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

EXATROL-N Level 1

Quality control serum for clinical biochemistry analysis

REF 95010	**R1** 10 x 5 mL	**R2** 1 x 60 mL
REF 95110	**R1** 5 x 5 mL	**R2** 1 x 30 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made in France

Latest revision : www.biolabo.fr

I: corresponds to significant modifications

I INTENTED USE

REF 95010, REF 95110 : EXATROL-N Level 1
Assayed multicomponent sera designated for professional use in laboratory (manual or automated procedure) using reagents listed in the batch specific table of values.

I GENERALITIES

Quality control serum to monitor accuracy and precision of indicated methods for clinical chemistry:

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, Sodium, Kalium.
Proteins:	Total protein, Albumin
Lipids:	Total Cholesterol, Triglycerides
Substrates:	Total and direct Bilirubin (BT, BD), Creatinine, Glucose, Urea, Uric acid.

Added enzymes are from animal origin.

QUALITY CONTROL

Verify the integrity of the vial and batch-specific value before use

I REAGENTS

R1 **EXATROL-N** Level 1
Lyophilised serum — Human Origin

R2 **EXATROL-N** Diluent
Demineralized water, preservative

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

VALUES AND RANGE (3) (4 (5)

Refer to the Batch-Specific Table of values.

- It is recommended to validate each new batch-specific values before use.
- For an optimal use, laboratories should establish their own values and range.

PERFORMANCES (3) (4 (5)

- BIOLABO reagents and controls are traceable to a reference method or material, using statistical techniques and metrologically controlled instrument (see batch specific table of values).
- Each value and range 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

SAFETY CAUTIONS (1) (2)

- Refer to current Safety Data Sheet available on request or on www.biolabo.fr
- Each human donation was tested with approved tests and found negative for HBsAg, anti-HCV and anti-HIV I and II.
- 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 R1 carefully and add slowly exactly 5 mL of diluent (R2) at room temperature.
  Wait for 5 to 10 minutes at room temperature. Gently agitate before use (avoid the formation of foam).

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.

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 (4 hours BD, ALP, ACP)
- ✓5 days at 2-8°C (24h BT, BD, ACP, ALT)
- ✓30 days at –20°C (2 weeks BT, BD, ACP, ALP)

Aliquot and freeze once only. Discard any serum if cloudy.
ALP: activity may increase with time

PROCEDURE

Run in accordance with the IFU of the reagent used.

LIMITS

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

I REFERENCES

(1) *Council Directive (2000/54EC). Official Journal of the European Communities No. L262 from Oct. 17th, 2000.*
(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) *Documentation Qualité BIOLABO*
(5) *International Federation of Clinical Chemistry (IFCC) Education Division, Expert Panel of Quantities and Units: A Protocol for the Conversion of Clinical Laboratory data, Journal of Automatic Chemistry Vol. 11, No 5 (Sept – Oct 1989), pp. 223-226*

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