SyRe Accute

AGAPPE

GLUCOSE

6 x 50 mL
12006013

Intended Use
This reagent is intended for *in vitro* quantitative determination of Glucose in serum, plasma & CSF
-GOD –PAP methodology
-Linear up to 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 constant level. Excessive glucose is stored as a 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.

$$\text{Glucose} + O_2 + 2H_2O \xrightarrow{\text{GOD}} H_2O_2 + \text{Gluconic acid}$$

$$2H_2O_2 + \text{Phenol} + \text{4-AAP} \xrightarrow{\text{POD}} \text{Quinonimine} + 4H_2O$$

GOD – Glucose Oxidase
POD – Peroxidase

Kit Components

Reagent/ Component	Product Code 12006013	Description	
Glucose Reagent	6 x 50 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

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

Reagent Preparation
Glucose Reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8°C.

Open Vial Stability
Once opened the reagents are stable up to 60 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 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 fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. 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
Fresh serum / plasma (Do not use lipemic or hemolysed sample) / CSF

Interferences
No interference for
Bilirubin up to 20 mg/dL
Haemoglobin up to 1000 mg/dLMaterials provided
Glucose Reagent

Reagents required but not provided
Multicalibrator (Product Code: 11610001), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

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

Calibration
Agappe Multicalibrator (Product Code: 11610001) is recommended for calibration of the assay.

Quality control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure. Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should 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
The reagent is linear up to 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= 0.9785 and a regression equation of y = 1.012x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	86.5	275.2	86.9	272.1
SD	2.35	8.52	2.45	8.35
CV(%)	2.72	3.10	2.82	3.07

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	90 ± 19.6	90
Control Level 2	289 ± 48	284
Qualicheck Norm	95 ± 10.60	96
Qualicheck Path	255 ± 27	260

4. Sensitivity
Lower detection Limit is 1.0 mg/dL

Bibliography

1. Trinder, P.Ann Clin Biochem. 6,24 (1979)
2. Dingeon, 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.

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.
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REV. NO.: ADL/IFU/GLU/40FR/R01 | CE | ISO 9001:2015 EN ISO 13485:2016

GLUCOSE

6 x 50 mL
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Accute 40 FR Assay Parameter

Page 1	
Test	GLUCOSE
Reaction Mode	End
Reference Test ID	**
Test WL	500
Blank WL	604
Test Read Timing	58 - 62
Blank Read Timing	NA
Sample	3 µL
R1	250 µL
R2	NA
Stirrer	OFF
Cal Mode	std
Page 3	
Calibration Mode	Linear
** Not applicable	
# - Input Programme Number only for sample Blanking parameters	

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