Glucose Test Kit

REF	Pack Size	Reagent
GLULMA01	5 x 20	1 x 20ml

INTENDED USE
Glucose reagent is used for the quantitative determination of glucose concentration in human serum or plasma.

CLINICAL SIGNIFICANCE
Glucose is a major source of energy for most cells of the body; insulin facilitates glucose entry into the cells. Diabetes is a disease manifested by hyperglycemia; patients with diabetes demonstrate an inability to produce insulin. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

METHOD
Enzymatic End Point, Single reagent chemistry,
GOD – POD Method

TEST PRINCIPLE

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

$$2H_2O_2 + 4\ \text{Amino phenazone} + \text{phenol} \xrightarrow{\text{POD}} 4 - (\text{p-Benzoquinone-mono-amino})\ \text{phenazone} + H_2O$$

KIT CONTENTS/COMPONENTS
Reagent : Buffered Enzyme solution

Material Required but Not provided.
Fully Auto Biochemistry Analyzer: LM1015-200TPH.
Calibrator
Controls.

REAGENT PREPARATION, STORAGE AND STABILITY
Reagent is Ready to use keep away from direct light sources. Stability: up to expiration Date on labels at 2-8 °C.
Stability since first opening of bottle: preferable within 60 days at 2-8 °C.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

SPECIMEN
Use fresh serum and fresh plasma. The stability of glucose in specimen is reduced by bacterial contamination and by glycolysis. Serum/plasma is stable for 3 days 2-8°C. it is recommended to perform the assay with freshly collected samples.

APPLICATION For LM1015-200 TPH

Method	End Point
Blank	Reagent blank
Primary filter	510
Secondary filter	No
R1 Volume	300
R1 Position	*
Incubation time (Sec)	560
R2 Volume	-
R2 Position	-
Incubation time (Sec)	-
Sample Volume	3
Read Time	40
Calibrator Concentration	As on vial label
Mix speed set	Middle
Unit	mg/dl
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Glucose concentration of each sample.

NORMAL VALUES
Fasting Blood Glucose 70 – 110 mg/dl
Postprandial blood glucose < 145 mg/dl
Note: Expected range varies from population to population therefore each laboratory should establish its own normal range.

LIMITATIONS
If the value exceeds 500mg/dl, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result. Using the recommended multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dl)	85.66	285.1	85.8	285
SD	2.19	1.8	2.2	2.06
CV (%)	0.02	0.006	0.03	0.01

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturing Date		Storage temperature
	Expiry Date		Manufacturer

IFU/GLU/02 Rev.: 00; Rev Date.: 22/07/2024

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