



BIOLABO
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Normal Control AMMONIA ALCOHOL BICARBONATE

For quality control by monitoring accuracy and precision
 for the quantitative determination of the analytes as specified in the value table

REF 95013 R1 1 x 10 mL

TECHNICAL SUPPORT AND ORDERS

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IVD IN VITRO DIAGNOSTIC USE

INTENDED USE

This liquid ready for use control is intended to monitor the reproducibility and accuracy of methods and analysis performed with BIOLABO kits for the following analysis:

BIOLABO Ammonia (enzymatic method)

REF 99261: R1 6 x 20 mL (Buffer-Coenzyme), R2 1 x 1,5 mL (Enzymes), R3 1 x 10 mL (Standard 5000 µg/L)

BIOLABO Alcohol (enzymatic method)

REF 99029: R1 10 x 10 mL (Working Reagent) R2 1 x 5 mL (Standard)

REF 99059: R1 2 x 100 mL (Working Reagent) R2 1 x 10 mL (Standard)

BIOLABO Bicarbonate (enzymatic method)

REF 99832: R1 8 x 30 mL (Working Reagent) R2 1 x 30 mL (Standard)

REF 99852: R1 6 x 100 mL (Working Reagent) R2 1 x 30 mL (Standard)

Suitable for manual procedure or automated instruments.

In case of use with another reagent, refer to corresponding instructions.

REAGENTS COMPOSITION

Vial R1 NORMAL CONTROL "AMMONIA, ETHANOL, CO2"

Aqueous solution containing ammonia, ethanol and sodium bicarbonate
 Preservatives

The exact target values and ranges of reactive components are indicated in the batch specific values table.

These concentrations are usually in the normal range or at the normal / pathological threshold.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Reagents and Standards

PREPARATION AND HANDLING

Liquid ready for use. Mix carefully before use (to prevent foam).

Do not transfer directly from the vial. Dispense the required volume in the sample cup. Recap promptly the vial and store at 2-8°C. Analyze in the same way as patients samples

Reject any cloudy or contaminated control. Eliminate any control stored in an open vial during more than 1 hour.

STABILITY AND STORAGE

Store at 2-8°C, well recapped in the original vial and away from light.

- Unopened, aqueous control is stable until expiry date stated on the label.
- Once opened, Control is stable for:
 - ✓ 1 hour at 15-25°C in sample cup or open vial
 - ✓ 2 months at 2-8°C, provided that dispensing of the control takes place without contamination (see § Preparation and Handling)
 - ✓ **No not freeze**

Do not use after expiry date stated on the label

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagent contains sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

TARGET VALUES AND RANGES ⁽¹⁾

| BATCH | (IS) Units | Conventional units |
|---------------------------------------|-------------------------------|-----------------------------|
| Ammonia (enzymatic method) | 77.0 µmol/L (53.5 – 100.5) | 131 µg/dL (91.1 – 171) |
| Alcohol (enzymatic method) | 10,9 mmol/L (8,68 – 13,02) | 50 mg/dL (40 – 60) |
| Bicarbonate (enzymatic method) | 18,1 mmol/L (14,5 – 21,7) | 18,1 mEq/L (14,5 – 21,7) |

Target values and range are obtained by using:

- BIOLABO reagents and calibrators traceable to NERL standards
- Recommended and validated statistical techniques.
- Metrologically controlled instrument.

Target values are the mean of values obtained during several determinations of each analyte and range are ±2 or 3 standard deviations. It is recommended that each laboratory validate each new batch-specific values before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically retested.

REFERENCES

(1) SMQ BIOLABO: SOP réf. 81 INS 01 « évaluation et titrage des sérums de contrôles et calibrateurs »

