

REF 10794 12 X 5 ML BOTTLES, LEVEL B

CHEMISTRY/ELECTROLYTES QC MATERIAL LEVEL B

Vials each containing 5.0 mL of lyophilized, human serum base, multiconstituent QC powder.

INTENDED USE

For use as quality control material in clinical chemistry assays on the Medica EasyRA[®] Chemistry Analyzer.

SAFETY PRECAUTIONS AND WARNINGS

The human source material from which this product has been derived and tested at the single donor unit basis and found non-reactive for HBsAg, anti-HIV 1 / 2, anti-HCV and HIV-1 Ag. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled and disposed of as though they are capable of transmitting infectious diseases.

INSTRUCTIONS FOR HANDLING, STORAGE AND STABILITY

The dry QC material is stable until the expiration date on the label if stored at 2° - 8°C. After reconstitution, store the QC material closed at 2° - 8° C. The components of the QC material are stable for:

- Direct and Total Bilirubin: 3 days stored in the dark at 2° - 8°C.
- Other Analytes: 5 days stored at 2° - 8°C.

Note: ALP levels will rise over the stability period.

INSTRUCTIONS FOR USE

1. Before reconstitution, allow the vial to warm to ambient temperature.
2. Carefully reconstitute each vial of lyophilized serum with exactly 5.0 mL of ambient temperature reagent-grade water using a volumetric pipet.
3. Replace the stopper and allow the control to stand for 20 minutes, swirling occasionally.
4. Before sampling, gently swirl the vial several times to ensure homogeneity. DO NOT VORTEX.

QC RANGES

The Table below contains the acceptable QC ranges for each analyte: Level B, Lot No. 18276, Expires: 2021-06-30

Analyte	Units	Level B
ALB	g/dL	4.2 (3.7 – 4.7)
ALP	U/L	276 (236 – 316)
ALT	U/L	106.6 (91.6 – 121.6)
AMY	U/L	206 (186 – 226)
AST	U/L	168.0 (153.0 – 183.0)
DBIL	mg/dL	2.36 (1.66 – 3.06)
TBIL	mg/dL	7.05 (6.25 – 7.85)
CA	mg/dL	12.26 (11.26 – 13.26)
CO ₂	mmol/L	16.2 (11.2 – 21.2)
CHOL	mg/dL	209 (189 – 229)
CK	U/L	273 (223 – 323)
CREA	mg/dL	5.56 (5.06 – 6.06)
FE	µg/dL	188 (158 – 218)
GGT	U/L	86 (77 – 95)
GLUH	mg/dL	218 (203 – 233)
GLUT	mg/dL	216 (201 – 231)
HDL	mg/dL	65 (55 – 75)
LDH	U/L	320 (270 – 370)
LDL	mg/dL	110 (100 – 120)
LIP	U/L	223.3 (183.3 – 263.3)
MG	mg/dL	5.94 (5.44 – 6.44)
PHOS	mg/dL	6.84 (6.34 – 7.34)
TIBC	µg/dL	393 (363 – 423)
TP	g/dL	6.4 (5.4 – 7.4)
TRIG	mg/dL	253 (238 – 268)
BUN	mg/dL	46.3 (40.3 – 52.3)
URIC	mg/dL	9.25 (8.25 – 10.25)

Na+	mmol/L	142.8 (137.8 – 147.8)
K+	mmol/L	6.98 (6.68 – 7.28)
Cl-	mmol/L	91.3 (86.3 – 96.3)
Li+	mmol/L	2.09 (1.79 – 2.39)