respons®910

Ethanol FS

Order Information

Cat. No.	Kit size
1 0881 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of ethanol in human serum or heparin plasma on automated DiaSys respons®910.

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.

Performance Characteristics

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

Measuring range up to 3.5 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**	0.03 g/L
Onboard stability	42 days
Calibration stability	3 days

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [g/L]
Ascorbic acid	30 mg/dL	1.82
Bilirubin (conjugated)	40 mg/dL	0.13
	60 mg/dL	1.18
Bilirubin (unconjugated)	20 mg/dL	0.16
	65 mg/dL	1.12
Creatinine	250 mg/dL	1.65
Glucose	2000 mg/dL	1.48
Hemoglobin	200 mg/dL	0.09
	1000 mg/dL	1.04
LDH	2000 U/L	1.53
Lipemia (triglycerides)	1600 mg/dL	0.11
	2000 mg/dL	1.04
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]	0.47	0.79	1.94
CV [%]	2.23	1.67	1.64
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.47	0.80	2.00
CV [%]	2.46	1.62	1.94

Method comparison (n=110)	
Test x	DiaSys Ethanol FS (Hitachi 911)
Test y	DiaSys Ethanol FS (respons®910)
Slope	0.982
Intercept	–0.011 g/L
Coefficient of correlation	0.999

** according to CLSI document EP17-A, Vol. 24, No. 34

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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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	ETH
Shortcut:	
Reagent barcode reference:	033
Host reference:	033

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	380
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	09:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.1000
Concentration technical limits-Upper	3.5000
SERUM	
Normal volume [µL]	2.2
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2.2
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.2
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.2
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.2
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.2
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.2
Above normal dilution (factor)	6

Results	
Decimals	2
Units	g/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.0040
Cal. 2	0.0300
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value