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For use in quality control/manufacturing process only.

Ethanol Bio HT

Cedex Bio HT

REF 08 055 661 001 100 tests

Applications ETOHB (248), ETOHD (242)

Version 01
Content version: January 2017
Store at +2 to +8°C

Intended Use

This product is intended for quantitative determination of ethyl alcohol (ethanol) in aqueous solutions using the Cedex Bio HT Analyzer.

Test Principle

Ethyl alcohol (ethanol) and NAD are converted to acetaldehyde and NADH by alcohol dehydrogenase (ADH). The increase of NADH is directly proportional to the ethyl alcohol concentration and measured photometrically at 340 nm.

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

Contents

Vial	Function / Composition
ETOHB reagent cassette for 100 tests	Reagent 1: Buffer, preservatives Reagent 2: NAD ≥ 3 mmol/L; ADH ≥ 37 U/mL; stabilizers; preservatives

Storage and Stability

Store at +2 to +8°C and at +2 to +15°C for on-board use.

The kit is stable at +2 to +8°C until the expiration date printed on the label when stored unopened and kept free of contamination.

On-board stability: After first use on the analyzer, the kit is stable for up to 8 weeks on board.

Sample Handling

Due to the high volatility of ethanol, vials containing samples and controls must be kept tightly closed until just before measuring. After opening the vials, start the ethanol test on the instrument within 5 min to avoid reduced ethanol concentrations due to evaporation.

If additional tests need to be run using the same sample, then the ethanol test should be started first. Order other tests after sampling for the ethanol test has finished.

If sample results are flagged because results are higher than the measuring range, use another freshly opened sample vial for a rerun with predilution (ETOHD). Do not use the rerun function on the same open sample.

Do not use disinfectants that contain alcohol in the environment of the samples.

Additional Materials Required

- Cedex Bio HT Analyzer, Cat. No. 06 608 116 001, with general accessories and disposables
- Standard laboratory equipment
- Calibrator E Bio, Cat. No. 08 083 703 001
- Control E Level 1 Bio, Cat. No. 08 083 797 001
- Control E Level 2 Bio, Cat. No. 08 083 819 001
- Control E Level 3 Bio, Cat. No. 08 083 827 001

Test Protocol

ETOHB is the standard protocol for ethanol determination. If the ethanol concentration of samples is expected to be higher than 10.1 g/L (220 mmol/L), then protocol ETOHD should be used (same protocol with pre-set 1:20 sample predilution). Alternatively, select another predilution factor (up to a factor of 1:20) in the instrument software for testing samples with higher concentrations.

Cedex Bio HT test definition:

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	340/659 nm
Calc. first/last	44/54
Unit	mmol/L, mg/L

Pipetting parameters:

R1	50 µL
Sample	4 µL + 16 µL Diluent (H_2O)
R2	50 µL
Total volume	120 µL

Calibration:

Calibrator	Calibrator E Bio (CAL E, 07-1166-7)
Calibration mode	Linear regression
Calibration interval	56 days, and if recalibration is required due to QC results

Quality control (ETOHB):

Controls	Control E Level 1 Bio (CONE1, 07-1501-8)
	Control E Level 2 Bio (CONE2, 07-1502-6)
	Control E Level 3 Bio (CONE3, 07-1503-4)

Use the recommended control material for ETOHB. Other suitable control material can be used in addition.

Quality control (ETOHD):

For quality control of ETOHD, use custom controls with ethanol concentrations in the high range of 15 to175 g/L. The Control E Levels 1-3 cover the lower range of protocol ETOHB and are not suitable for ETOHD.

Control intervals and acceptance limits should be adapted to each laboratory's individual requirements. If values do not fall within the defined limits, corrective measures and recalibration are required.

Measuring Range

Ethanol concentration can be determined in following range:

- ETOHB: 0.5 to 10.1 g/L (11 to 220 mmol/L)
- ETHOD: 10 to 202 g/L (0.22 to 4.4 mol/L)

Conversion Factors

Conversion factors for formate concentration:

- 1 mmol/L = 46.07 mg/L
- 1 g/L = 21.71 mmol/L

Traceability

This method has been standardized against NIST-traceable standard materials.

Precision

Representative performance data on Cedex Bio HT Analyzers are shown. Results obtained in individual laboratories may differ.

Precision was determined in samples of three concentration levels. Coefficients of variation (CV) were calculated for in-run precision (n=21) and inter-run precision (on 10 days).

	Level 1	Level 2	Level 3
Mean	50 mmol/L (2.3 g/L)	100 mmol/L (4.6 g/L)	150 mmol/L (6.9 g/L)
CV in-run	0.9 %	1.1 %	0.6 %
CV inter-run	1.2 %	1.1 %	0.9 %

Changes to Previous Version

First Version

Trademarks

CEDEX is a trademark of Roche.

Regulatory Disclaimer

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Online Technical Support

Please visit our Online Technical Support site for additional information about this product: www.technical-support.roche.com

For more information about this product, as well as documentation such as Instructions for Use and Material Safety Data Sheets, please visit custombiotech.roche.com

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