BIOLABO
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MANUFACTURER:
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Les Hautes Rives
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Urinary Control Level 1 and Level 2

For quality control by monitoring accuracy and precision
for the quantitative determination of the analytes found in human urines

REF 95012	**R1** 1 x 10 mL	**R3** 1 x 10 mL
	R2 1 x 10 mL	**R4** 1 x 10 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC USE

INTENTED USE

These liquid ready for use controls are intended to monitor the reproducibility and accuracy of methods and analysis indicated in the table of values (batch specific).
Suitable for manual procedure or automated instruments.
In case of use with another reagent, refer to corresponding instructions.

REAGENTS COMPOSITION

Vial R1	**URINARY CONTROL LEVEL 1 :**	CONTROL 1 SET1
Vial R2	**URINARY CONTROL LEVEL 1 :**	CONTROL 1 SET2
Vial R3	**URINARY CONTROL LEVEL 2 :**	CONTROL 2 SET1
Vial R4	**URINARY CONTROL LEVEL 2 :**	CONTROL 2 SET2

SET 1 : Uric acid, Chlorides, Magnesium, Phosphorous, Glucose, Urinary Proteins, Urea.
SET 2 : Creatinine
The exact target values and ranges of reactive components are indicated in the batch specific values table.
Two levels of control are available to allow performance monitoring within the clinical range.

MATERIAL REQUIRED BUT NOT PROVIDED

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

PREPARATION AND HANDLING

Liquid ready for use.
This product should be treated the same as patients urines in accordance with the instructions enclosed with instrument, kit , or reagent being used.

- Before to use, allow to reach room temperature and swirl gently to ensure homogeneity
- 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.

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
  - ✓30 days at 2-8°C, provided that dispensing of the control takes place without contamination (see § Preparation and Handling)
  - ✓**Do not freeze**
- Do not use beyond 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.

LIMITATIONS

- Reject any cloudy or contaminated control. Eliminate any control stored in an open vial during more than 1hour.
- Do not use as a standard
- Creatinine values may gradually decrease over the product shelf life. Individual laboratory means may eventually fall outside of the confidence range indicated in the insert

TARGET VALUES AND RANGES (1)(2)

Target values and range are obtained by using:

- BIOLABO reagents and calibrators traceable to NIST SRM® (see specific batch table values)
- 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 usually ±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 « évaluation et titrage des sérums de contrôles et calibrateurs »*
(2) *National Institute of Standards and Technology: Standard Reference Material*
(3) *SRM: Standard Reference Material ®*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with