Cat. No 4-578

DIAGNOSTIC KIT FOR DETERMINATION OF ETHYL ALCOHOL CONCENTRATION

HC – ETHANOL

INTRODUCTION

Ethanol after consumption is absorbed in alimentary tract and transported with blood to whole organism. A little amount of ethanol is excreted with urine or exhaled with air, but majority is metabolized by liver to acetic aldehyde, then to acetate, finally to carbon dioxide and water. Ethanol consumption is often cause of various types of accidents, and ethanol poisoning may be cause of decease.

METHOD PRINCIPLE

Enzymatic method with alcohol dehydrogenase.

$$\text{ethanol} + \text{NAD}^+\text{analog} \xrightarrow{\text{ADH}} \text{acetic aldehyde} + \text{NADH analog}$$

The rate of absorbance changes measured at λ=340 nm or λ=380 nm is proportional to the quantity of ethyl alcohol in the sample.

REAGENTS

Package

1-Reagent	2 x 49 ml

The reagent when stored tightly capped at 2-8°C is stable up to expiry date printed on the package. The reagents are stable for 5 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

buffer (pH 7,3)	
NADanalog	1.35 mmol/l
alcohol dehydrogenase	> 203 kU/l
stabilizers, preservatives	

Warnings and notes

- Product for in vitro diagnostic use only.
- Avoid contact with skin and mucous membranes.
- Turbidity would indicate contamination or deterioration of reagent.

SPECIMEN

Serum or plasma (heparin, EDTA or citrate), free from hemolysis, urine.

Samples may be stored tightly closed in temp. 2-8°C up to 3 days. Urine samples should be stored with as little dead air space as possible.

Nevertheless it is recommended to perform the assay with freshly collected samples!

- Do not use ethanol to swab venipuncture site and to clean or sterilize glassware or other equipment used to collect the specimen or perform the assay.
- Samples should be at room temperature for testing.
- Before opening mix samples by inverting the container.

PROCEDURE

The reagent is ready to use.

This reagent may be used in automatic analyser Hitachi 911/912.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [6]

Ethanol consumption cause following symptoms:

blood ethanol concentration (mg/dl)	clinical symptoms
30 – 120	euphoria; sociability; talkativeness; diminution of attension, judgment and control; some sensory-motor impairment
90 – 250	emotional instability; loss of critical judgment; impairment of perception, memory and comprehension; increased reaction time; sensory-motor incoordination; drowsiness;
180 – 300	disorientation; mental confusion; dizziness; staggering gait; slurred speech; disturbances of vision; increased pain threshold; apathy; lethargy;
250 – 400	general inertia; markedly decreased response to stimuli; vomiting; incontinence of urine and feces; sleep or stupor;
350 – 500	complete unconsciousness; coma; depressed or abolished reflexes; impairment of circulation and respiration; possibile death.

Please refer to the local regulations concerning legal ethanol limits for drivers.

Conversion factor of the blood ethanol concentration: 100 mg/dl = 1‰.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY AMMONIA/ETHANOL CONTROLS (Cat. No 5-163).

For the calibration of automatic analysers the CORMAY ETHANOL CALIBRATORS (Cat. No 5-105) is recommended. **Calibrators** and 0.9% NaCl should be used for calibration.

The calibration curve should be prepared every 2 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Hitachi 912 and Beckman CX5. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 10 mg/dl (2,2 mmol/l).
- **Linearity:** up to 600 mg/dl (130,3 mmol/l).
- **Specificity / Interferences**
  Haemoglobin up to 0.6 g/dl, bilirubin up to 40 mg/dl, intralipid up to 1000 mg/dl do not interfere with the test.
  Acetone up to 2000 mg/dl, butanol up to 200 mg/dl, ethylene glycol up to 2000 mg/dl, methanol up to 2000 mg/dl and izopropanol up to 2000 mg/dl do not interfere with the test, do not interfere with the test, which confirms that assay is specific to ethanol.
- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	36.58	1.80	4.91
level 2	251.25	2.74	1.09

Reproducibility (day to day) n = 40	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	40.3	1.8	4.6
level 2	98.1	2.6	2.6
level 3	245.1	6.1	2.5

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 40 serum samples, gave following results:
y = 1.06 x - 2.45 mg/dl;
R = 0.9994 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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