

Intended Use

This reagent is intended for *in vitro* quantitative determination of Glucose in serum, plasma & CSF.

- GOD-PAP methodology
- Linear upto 600 mg/dL

Clinical Significance

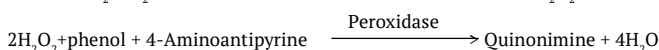
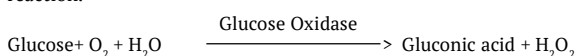
Glucose is a major carbohydrate present in the blood & serves as a primary source of energy. It is usually obtained from ingested starch & sugar. The glucose concentration is normally maintained at a constant level. Excessive glucose is stored as inactive glycogen mainly in the liver & little in the muscles.

Elevated blood glucose levels are found in diabetes mellitus, hyperthyroidism, hyperadrenalism & certain liver diseases.

Decreased levels are found in Insulinoma, hypothyroidism, hypopituitarism.

Principle

Enzymatic colorimetric determination of glucose according to the following reaction.

**Kit Components**

Reagent/Component	Product code 11406001	Product code 11406002	Description
Glucose Reagent R1	5 x 100 mL	1 x 1000 mL	Tris Buffer (pH 7.40) - 92 mmol/L Phenol - 0.3 mmol/L Glucose Oxidase - 15000 U/L 4- Aminophenazone - 2.6 mmol/L
Glucose Standard	1 x 4 mL	1 x 4 mL	Glucose standard concentration -100 mg/dL

Risk & safety

Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation

Glucose Reagent & Standard are ready to use.

Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2-8°C, if contamination is avoided.

Onboard Calibration Stability

On-board Calibration stability is 20 days

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents

Waste Management

Reagents must be disposed off in accordance with local regulations

Sample

Serum / plasma (free of hemolysis) / CSF

Interferences

No interference for

Bilirubin up to 20 mg/dL

Haemoglobin up to 1000 mg/dL

Materials provided

Glucose reagent & Standard

Materials required but not provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Procedure

Semi Auto Analyser	
Mode of Reaction	End Point
Slope of reaction	Increasing
Wavelength	505 (490-550 nm)
Temperature	37°C
Standard Concentration	100 mg/dL
Linearity	600 mg/dL
Incubation Time	10 Minutes
Blank	Reagent
Sample volume	10 µL
Reagent volume	1000 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg / dL	mmol/L	x 0.055

Calibration

Agappe multicalibrator is recommended for Calibration of this assay in fully auto analyzers.

Provided standard is recommended for calibration of this assay on Semi auto analyzer.

Procedure notes

Laboratory procedure for Semi Auto Analyzer			
	Blank	Calibrator	Sample/control
Glucose Reagent	1000 µL	1000 µL	1000 µL
Standard	-	10 µL	-
Sample / control	-	-	10 µL

Mix & incubate for 10 minutes at 37°C. Read the absorbance of standard and sample against reagent blank.

Calculation

Glucose Concentration (mg/dL) = $\frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times \text{standard conc.}$

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE SEE PACKAGE INSERT FOR PROCEDURE LOT LOT NUMBER MANUFACTURER'S ADDRESS MANUFACTURING DATE EXPIRY DATE TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
 'Agappe Hills', Dist. Ernakulam, Kerala, India-683 562.
 Tel. +91 484 2867 000 | Customer Support No.: 1800 425 7151 (Toll Free)
 customersupport@agappe.in | www.agappe.com

REV. NO.: ADL/IFU/GLU/LIQ/R01

ISO 9001 : 2015
EN ISO 13485: 2016

Quality control

It is recommended to use Agappe Qualicheck Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory establish its own reference values.

The following value may be used as guide line.

Serum / Plasma	: New born
	: 1 day :40-60 mg/dL
	: >1 day :50-80 mg/dL
	: Child :60-100 mg/dL
	: Adult :74-100 mg/dL
	: >60 Years :82-115 mg/dL
	: >90 Years :75-121 mg/dL
WB(Hep)	: Adult :65-95 mg/dL
CSF	: Infant child :60-80 mg/dL
	: Adult :40-70 mg/dL
Urine	: 1-15 mg/dL
U-24 hrs	: <0.5 gram/day

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance**1. Linearity**

This reagent is linear upto 600 mg/dL.

If the concentration is greater than linearity (600 mg/dL) dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.9989$ and a regression equation of $y = 1.0016x$.

3. Precision

Intra Run		
	Control Level 1	Control Level 2
n	20	20
Mean (mg/dL)	88.4	273.2
SD	2.56	8.77
CV(%)	2.89	3.21

Inter Run		
	Control Level 1	Control Level 2
n	20	20
Mean (mg/dL)	87.20	269.43
SD	2.48	8.86
CV(%)	2.84	3.29

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	90 ± 19.60	89.7
Control Level 2	289 ± 48	294.8
Qualicheck Norm	95 ± 10.60	97.3
Qualicheck Path	259 ± 27	264.4

4. Sensitivity

Lower detection Limit is 1.0 mg/dL

Bibliography


1. Trinder, P.; Ann Clin Biochem. 6,24 (1969)
2. Dineon, B.; Ann.Bio.Clin 33,3 (1975)
3. Lott, J. ; Clin.Chem. 21, 1754 (1975)
4. Burtis, Ashwood, Bruns & Saunders : Tietz Text Book of Clinical Chemistry 4th Edition -2006

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