BioMajesty®

Ethanol FS

Order Information

Cat. No.	Kit size
1 0881 99 10 964	Σ 540 (R1: 6 x 90, R2: 6 x 90)

Intended Use

Diagnostic reagent for quantitative in vitro determination of ethanol in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

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)

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

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. The bottles are placed directly into the reagent rotor.

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.

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.

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Performance Characteristics

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

Measuring range up to 2.5 g/L. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.1 g/L
Onboard stability	7 days
Calibration stability	1 day

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.

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

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.

IVD CE

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* Fluid Stable

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Ethanol FS

Chemistry code 10 088

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	160
R2e volume	0
R2 volume	40
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	ETH
Digits	3
M-wave L.	340
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Linear	**Axis Conv**	No conv
Blank	Blank is 0	**Points**	4

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	0.000	1	No dil	0	0	0	9.999	-9.999
1	0.500	1	No dil	0	0	0	9.999	-9.999
2	1.000	1	No dil	0	0	0	9.999	-9.999
3	2.000	1	No dil	0	0	0	9.999	-9.999
4	0.000	1	No dil	0	0	0	9.999	-9.999
5	0.000	1	No dil	0	0	0	9.999	-9.999

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