Ethanol FS

Order Information

Cat. No.	Kit size		
1 0881 99 10 930	R1 4 x 20 mL	+	R2 2 x 10 mL

Intended Use

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

Summary

Ethanol determination belongs to the most frequent analyses in the forensic and toxicological laboratory. It serves for the diagnosis of intoxications, particularly for emergency room patients [1].

Method

Enzymatic UV test with alcohol dehydrogenase (ADH)

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

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

Reagents

Components and Concentrations

R1:	Buffer	pH 9.0	300 mmol/L
R2:	Buffer	pH 6.6	40 mmol/L
	NAD		≥ 10 mmol/L
	Alcohol dehydrogenase	(ADH)	≥ 200 kU/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The in-use stability of the reagent is 15 months.

Warnings and Precautions

1. Components contained in Ethanol FS are classified according to EC regulation 1272//2008 (CLP) as follows:

⚠ Reagent 1: Warning. H315 Causes skin irritation. H319 Causes serious eye irritation. P264 Wash hands and face thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection. P302+P352 IF ON SKIN: Wash with plenty of water/soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention.

2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [2].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
7. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Due to alcohol evaporation, the sample container has to be filled as complete as possible, tightly closed, and should not stand open for longer than 5 minutes.

Do not use alcohol or volatile disinfectants during ethanol measurement.

Stability [3]:

2 weeks	at	20 – 25°C
6 months	at	4 – 8°C
6 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	340 nm
Temperature	37°C
Measurement	Endpoint
Sample/Standard	1.0 µL
Reagent 1	160 µL
Reagent 2	40 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

One point or multi-point calibration

One-Point Calibration
With Ethanol Standard FS (3.0 mg/mL)

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

Multi-Point Calibration
The ethanol concentration of unknown samples is derived from a calibration curve using a linear algorithm. The calibration curve is obtained with four standards at different levels and NaCl solution (9 g/L) for determination of the zero value.

Conversion Factor
Ethanol [g/L] x 21.7 = Ethanol [mmol/L]
Ethanol [g/L] x 0.8 = Ethanol ‰ (whole blood)

Calibrators and Controls

DiaSys Ethanol Standard FS is recommended for calibration. Standard values are traceable to the initial weight of a primary material with a purity of 99.9% ethanol. Use DiaSys TruLab Ethanol for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
Ethanol Standard FS (0.5 mg/mL)	1 4010 99 10 063 (1 0890 99 10 349)	10 x 1 mL
Ethanol Standard FS (1.0 mg/mL)	1 4030 99 10 063 (1 0910 99 10 349)	10 x 1 mL
Ethanol Standard FS (2.0 mg/mL)	1 4040 99 10 063 (1 0920 99 10 349)	10 x 1 mL
Ethanol Standard FS (3.0 mg/mL)	1 4050 99 10 063 (1 0930 99 10 349)	10 x 1 mL
TruLab Ethanol	5 4020 99 10 063 (5 0900 99 10 349)	10 x 1 mL

Note: Cat. no. for screw cap vial highlighted in grey; cat. no. for glass ampoule in brackets.

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 2.5 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.

Limit of detection**	0.1 g/L

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [g/L]
Ascorbic acid	30 mg/dL	1.25
Bilirubin (conjugated)	60 mg/dL	1.25
Bilirubin (unconjugated)	60 mg/dL	1.27
Creatinine	250 mg/dL	1.65
Glucose	2000 mg/dL	1.48
Hemoglobin	1000 mg/dL	1.26
LDH	2000 U/L	1.53
Lipemia (triglycerides)	2000 mg/dL	1.28
Urea	2000 mg/dL	1.49

For further information on interfering substances refer to Young DS [4,5].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.164	0.773	1.65
CV [%]	4.97	1.83	1.42
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.168	0.782	1.68
CV [%]	4.69	2.80	1.12

Method comparison (n=91)	
Test x	Competitor Ethanol
Test y	DiaSys Ethanol FS
Slope	0.990
Intercept	–0.019 g/L
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [6]

Ethanol is present in serum and blood only after ingestion.

0.3 – 1.2 g/L	6.5 – 26.0 mmol/L	Slowed reflexes, diminution of attention, judgment and control
1.2 – 2.5 g/L	26.0 – 54.3 mmol/L	Reduced visual acuity and increased reaction time
2.5 – 3.5 g/L	54.3 – 76.0 mmol/L	Muscular incoordination, decreased response to stimuli
> 3.5 g/L	> 76.0 mmol/L	Impairment of circulation and respiration, possible death

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Külpmann WR. Poisoning and drug of abuse. In: Clinical Laboratory Diagnostics [Internet]. Prof. Dr. Lothar Thomas 2020 [cited 2021 Dec 20]. Available from: https://www.clinical-laboratory-diagnostics-2020.com/
2. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med. 2007;45:1240-1243.
3. Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 28-9.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington DC: The American Association for Clinical Chemistry Press; 2000.
5. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products [Internet]. AACC Press and John Wiley and Sons, Inc; 2021 [cited 2021 July]. Available from: https://clinfx.wiley.com/ aaccweb/aacc/
6. Porter WH. Clinical Toxicology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 922-923.

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

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