GLUCOSE

GOD – PAP

Diagnostic reagent for determination of Glucose concentration.

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2191	5 x 100 mL	L2191	2667 Tests	S2191	1364 Tests	K2190	3182 Tests
A2192	5 x 50 mL	DM2190	990 Tests	BY2190	7955 Tests	K2191	2273 Tests
T2190	5294 Tests	R2190	1364 Tests	BY2191	5682 Tests	M2190	2727 Tests
T2191	2941 Tests	R2191	455 Tests	N2190	758 Tests	M2191	1818 Tests
L2190	5000 Tests	S2190	2182 Tests	N2191	424 Tests		

INTENDED USE

The test is applied for the quantitative determination of glucose in Serum, plasma, urine and CSF (cerebrospinal fluid).

TEST PRINCIPLE

The enzyme glucose oxidase catalyzes the oxidation of glucose to gluconic acid and H_2O_2. The H_2O_2 reacts with phenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of color formed is proportional to the glucose concentration and can be measured photometrically between 480 and 520 nm.

TEST PARAMETERS

Method	: Colorimetric, Endpoint, Increasing Reaction GOD - PAP.
Wavelength	: 500 nm, Hg 546 nm
Temperature	: 37°C
Sample	: Serum, heparinized or EDTA-Plasma
Linearity	: 3 mg/dL - 500 mg/dL (22 mmol/L)

REAGENT COMPOSITION

Phosphate buffer pH 6.50	≤ 240 mM,
GOD	≥ 15000 U/l,
POD	≥ 500 U/l,
4-AAP	≤ 1 mM,
Phenol	≤ 15 mM,
Surfactant.	

REAGENT PREPARATION

Reagents are ready to use.

REAGENT STABILITY AND STORAGE

Use reagent ready to use.
Reagents are stable up to expiration date on labels at 2-8°C.

Once opened vials (reagent 1) are stable minimum 60 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum, plasma, urine, CSF (cerebrospinal fluid). Separated and nonhemolyzed samples are stable 8 hours at 25°C and 3 days at 2-8°C. Variable stability is observed with longer storage periods.

Glycolysis decreases serum glucose by approximately 5 to 7% in 1 h (5 to 10 mg/dl) in normal uncentrifuged coagulated blood at room temperature. The rate of in vitro glycolysis is higher in the presence of leukocytosis or bacterial contamination. Plasma, removed from the cells after moderate centrifugation, contains leukocytes that also metabolize glucose, although cell-free sterile plasma has no glycolytic activity. Glycolysis can be inhibited and glucose stabilized for as long as 3 days at room temperature by adding sodium iodoacetate or sodium fluoride (NaF) to the specimen.

Although fluoride maintains long-term blood glucose stability, the rate of decline in the first hour after sample collection is not altered. Cerebrospinal fluid (CSF) may be contaminated with bacteria or other cells and should be analyzed for glucose immediately.

If a delay in measurement is unavoidable, the sample should be centrifuged and stored at 4°C or -20 °C. In 24-h collections of urine, glucose may be preserved by adding 5 ml of glacial acetic acid to the container before starting the collection. The final pH of the urine is usually between 4 and 5, which inhibits bacterial activity. Urine samples may lose as much as 40% of their glucose after 24 h at room temperature.Samples are collected by standard procedures.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\text{Absorbance Sample}}{\text{Absorbance Standard}} \times \text{Conc. of Standard(100)}$$

= mg/dL (mmol/L) Glucose in sample.

Unit Conversion

mg/dL x 0.055 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Plasma/serum (fasting patient)

Adults	: 70 - 105 mg/dL
Children	: 70 - 105 mg/dL
Premature neonates	: 25 - 80 mg/dL
Term neonates	: 30 - 90 mg/dL
CSF	: 40 - 75 mg/dL

(60% of plasma value)
Urine (fasting patient)

Random urine	: < 30 mg/dL
24h urine	: < 500 mg/24h

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with glucose values determined by this method can be used. We recommend:

A3910	**ARCON N** Assayed Control Serum Normal
A3920	**ARCON P** Assayed Control Serum Abnormal

The assay requires the use of a Glucose Standard. We recommend:

A2190S Standard conc. 100mg/dL
A39050 Calibrator (ARCAL AUTO)

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 3 mg/dL

High Linearity: 500 mg/dL
Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
95.20 mg/dL	1.32 mg/dL	1.4%	10
224.3 mg/dL	2.36 mg/dL	1.1%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
96.47 mg/dL	2.78 mg/dL	2.9%	20
252.06 mg/dL	9.56 mg/dL	3.8%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 1 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:

Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 30 mg/dL
Lipids	≤ 1000 mg/dL

Methods comparison: A comparison between Archem and a commercially available product gave the following results:
Glucose UV Archem = x
Glucose competitor = y
n = 100
$y = 0.953x + 1.05$ mg/dl $r^2 = 0.99$

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.

5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CSF : Cerebrospinal Fluid
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

1. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press (1990).
3. Methods in Enzymatic Analysis, Vol. VI, Verlagsgesellschaft,Germany 1984-1988, pp. 163-171.
4. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
5. International Federation of Clinical Chemistry, Committee on Reference Systems for Enzymes, Chem Clin Lab Med 2002; 40 (7):718–724.

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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