CE IVD DIALAB

Liquid Reagents – ready to use

ETHANOL

Enzymatic, UV
2 Reagents

Diagnostic reagent for quantitative in vitro determination of ethanol in human serum or plasma on photometric systems

REF Cont.

D07840	**5 x 25 mL**	4 x 25 mL	Reagent 1
		1 x 25 mL	Reagent 2
D07850	**5 x 10 mL**	4 x 10 mL	Reagent 1
		1 x 10 mL	Reagent 2

Additionally offered:

Z05880	4 x 1 mL	Ethanol Calibrator/Control Set

TEST PARAMETERS

Method:	Enzymatic, UV, Increasing Reaction
Wavelength:	376 nm (360 – 380 nm)
Temperature:	37°C
Sample:	Serum or plasma (heparin, EDTA)
Linearity:	up to 350 mg/dL (3.5 g/L)
Sensitivity:	The lower limit of detection is 10 mg/dL (0.1 g/L)

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1	
Buffer, pH 9.0	300 mmol/L
Stabilizers and preservatives	
Reagent 2	
Buffer, pH 6.6	40 mmol/L
NAD	≥10 mmol/L
Alcohol dehydrogenase (ADH)	≥200 kU/L
Stabilizers and preservatives	

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light
	close immediately after use
	Do not freeze the reagents !
Storage:	at 2 – 8°C
Stability:	up to the expiration date

SAMPLE STABILITY AND STORAGE

Serum and plasma (heparin and EDTA) [3]

Stability:	at 20 - 25°C	2 weeks
	at 4 - 8°C	6 months
	at -20°C	6 months

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

STANDARDS/CONTROLS

(have to be ordered separately)

Concentration	0, 50, 100, 300 mg/dL
Storage:	2 – 8°C
Stability:	up to the expiration date

CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid	30 mg/dL
bilirubin	60 mg/dL
creatinine	250 mg/dL
glucose	2000 mg/dL
hemoglobin	1000 mg/dL
LDH	2000 U/L
triglycerides	2000 mg/dL
urea	2000 mg/dL

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Substrate start

Pipette into test tubes	Blank	Standard	Sample
Sample, Standard	-	10 µL	10 µL
Dist water	10 µL	-	-
Reagent 1	1000 µL	1000 µL	1000 µL
Mix and incubate 5 min at 37°C. Read absorbance A1 against reagent blank, than add:			
Reagent 2	250 µL	250 µL	250 µL
Mix and incubate 5 min. at 37°C. Read absorbance A2 immediately. $\Delta A = (A2 - A1)$			

The observance of exact measuring times and absolute equal treatment of all samples, standards and controls must be respected.

CALCULATION

$$\text{Ethanol [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \times \text{Conc. Standard [mg/dL]}$$

UNIT CONVERSION

Ethanol [mg/dL] x 0.217 = Ethanol [mmol/L]
Ethanol [mg/dL] (plasma/serum) x 0.008 = Ethanol ‰
Ethanol [g/L] x 21.7 = Ethanol [mmol/L]
Ethanol in [g/L] (plasma/serum) x 0.8 = Ethanol ‰

REFERENCE RANGE [2]

Ethanol is present in serum and blood only after ingestion.

30 – 120 mg/dL (0.3 – 1.2 g/L)	Slowed reflexes, diminution of attention, judgment and control
120 – 250 mg/dL (1.2 – 2.5 g/L)	Reduced visual acuity and increased reaction time
250 – 350 mg/dL (2.5 – 3.5 g/L)	Muscular incoordination decreased response to stimuli
> 350 mg/dL (> 3.5 g/L)	Impairment of circulation and respiration, possible death

TEST PRINCIPLE

Ethanol $\xleftarrow{ADH}$ Acetaldehyde + NADH + H^+

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

PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine ethanol concentrations up to 350 mg/dL (3.5 g/L). When values exceed this range samples should be diluted 1+1 with NaCl solution (9 g/L) and the result multiplied by 2.

PRECISION (at 37 °C)

Intra-assay n = 20	Mean [g/L]	SD [g/L]	CV [%]
Sample 1	0.51	0.01	1.67
Sample 2	0.98	0.02	1.95
Sample 3	1.99	0.01	0.66

Inter-assay n = 20	Mean [g/L]	SD [g/L]	CV [%]
Sample 1	0.51	0.02	3.36
Sample 2	1.01	0.02	2.03
Sample 3	1.99	0.03	1.66

METHOD COMPARISON

A comparison between Dialab Ethanol (y) and a commercially available test (x) using 30 samples gave following results: y = 1.00 x – 0.10 g/L; r= 0.999.

QUALITY CONTROL

All controls with ethanol values determined by this method can be used.

We recommend:

REF Cont.

Z05880 4 x 1 mL **Ethanol Calibrator/Control Set**

CALIBRATION

The assay requires the use of an ethanol standard.

We recommend:

REF Cont.

Z05880 4 x 1 mL **Ethanol Calibrator/Control Set**

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1168-1170.
2. William H., Porter Ph.D. Clinical Toxicology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 922-923.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p 28-9

2°C 8°C IVD

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