mti diagnostics
medizin.-techn. Investitionsprojekte GmbH

IVD CE

Alcohol Ethanol

Method: Alcohol Dehydrogenase Method

Cat.NO.	Package Size	Tybe
557-939	10x10ml	Liquid ready to use
557B-939	R1: 1x18 ml + R2: 1x6 ml	
557B-199	R1: 1x60ml + R2: 1x20ml	

INTENDED USE

For the in vitro quantitative determination of alcohol ethanol in human serum or plasma or whole blood or urines.

The determination of alcohol ethanol in clinical practice is commonly seen in the diagnosis of alcohol-related diseases and the forensic identification of alcohol-related driving [1].

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

1.The reagent is sealed and stored in dark at 2-8 □ for 12 months.

2. Do not mix different batch reagents.

3. Reagents cannot be frozen.

4. See date of manufacture and date of expiration on the label.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 340nm.

It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

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

Operate 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。	

CALIBRATION

mti Ethanol calibrator is recommended to use. The calibration product is traceable to pure ammonium chloride.

1. According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.

2 Requirements for calibration and frequency: It is recommended to calibrate the reagent blank every day and reagents every 3 days. When the following situations occur, it is recommended to re-calibrate: change the reagent batch number, the indoor quality control runs out

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of control, the biochemistry analyzer carries out major maintenance or replaces the main parts such as light source or cuvette.

QUALITY CONTROL

Choosing control matches the mti calibrator. The measured value control should be within the range of value.If the results deviate from the scope, please find out the reason by following steps:

1 Check the parameter setting and light source.

2 Check the cleanliness of the cuvette and sampling needle.

3 Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.

4 Check the reaction temperature.

5 Check the validity of the kit.

CALCULATION OF RESULT

Setting calibration curve by calibrator concentrations against the corresponding ΔA values. The concentration of AAT in the sample is obtained by ΔA value read from the calibration curve.

REFERENCE RANGE

Coma may occur when the blood ethanol concentration ≥ 3.00g /L.

Normal human plasma: < 47 μmol/L

Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of Bilirubin ≤ 50 mg/dL, Hemoglobin ≤ 1000 mg/dL, Ascorbic acid ≤ 100 mg/dL, Intralipid ≤ 1000 mg/dL, Lactate dehydrogenase ≤ 1600U/L, was less than 10%.

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 .

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:

A) Repeatability Precision

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

B) Intermediate Precision

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

2.Batch difference

The relative range (R) of three randomly choosen kits should be no more than 15%.

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.

2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.

3. Do not mix or exchange reagents with different batches in the process of detection.

4. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.

5. Please dispose test tubes and other instruments that have touched the test sample according to the relevant medical waste disposal regulations.

REFERENCES

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

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2°C 8°C	Stored at 2-8□
	Attention:See instruction for use

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REP Authorized Representative in the European Company

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