

# Ammonia/Ethanol/CO<sub>2</sub> Control N



Ammonia/Ethanol/CO<sub>2</sub> Control Normal

REF 20752401 190

5 x 4 mL Control

## English

### System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 100.

For use on COBAS INTEGRA analyzers the system ID is 07 5240 1.

### Intended use

Ammonia/Ethanol/CO<sub>2</sub> Control Normal is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

### Summary

Ammonia/Ethanol/CO<sub>2</sub> Control Normal is a liquid ready-for-use control based on a buffered aqueous solution. The adjusted concentrations of the control components are usually in the normal range or at the normal/pathological threshold.

Some methods specified in the relevant value sheet may not be available in all countries.

### Reagents – working solutions

#### Reactive components:

Aqueous buffer solution containing ammonia, ethanol and sodium bicarbonate

#### Non-reactive components:

Preservative.

The concentrations of the components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for Roche/Hitachi MODULAR, COBAS INTEGRA and **cobas c** 111 analyzers.

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

### Target values and ranges

The target values were determined using the method stated in the electronically available or enclosed value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents. The target value specified is the mean of all values obtained. The corresponding control range is calculated as the target value  $\pm$  3 standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

A clinically insignificant difference may be seen between the value(s) listed on the value sheet and the value(s) obtained from the instrument readable data. This is caused by:

- the rounding of value(s) during conversion from the unit in the instrument readable data to the unit that is being used.
- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

### Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

### Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for the Roche/Hitachi MODULAR analyzers and **cobas c** systems to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

### Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:  
Recovery within  $\pm$  10 % of initial value.

#### Stability:

Unopened:	up to the stated expiration date at 2-8 °C
Open vial:	2 hours at 15-25 °C
Sample cup:	1 hour at 15-25 °C
After opening:	8 weeks at 2-8 °C, provided that dispensing of the control occurs without microbial contamination, e.g. by pouring out.

Store control tightly capped and protected from light when not in use.

### Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

### Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

### Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory's requirements.

Follow the applicable government regulations and local guidelines for quality control.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

 CONTENT

Contents of kit



Volume after reconstitution or mixing

### FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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Significant additions or changes are indicated by a change bar in the margin.

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