GLUCOSE

Diagnostic reagent for determination of Glucose concentration.
Liquid. Mono Reagent. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack
MH-472	200 mL
MH-473	120 mL

Changes made in the instructions for use are marked as grey.

INTENDED USE

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

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]

These measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders such as diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose.

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 formed color is proportional to the glucose concentration and can be measured photometrically between 480 and 520 nm.

$$Glucose + O_2 \xrightarrow{Glucose\ Okxidase} Glycolic\ acid + H_2O_2$$

$$H_2O_2 + 4 - Aminophenazone + Phenol \xrightarrow{Peroxidase} Quinonimine\ dye\ complex$$

TEST PARAMETERS

Method	:Colorimetric, Endpoint, Increasing Reaction GOD - PAP.
Wavelength	: 500 nm, Hg 546 nm
Linearity	: 400 mg/dL

REAGENT COMPONENTS

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 for use.

REAGENT STABILITY AND STORAGE [6]

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 60 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE [7]

Serum, plasma, urine, CSF are collected according to the standard procedure.

Urine: Store 24-hour samples by adding 5 mL of glacial acetic acid to the container before starting their collection.

CSF: Process immediately to avoid false low results.

Serum and plasma are stable for:
2 days at +20/+25°C,
7 days at +2/+8°C,
3 months at -20°C.

Urine is stable for:
2 hours at +20/+25°C,
2 hours at +2/+8°C,
2 days at -20°C.

CSF is stable for:
5 hours at +20/+25°C,
3 days at +2/+8°C',
1 month at -20°C.

Unit Conversion:
mg/dL x 0.055 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) [8]

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.

Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

Arcon N (Level I Control) Lyophilized
Ref.No: VT-001

Arcon P (Level II Control) Lyophilized
Ref.No: VT-002

The assay requires the use of an Arcal Auto Calibrator and Glucose Calibrator. We recommend:

Arcal Auto Calibrator
Ref.No: VT-003

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 60 days.

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

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

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is 1 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) %≤20]**:**[9] 3 mg/Dl

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The test is linear up to 400 g/L.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may considerably vary depending on the instrument used.

Precision Studies:[10]

Repeatibility (Within Run)

Mean Concentration	SD*	CV%	n
121.85 mg/dL	1.78	1.46	40
285.79 mg/dL	2.24	0.78	40

Reproducibility (Day-to-Day Run)

Mean Concentration	SD	CV%	n
89.47 mg/dL	1.53	1.71	84
286.45 mg/dL	4.41	1.54	84

*SD: Standard Deviation
*CV: Variation Coefficient

Deviations of ±10% CV% between devices may be observed.

Precision studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[11, 12]
Correlation with a comparative method is: r= 0.99
According to Passing-Bablok Fit:
Slope: 0.953
Intercept: 1.05

Interference:[1, 2, 3, 13]
No significant interference was observed for hemoglobin, conjuge bilirubin, lipemia up to the interferent concentration given in the table.

Interferant and Concentration	Glucose Target (mg/dL)	N	%Observed Recovery
Hemoglobin 990 mg/dL	103	3	109
Bilirubin 23,63 mg/dL	108,5	3	90
Lipemi 433,4 mg/dL	106,6	3	108

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

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

WARNINGS AND PRECAUTIONS

IVD**:** For in Vitro Diagnostic use only.

Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.

Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032 :Releases a very toxic gas if contacts with acid.

H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.

P264 :Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

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Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Turkey
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr **www.archem.com.tr**
info@validity.com.tr **www.validity.com.tr**

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests