respons®910

Ethanol FS*

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

Order Information

Cat. No. 1 0881 99 10 921
4 twin containers for 120 tests each

Method

Enzymatic UV test with alcohol dehydrogenase (ADH)

Principle

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

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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry if stored at 2 - 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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. In very rare cases, samples of patients with gammopathy might give falsified results.
3. Please refer to the safety data sheets 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent tray.

Specimen [1]

Serum and plasma (heparin and EDTA)
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 min. The stability in serum and plasma is 2 weeks at 20 - 25 °C, 6 months at 4 - 8 °C and 6 months at -20 °C in tightly closed stored samples.
Do not use alcohol-containing or volatile disinfectants for blood collection or during ethanol measurement in the workplace.
Discard contaminated specimens.

Calibrators and Controls

DiaSys Ethanol Standards FS are recommended for calibration. The values of Ethanol Standard FS have been determined using a NIST SRM 2893 qualified Headspace gas chromatography/flame ionization detector (GC/FID). For internal quality control DiaSys TruLab Ethanol should be assayed. 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 0890 99 10 349	10 x 1 mL
Ethanol Standard FS 1.0 mg/mL	1 0910 99 10 349	10 x 1 mL
Ethanol Standard FS 2.0 mg/mL	1 0920 99 10 349	10 x 1 mL
Ethanol Standard FS 3.0 mg/mL	1 0930 99 10 349	10 x 1 mL
Ethanol Standard FS 4.0 mg/mL	1 0940 99 10 349	10 x 1 mL
TruLab Ethanol	5 0900 99 10 349	10 x 1 mL

Performance Characteristics

Measuring range from 0.1 to 3.5 g/L ethanol (in case of higher concentrations re-measure samples after manual dilution or use rerun function)	
Limit of detection**	0.03 g/L ethanol
On-board stability	42 days
Calibration stability	3 days

Interfering substance	Interferences < 10%	Ethanol [g/L]
Ascorbate	up to 30 mg/dL	1.82
Hemoglobin	up to 200 mg/dL	0.09
	up to 1000 mg/dL	1.04
Bilirubin, conjugated	up to 40 mg/dL	0.13
	up to 60 mg/dL	1.18
Bilirubin, unconjugated	up to 20 mg/dL	0.16
	up to 65 mg/dL	1.12
Lipemia (triglycerides)	up to 1600 mg/dL	0.11
	up to 2000 mg/dL	1.04
Creatinine	up to 250 mg/dL	1.65
Glucose	up to 2000 mg/dL	1.48
Urea	up to 2000 mg/dL	1.49
LDH	up to 2000 U/L	1.53
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.47	0.79	1.94
Coefficient of variation [%]	2.23	1.67	1.64
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.47	0.80	2.00
Coefficient of variation [%]	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 NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

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

Reference Range [3]

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

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 28-9.
2. 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.
3. 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.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1168-1170.

Manufacturer

IVD CE

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respons®910

Ethanol FS

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
Name:	ETH
Shortcut:	
Reagent barcode reference:	033
Host reference:	

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	45
Blanc correction	Yes
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 [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0
Concentration technical limits-Upper	4
SERUM	
Normal volume [µL]	2.2
Normal dilution (factor)	1
Below normal volume [µL]	4.4
Below normal dilution (factor)	1
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]	4.4
Below normal dilution (factor)	1
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]	4.4
Below normal dilution (factor)	1
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]	4.4
Below normal dilution (factor)	1
Above normal volume [µL]	2.2
Above normal dilution (factor)	6

Results	
Decimals	2
Units	g/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*

	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0300
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X degree
Degree	1

* Enter calibrator value