



BIOLABO
 www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
 Les Hautes Rives
 02160, Maizy, France

BIOLABO MULTICALIBRATOR

Multiparametric calibrator

For clinical biochemistry analysis

REF 95015 R1 10 x 5 mL R2 1 x 60 mL

TECHNICAL SUPPORT AND ORDERS

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IVD IN VITRO DIAGNOSTIC

PRINCIPLE AND INTENDED USE

BIOLABO MULTICALIBRATOR is a calibrator for clinical chemistry analysis (substrates, electrolytes, lipids, enzymes and proteins) suitable for manual procedure or automated instruments.

REAGENTS

flacon R1 Lyophilised bovine serum

flacon R2 Diluent

MULTICALIBRATOR analytes are as follows:

Enzymes: ALT (GPT), AST (GOT), Amylase, Gamma-GT, Alkaline Phosphatase, 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.

The concentrations/activities of each analyte are batch-specific.

SAFETY CAUTIONS (1) (2)

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

- This serum and all specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.
- Verify the integrity of the contents before use.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In the event of exposure the directive of the responsible health authorities should be followed.
- Material Safety Data Sheet is available upon request.

Waste disposal: Respect legislation in force in the country.

REAGENTS PREPARATION

- Carefully open one bottle of vial R1 avoiding the loss of lyophilisate.
- Pipette into vial R1 exactly 5 mL of diluent (vial R2).
- Carefully close the bottle.
- Let stand at room temperature and away from light for 15-30 minutes.
- Dissolve the contents by occasional gentle swirling (avoiding the formation of foam).
- Lyophilisate should be completely dissolved before use.

WARNING: Do not shake. Store away from light.

Notes:

- For CK determination, diluent with a temperature below 10°C should be used.
- For ALP determination, allow the reconstituted serum to stand for one hour at room temperature.
- CK and bilirubin are light-sensitive.

MATERIAL REQUIRED BUT NOT PROVIDED

- Basic medical analysis laboratory equipment.
- Reagents Kits and control sera.

INTERFERENCES

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

STABILITY AND STORAGE

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

• Unopened, lyophilised serum (vial R1) and diluent (vial R2) are stable until expiry date stated on the label stated on the label of the kit, when stored and used as described in the insert.

• **Reconstituted serum:** Transfer the requested quantity; tightly cap the vial and store at 2-8°C. Under these conditions, analytes are usually stable for:

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

Shorter stabilities in reconstituted serum applies to:

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.

Discard reconstituted serum if cloudy or if absorbance of diluted serum (1+19) in saline solution measured at 600 nm > 0.060.

Don't use reconstituted serum after expiry date stated on the label of the vial. Discard serum if cloudy or if the absorbance of diluted serum (1+19) in saline measured at 600 nm is > 0.060.

PROCEDURE

This multicalibrator should be used with reagents or kits referring to the same method in accordance with technical data sheet of the reagent in use. BIOLABO MULTICALIBRATOR has to be handled as patient serum.

QUALITY CONTROL

BIOLABO EXATROL-N Level I REF 95010,
 BIOLABO EXATROL-P Level II REF 95011,
 or other assayed control sera referring to the same method.

It is recommended to:

- ✓ Participate to external quality control program.
- ✓ Control with frequency stated in technical sheet of the reagent in use.
- ✓ Validate Calibration values when using other reagents that BIOLABO reagents.

CALIBRATION VALUES AND UNCERTAINTY (3)

Refer to indicated values. Calibration values were determinate in several independent laboratories or in our laboratory using:

- BIOLABO procedure and calibrator referring to international standards (SRM®: Standard Reference Material®).
- Recommended and validated statistical techniques.
- Metrologically controlled instrument.

Assigned value is the median of values obtained for each analyte.

Values in brackets indicate the composed uncertainty taking into account all the sources of error which may influence the result.

REFERENCES

- Occupational Safety and Health Standards; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998); 6, p.267-280
- Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990, p.1-12
- Data on file at BIOLABO Diagnostics

