MEDICA EASYCAL

IVD CE

REF 10651 12 X 5 mL BOTTLES

CHEMISTRY CALIBRATOR
Vials each containing 5.0 mL of lyophilized serum, multiconstituent calibrator powder

INTENDED USE
For use as a calibrator 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 ½, anti-HCV and HIV-1Ag. 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 calibrator is stable until the expiration date on the label if stored at 2º - 8ºC. After reconstitution, store the calibrator closed at 2º - 8º C. The components of the calibrator are stable for:

- Direct and Total Bilirubin and Iron: 1 day stored in the dark at 2º - 8º C.
- Other Analytes: 5 days stored at 2º - 8º C.

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 calibrator to stand for 20 minutes, swirling occasionally.
4. Before sampling, gently swirl the vial several times to ensure homogeneity. DO NOT VORTEX.

The recommended calibrator sample volumes are as follows:

1. If calibrating a single analyte use 0.2 mL of calibrator in a 2mL sample cup.
2. If calibrating 1-5 analytes use 0.5 mL of calibrator in a 2mL sample cup.
3. If calibrating 5-14 analytes use 1.0 mL of calibrator in a 2mL sample cup.

VALUE ASSIGNMENT
The Table below contains the assigned values for each analyte:

Lot No. 21305 Expires: 2025-09-30

Analyte:	Assigned Value	Units
ALB	4.1	g/dL
DBIL	3.40	mg/dL
TBIL	4.67	mg/dL
Ca	9.86	mg/dL
CHOL	210	mg/dL
CREA	3.52	mg/dL
GLU H	197	mg/dL
GLU T	197	mg/dL
FE	185	µg/dL
LIP	104.9	µ/L
MG	3.20	mg/dL
PHOS	5.00	mg/dL
TP	6.2	g/dL
TRIG	121	mg/dL
BUN	36.4	mg/dL
URIC	5.20	mg/dL

Medica Corporation, 5 Oak Park Drive
Bedford, MA 01730-1413 USA

EC REP Emergo Europe, Prinsessegracht 20
2514 AP The Hague, The Netherlands