

Ana-Chek® GLUCOSE

METHOD – GOD-POD
PRODUCT CODE – LG03

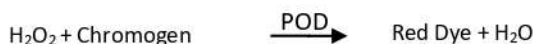


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of glucose in serum / plasma using GOD-POD method.

SUMMARY AND PRINCIPLE

Ana-Chek® Glucose is a single reagent set for determination of true glucose using GOD & POD. Ana-Chek® Glucose reagent estimates glucose in just 10 minutes at 37 °C or 15 minutes at R.T. by end point method. The GOD-POD method is specific to glucose only.



KIT COMPONENTS

Reagent 1 : Glucose Reagent
Reagent 2 : Glucose Standard (100 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Glucose is a single ready to use reagent. The reagent kit should be stored at 2 - 8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.300 O.D. against D/W at 546 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Glucose	Reagent Volume	1000 µl
Reaction Type	End Point	Sample Volume	10 µl
Wavelength	546 nm	Temperature	37 °C
Flow Cell Temp	37 °C	Incubation Time	10 min.
Blank setting	Reagent	Standard Conc.	100 mg/dL
Blank abs limit	< 0.300	Linearity	500 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Plasma (using sodium fluoride) is preferred as sample. Sodium fluoride acts as anti-glycolytic agent as well as anticoagulant. Glucose is stable for 24 hours at 2 – 8 °C and 30 days at -10 °C in neatly separated plasma or serum.

COMPONENTS OF REAGENT

Component	Concentration
Phosphate Buffer, pH 7.0	170 mmol/l
Glucose Oxidase	15000 IU/L
Peroxidase	1500 IU/L
Chromogen	0.28 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 10 minutes at 37°C or 15 minutes at room temperature.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final color is stable for 2 hours if not directly exposed to light.			

CALCULATION

$$\text{Glucose (mg/dL)} = \frac{\text{Abs. of sample} \times 100}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Fasting Blood Glucose: 60 – 110 mg/dL
Postprandial Blood Glucose: <145 mg/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 20-500 mg/dL. If the Glucose value exceeds linearity limit (above 500 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct glucose value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL, Ascorbic Acid upto 8 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	86.4	0.16	1.4	90	2.1	2.4
High Value Serum	272	3.03	1.7	280	2.4	1.1

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Glucose. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

BIBLIOGRAPHY

1. Trinder P. Annals. Clin. Biochem. 6, 24 (1969).
2. Young D.S. et al, Clinical Chemistry 21, 1D (1975).
3. Bergmayer H. V., "Methods of Enzymatic Analysis", A.P., N. Y. (1974). Page 1196.
4. M. Dashora et al, Proceeding of XI Annual Conf. ACBI.
5. M. Dashora, Proceeding of XIII Annual Conf. ACBI, Page 17.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry