done to compare our reagent with another commercial Glucose Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum / Plasma (Fasting) : 70 - 110 mg/dl

(2 hrs. P. P.) : upto 150 mg/dl

CSF : 50 - 80 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTES

Glucose is reported to be stable in the sample for 7 days when stored at 2-8°C. To avoid glycolysis the serum should be separated from the clot as soon as possible, and plasma should be collected in an EDTA + fluoride bulb (0.5 mg + 1 mg per ml of blood). The reagent may be used in several automated analyzers. Instructions are available on request. Standard is traceable to standard reference material (SRM) 965a. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Trinder P., (1969) Ann. Clin. Biochem. 6:24.
2. Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop, et.al., 5th Edition.

Mfd. for:

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EC REP

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