ETHANOL

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

Ref No	Pack
MH-172	75 mL
MH-173	50 mL

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

INTENDED USE

The test is applied for the quantitative determination of ethanol in serum and plasma on photometric systems.

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

The determination of ethanol belongs to the most frequent analyses in the forensic and toxicological laboratory. It serves for the diagnosis of intoxications and poisonings.

$$\text{Ethanol} + \text{NAD} \xrightarrow{\text{ADH}} \text{Acetaldehyde} + \text{NADH} + \text{H}$$

In the presence of NAD ethanol is converted by the alcohol dehydroganese. The measured absorbance of the produced NADH is proportional to the ethanol concentration in the sample.

TEST PARAMETERS

Method	: Enzymatic UV test with alcohol dehydrogenase (ADH)
Wavelength	: 376 nm (360 – 380 nm) (also 340 nm is acceptable)
Linearity	: 3.5 g/L

REAGENT COMPONENTS

Reagent 1:

Buffer	pH 9.0	≤ 260 mol/L
Stabilizers		
Preservatives		

Reagent 2:

Buffer	pH 6.6	≤ 10 mmol/L
NAD		> 2 mmol/L
Alcohol dehydrogenase (ADH)		> 40 Ku/L
Stabilizers		
Preservatives.		

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 30 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

Serum and Plasma (heparin and EDTA) are collected according to the standard procedures.

Serum and plasma are stable for:
2 weeks at +20/+25°C,
6 months at +2/+8ºC
6 months at -20°C.

Samples must be stored tightly closed. Don't use alcohol or Volatile disinfectants during ethanol measurement. Discard contaminated specimens.

Unit Conversion:
Ethanol [g/L] x 21.7= Ethanol [mmol/L]
Ethanol [g/L] x 0.8 = Ethanol %0.

REFERENCE INTERVAL (NORMAL VALUES) [7]

Ethanol is present is serum and blood only after ingestion

0.3 - 1.2 g/L : Slowed reflexes, diminution of attention judgment and control

1.2 - 2.5 g/L : Reduced visual acuity and Increased Reaction time.

2,5 - 3.5 g/L : Muscular Incoordination, decreased response to stimuli.

> 3.5 g/L : Impairment of circulation and respiration, possible death.
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:

Ethanol Control Level I Liquid
Ref.No: VT-033

Ethanol Control Level II Liquid
Ref.No: VT-034

The assay requires the use of an Ethanol Calibrator Liquid. We recommend:

Ethanol Calibrator-Liquid
Ref.No: VT-035

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 13 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 0.1 g/L
Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) %≤20]**:**[8] 0.2 g/L.

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

High Linearity: The method is linear up to 3.5 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:[9]
Repeatibility (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
0.51 g/L	0.01	1.67	40
0.98 g/L	0.02	1.95	40
1.99 g/L	0.01	0.66	40

Reproducibility (Run to Run) (Inter-Assay)

Mean Concentration	SD	CV%	n
0.51 g/L	0.02	3.36	40
1.01 g/L	0.02	2.03	40
1.99 g/L	0.03	1.66	40

*SD: Standard Deviation

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

Interference:[3, 4, 5, 12]
No significant interference was observed for Hemoglobin, Bilirubin, Ascorbic Acid, Urea LDH, Lipemia, up to the interferent concentration given in the table.

Ascorbic Acid	: < 30 mg/dL
Bilirubin	: < 60 mg/dL
Lipemi	: < 2000 mg/dL
Trigliseritler,	
Hemoglobin	: < 2000 mg/dL
Urea	: < 2000 mg/dL
LDH	: < 2000 mg/dL

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.

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.

REFERENCES

1. Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
2. Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
3. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
4. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
5. Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
6. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
7. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
8. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
9. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
10. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26.783-79.
11. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline.CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
12. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline.CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition.CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)
13. Tietz Textbook of Clinical Chemistry 3.Ed. Philadelphia : W.B Saunders Company 1999 p.922-923
14. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press; 1990.
15. Burtis CA, Ashwood ER, eds. In: Tietz NW. Textbook of Clinical Chemistry. Toronto: WB Saunders Co; 1994:1170-1175.
16. Thomas L. Cliniacl Laboratory Diagnostics. 1. Ed. Frankfurt: TH-Books Verlagsgesellschaft ; 1998 p. 1168-1170
17. Lundquist F. The Determination of Ethyl Alcohol in Blood and Tissues. In: Glick D, ed. Methods Biochem Anal. Vol III. New York, NY: Interscience publishers; 1957:217-251.
18. William H. Porter Ph.D.Cliniacl Toxicology In: Burtis CA, Ashwood ER, editorts.
19. Bonnichsen RK, Theorell H. An Enzymatic Method for the Micro Determination of Ethanol. Scand J Clin Lab Invest. 1951;3:58.
20. Clinical and Laboratory Standards Institute (formerly NCCLS). How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory; Approved Guideline. Wayne, PA: NCCLS; 1995. Clinical and Laboratory Standards Institute Document C29-A.
21. 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.

Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. Sanayi A.Ş. Company)
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**

CE

SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practice
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