Ethanol Assay Kit

(ETOH)

Method: Alcohol Dehydrogenase Method

SIZE
R1:3 × 20mL R2:1 × 20mL
R1：6×20mL R2：2×20mL
R1：1×30mL R2：1×10mL
R1：2×30mL R2：2×10mL
R1: 12×3.8mL R2：6×2.6mL
R1：1×57mL R2：1×19mL
R1：3×19mL R2：1×19mL
Calibrator (5 levels): 5x1mL
Control (2 levels): 2x1mL

INTENDED USE

For the in vitro quantitative determination of ethanol in human serum or plasma.

ASSAY PRINCIPLE

$$\text{Alcohol} + \text{NAD+} \xrightarrow{\text{Alcohol dehydrogenase}} \text{Aldehyde} + \text{NADH}$$

In the presence of NAD, ethanol is converted into acetaldehyde by ethanol dehydrogenase, and Concomitant with this oxidation, the cofactor NAD+ is reduced to NADH. The change in absorbance caused by NADH at 340nm is proportional to the concentration of ethanol.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Sodium pyrophosphate buffer	>50.00 mmol/L
Reagent 2 (R2)	
Good's buffer	>10.00 mmol/L
NAD+	≥2.00 mM
Alcohol dehydrogenase	≥40.00 KU/L

STABILITY AND PREPARATION OF REAGENTS

Reagents are ready to use.

Stable up to 12 months when stored at 2-8℃.

Avoid repetitively freeze-thawing.

SAMPLE COLLECTION AND PREPARATION

1. Serum or EDTA potassium salt, heparin lithium anticoagulant plasma are recommended.

2. Samples must be sealed to prevent the loss of ethanol evaporation in the sample.

3. No alcohol or volatile disinfectant can be used to collect and process samples, and contaminated samples should not be used in ethanol detection.

4. Samples are stable for a week under 4 ℃ and half a year under -20 ℃ with sealing condition.

ASSAY PROCEDURE

Test conditions:

Main Wave length	340 nm	Sample（S）	2 μL
Sub Wave length	405 nm	Reagent（R1）	180μL
Reaction Temp.	37℃	Reagent（R2）	60μL
Cuvette diameter	1cm	Assay mode	End-point

Test Procedure

Add the sample and reagents into colorimetric cup:	
Sample（S）	2 μL
Reagent（R1）	180 μL
Mix and then incubate for 5 minutes at 37℃, read absorbance A1	
Reagent（R2）	60 μL
Mix and then incubate for 5 minutes at 37℃, read absorbance A, caculate ΔA=A2-A1。	

Note: the above parameters are set on Hitachi 917 analyzer as an example. The parameter settings are slightly different on diverse analyzers, it's suggested to read and check the user manual of the analyzer first.

CALIBRATION

Gcell Ethanol calibrator is recommended to use.

QUALITY CONTROL

Use Gcell control as daily quality control, which can be purchased separately. Values should fall within a specific range. If these values fall outside the range, the following steps should be taken:

1. Check instrument settings and light source.

2. Check reaction temperature.

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,
Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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3. Check expiration date of kit and contents.

NORMAL VALUE

No ethanol can be detected in for normal people who do not drink alcohol;

When the alcohol concentration ≥3.00 g/L, coma might occur.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURACY

The relative deviation of the kit should be no more than ±10% with the international standard material SRM 2896.

LINEARITY

In the range of [0.05, 3.00] g / L, the linear correlation coefficient r ≥ 0.990, the linear absolute bias should not exceed ±0.10 g / L in [0.05,1.00] g / L , and the linear relative deviation should not exceed ±10.00% in (1.00,3.00] g / L .

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere (the relative deviation shall be no more than ±10%):

Bilirubin ≤ 50 mg/dL,

Hemoglobin ≤ 1000 mg/dL,

Ascorbic acid ≤ 100 mg/dL,

Intralipid ≤ 1000 mg/dL,

Lactate dehydrogenase ≤ 1600U/L

SENSITIVITY

When the sample concentration is 1.00 g / L, the absorbance change (ΔA) should be ≥ 0.2800.

PRECISION

According to CLSIEP5-A2 rules:Precision was determined using human samples and controls in an internal protocol. Repeatability (n = 20), intermediate precision (2 times per run, 2 runs per day, 20 days). The following results were obtained:

N=20	Mean	CV（%）
Level1	194.8	<1.5%
Level 2	501.5	<1%

N=80	Mean	CV（%）
Level1	205.88	<3.8%
Level 2	474.70	<2.6%

SAFETY PRECAUTIONS AND WARNINGS

1.For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents;

2.The reagents contains preservatives. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention;

3.Preservatives reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide;

4.All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

Zhang Xiuming and other editor-in-chief. Modern Clinical Biochemistry Laboratory, Beijing: people's military Medical Press, 2003. 1: 1089-1099.

Manufacture：Beijing Strong Biotechnology, Inc.

Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China

Tel：+86 10 61667168

EC REP :Lotus NL B.V.

Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail：peter@lotusnl.com

Tel：+31645171879(English), +31626669008（Dutch）