BIOLABO
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BIOLABO EXATROL-P Level 2

Quality control serum for clinical biochemistry analysis

REF 95011 **R1** 10 x 5 mL **R2** 1 x 60 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC USE

PRINCIPLE AND INTENTED USE

BIOLABO EXATROL-P is a quality control serum for clinical chemistry analysis (substrates, electrolytes, lipids, enzymes and proteins), suitable for manual procedure or automated instruments. BIOLABO EXATROL-P is for use to monitor accuracy and precision of indicated methods and analytes.

REAGENTS

vial R1	**Lyophilised bovine serum**
vial R2	**Diluent**

BIOLABO EXATROL-P analytes are as follows:

Enzymes:	ALT (GPT), AST (GOT), Amylase, Gamma-GT, Alkaline phosphatases (ALP), total (PAT) and prostatic (PAP) acid phosphatases, Lactate dehydrogenase (LDH), Creatine Kinase (CK), Lipase pancreatic
Electrolytes:	Calcium, Chlorides, Iron, TIBC, UIBC, Magnesium, Inorganic phosphorus.
Proteins:	Total protein, Albumin
Lipids:	Total Cholesterol, Triglycerides
Substrates:	Total and direct Bilirubin, Creatinine, Glucose, Urea, Uric acid.

Added enzymes are from animal origin.
The concentrations/activities of each analyte are batch-specific and usually in the pathological range.

SAFETY CAUTIONS (1) (2)

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

- Verify the integrity of the contents before 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.
- 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

1-Carefully open one bottle of vial R1 avoiding the loss of lyophilisate.
2-Pipette into vial R1 exactly 5 mL of diluent (vial R2).
3-Carefully close the bottle.
4-Let stand at room temperature and away from light for 15-30 minutes.
5-Dissolve the contents by occasional gentle swirling (avoiding the formation of foam).
6-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

1. Basic medical analysis laboratory equipment.
2. Reagents and standards/multicalibrator.

STABILITY AND STORAGE

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

- Unopened: Lyophilised sera (vial R1) and diluent (vial R2) are stable until expiry date stated on the label.
- Vial R2: stored and used as described in the insert, well recapped in the original vial and without contamination, contents of vial R2 is stable until expiry date stated on the label of the vial.
- Reconstituted serum: Transfer the requested quantity, recap and store at 2-8°C. Under these conditions, indicated 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 apply to:
  1-Bilirubin, CK, LDH: 1-2% decrease per 7 days at –20°C.
  2-LDH: 3% decrease per 24 h 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.

INTERFERENCES

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

PROCEDURE

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

CALIBRATION

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

It is recommended to:

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

ASSIGNATED VALUES AND RANGES (3) (4)

Refer to indicated values. Target and ranges are obtained by using:

- BIOLABO reagents and calibrators traceable to a reference method or material.
- Recommended and validated statistical techniques.
- Metrologically controlled instrument.

Target values are the mean of values obtained during several determinations of each analyte and range values 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 values have to be periodically retested.

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) Data on file at BIOLABO Diagnostics

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