



AN ITALIAN COMPANY THAT RESEARCHES, DEVELOPS AND PRODUCES READY TO USE KITS  
USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

## CALIBRATOR LIOPHYL. IN URINE FOR EDDP

**Code CC48116**  
**TO USE WITH THE KITS CODE GC48010, LC74010**

### PURPOSE

These urinary calibrators are used to calibrate the HPLC system for the quantitative measurement of analytes contained therein. Each analyte has a concentration that allows the construction of a curve on a point. The calibrators are freeze-dried human matrix and should be handled as if they were a real patient sample.

### RECONSTITUTION


Remove the metal seal and rubber stopper from the vial. Add exactly 5 ml of HPLC grade H<sub>2</sub>O in the vial. Replace the rubber stopper, shake and let stand for 5 to 10 minutes. Before use, mix by inverting the vial to dissolve the material until a homogeneous clear solution.

### STORAGE AND STABILITY

The calibrators are stable for 36 months from the date of preparation if stored at 2-8 ° C. After reconstitution are stable 2 days at 2-8 ° C and 2 months at -20 ° C. Do not use after the expiry date.

### PRECAUTIONS

These calibrators in human matrix should be treated with care and treated as potentially infectious.

LOT		

### PACKAGING AVAILABLE:



- CC48116 CALIBRATOR IN URINE FOR EDDP

*5 x 2 x 5 ml*

N° 004	06/2024
--------	---------

CONCENTRATIONS

CODE CC48116

LOT		

ANALYTE	UNITS OF MEASUREMENT	C1	OBTAINED MEDIUM VALUE C1 ± DS*	C2	OBTAINED MEDIUM VALUE C2 ± DS*	C3	OBTAINED MEDIUM VALUE C3 ± DS*	C4	OBTAINED MEDIUM VALUE C4 ± DS*	C5	OBTAINED MEDIUM VALUE C5 ± DS*
EDDP	ng/ml										

\* The procedures for production and validation / quality control of every batch shall be performed using the chromatographic method LC / MS / MS validated according to international guidelines of the Food and Drug Administration (FDA-May 2001) and the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH-Q2-R1-Nov 2005). The mean value and standard deviation were obtained during the validation phase of batch processing for level four bottles in duplicate. **This product fulfils all the requirements of Directive 98/79/EC of 27/10/1998 on *in vitro* diagnostic medical devices (IVD). The declaration of conformity is available upon request.**

CE

FOR IN VITRO DIAGNOSTIC USE ONLY



EUREKA S.R.L. LAB DIVISION  
 Via M. D'Antona 28  
 60033 Chiaravalle (AN) - Italy  
 Tel +39 071 7450790  
 eureka-support@sentinel.it  
 www.eurekakit.com