MISPA CCXL / CX4 / CXL PRO AGGLH AGAPPE

GLUCOSE HEXOKINASE

3 x 63/ 3 x 20 mL
12019027

Intended Use
This reagent is intended for *in vitro* quantitative determination of Glucose in serum /plasma .

Clinical Significance
Glucose is the main source of energy for the human body. Glucose is converted either in to glycogen to be stocked in the liver or in to triglycerides to be stocked in fatty tissues. Glucose concentration in blood is regulated by several hormones, including two antagonists insulin and glucagon.
Quantification of glucose in blood is used to diagnose metabolic carbohydrates disorders such as diabetes, neonatal glycaemia, idiopathic hypoglycemia and pancreatic disease.
The main physiological troubles are linked to hyperglycemia (type 1 Diabetes mellitus and type II diabetes mellitus). Type 1 diabetes mellitus is insulin dependent, and appears mainly before 30 years old. Type II diabetes mellitus is non-insulin dependent and usually appears after 40 years old, but can occur earlier for obese people. Other diabetes have secondary origin and appear after hepatic diseases.

Principle
Enzymatic determination of glucose according to the following reaction.

$$\text{Glucose + ATP} \xrightarrow[Mg^{2+}]{\text{Hexokinase}} \text{Glucose -6- Phosphate + ADP}$$

$$\text{Glucose -6-Phosphate + NAD}^{+} \xrightarrow{\text{G -6- PDH}} \text{D-Gluconate-6-Phosphate + NADH + H}^{+}$$

**G-6-PDH=Glucose-6-phosphate-dehydrogenase

Kit Components

Reagent/ Component	Product Code 12019027	Description
Reagent 1(R1)	3 x 63 mL	Pipes buffer,(pH - 7.6) 80 mmol/L NAD -4.1 mmol/L, Sodium Azide <0.1% ATP - 2.2 mmol/L
Reagent 2 (R2)	3 x 20 mL	Hexokinase-8500 U/L G-6-PDH- 8500 U/L, Sodium Azide <0.1% Magnesium Sulphate 20 mmol/L

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

Reagent Preparation
Glucose Hexokinase Reagent R1&R2 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^{0}C and protected from light.

Open Vial Stability
Once opened, the reagents are stable up to 60 days at 2-8^{0}C, if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 30 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. 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 (Collected in fluoride or heparin and free of hemolysis)

Interferences
No interference for

Bilirubin up to	20 mg/dL
Haemoglobin up to	300 mg/dL
Ascorbic acid	40mg/dL

Materials provided
Glucose hexokinase reagent R1& R2

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 multi Calibrator is recommended for calibration of this assay. Reconstitute with 2 mL of distilled water. Let it stand for 20 minutes at room temperature. Dissolve the content of the vial by swirling gently to avoid the formation of foam. Reconstituted calibrator is stable only for 2 days at 2- 8^{0}C and 30 days at -20^{0}C . (When aliquote and freeze once).

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 should establish its own reference values.
The following value may be used as guide line.
Serum /Plasma : 74 -106 mg/dL
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 900 mg/dL.
If the concentration is greater than linearity (900 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 which yielded a correlation coefficient of r^2= 0.9997 and a regression equation of y = 1.001x +1.9173.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	91.0	251.96	92.60	256.76
SD	0.77	1.89	1.78	4.53
CV(%)	0.84	0.75	1.92	1.76

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	83 .6(73.9-93.4)	76.14
Control Level 2	275 (252-298)	266.93

4. Sensitivity
Lower detection limit is 5.0 mg/dL

Bibliography

1)Sacks ,D.B, carbohydrates Tietz Fundamentals of Clinical Chemistry 5th Ed.Butis, C.A & Ashwood,E.R

2)Dods ,R.F,Diabetes Melitus Clinical Chemistry Theory Analysis , Correlation 4th Ed,Kapalan, L.A Pesce, A.J,Kazmierozak S.C

3) Teitz, N W Clinical Guide to laboratory test 3rd Ed.

4) Young, D S Effects of preanalytical variables on clinical laboratory tests 2nd edition, AACC press (1997)

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

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CE ISO 9001:2015
EN ISO 13485:2016