**BIOLABO**
**www.biolabo.fr**
**MANUFACTURER:**
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# MULTICALIBRATOR

## Multiparametric calibrator

For clinical biochemistry analysis

| | | |
|---|---|---|
| REF 95015 | **R1** 10 x 5 mL | **R2** 1 x 60 mL |
| REF 95115 | **R1** 5 x 5 mL | **R2** 1 x 30 mL |

**TECHNICAL SUPPORT AND ORDERS**
**Tel: (33) 03 23 25 15 50**
**support@biolabo.fr**
**Latest revision : www.biolabo.fr**

CE

IVD

Made in France

I: corresponds to significant modifications

## I INTENTED USE

Calibrator multicomponent (CC). Designated for professional use in laboratory with manual or automated procedure using reagents listed in the batch specific table of values.

## I GENERALITIES

MULTICALIBRATOR is suitable for clinical chemistry analysis as follows:

| | |
|---|---|
| Enzymes: | ALT (GPT), AST (GOT), Amylase, CK NAC, Gamma-GT, Alkaline Phosphatase (ALP), LDH. |
| Electrolytes: | Calcium, Chloride, Iron, Magnesium, Inorganic Phosphorus, Sodium, Kalium |
| Proteins: | Total protein, Albumin |
| Lipids: | Total Cholesterol, Triglycerides |
| Substrates: | Bilirubin, Creatinine, Glucose, Urea, Uric acid. |

Added enzymes are from animal origin.

## QUALITY CONTROL

- REF 95010, REF 95110 EXATROL-N Level I
- REF 95011, REF 95111 EXATROL-P Level II
- External quality control program
- Control with frequency stated in technical sheet of the reagent in use.

## I REAGENTS

**R1** **Multicalibrator** Multiparametric Calibrator

Freeze dried bovine serum

**R2** **Multicalibrator** Diluent

Demineralized water, preservative

According to 1272/2008 regulation, these reagents are not classified as dangerous

## CALIBRATION VALUES (3)

Refer to the Batch-Specific Table of values.

- Values were determined against International Standards (SRM® : Standard Reference Material®).
- Each value is the median of values obtained for each analyte on several analysers.
- Values in brackets indicate the composed uncertainty taking into account all the sources of error which may influence the result.

## I PERFORMANCES

- BIOLABO reagents and calibrators are traceable to a reference method or material, using statistical techniques and metrologically controlled instrument (see batch specific table of values).
- Each value is calculated as the mean of values obtained for each analyte on several analysers.
- Values may vary from one lot to another, but are clearly indicated for each batch.

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment
2. Spectrophotometer or Biochemistry Clinical Analyzer

## I SAFETY CAUTIONS (1) (2)

- Refer to current Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- Waste disposal: Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

## I REAGENTS PREPARATION

- Open the vial R1carefully and add exactly 5 mL of diluent (vial R2). Wait for 15 minutes at room temperature. Gently agitate before use (avoid the formation of foam).
- For CK, diluent with a temperature below 10°C should be used.
- For ALP, once reconstitute, let stand 1 hour at room temperature.
- CK and bilirubin are light-sensitive.

WARNING: Do not shake. Store away from light.

## STABILITY AND STORAGE

**Stored away from light, well caped in the original vial at 2-8°C, control is stable when stored and used as described in the insert:**

Unopened: Until expiry date stated on the label of the kit.

Once opened:

- R1 must be reconstituted immediately,
- R2 is stable until expiry date stated on the label.

Once reconstituted, values are usually stable for:

✓8 hours at 15-25°C or 7 days at 2-8°C.
✓30 days at –20°C. Aliquot and freeze once only.

Discard any reconstituted calibrator if cloudy.

Alkaline phosphatase: increase 1 to 2 % / 24 hours at 2-8°C.
Increase of 1 % / hour at 15-25°C.

LDH, CK, Bilirubin, Acid phosphatase:
Decrease 1 to 2 % / week at-20°C.

Acid phosphatase, LDH: decrease 1 to 2 % / 24 hours at 2-8°C.
Acid Phosphatase: decrease 1 % / hour at 15-25°C.
Phosphorus, Triglycerides: increase 1 to 2 % / 24 hours at 2-8°C.

## PROCEDURE

Run in accordance with the IFU of the reagent used.

## LIMITES

Factors which may influence results are bacterial contamination, precision of the volume dispensed during reconstitution, respect of automated instrument procedure, temperature control...

## REFERENCES

*(1) Occupational Safety and Health Standards ; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280*
*(2) Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990, p.1-12*
*(3) A. VASSAULT et Al., Ann. Biol. clin., 1986, 44, 686-745*
*(4) BIOLABO Standard Operating Procedures*

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|---|---|---|---|---|---|
| Manufacturer | Expiry date | In vitro diagnostic | Storage temperature | Dematerialized water | Biological risk |
| Product Reference | See Insert | Batch number | Store away from light | Sufficient for | Dilute with |