



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

CALIBRATOR LIOPHYL. IN URINE FOR DRUGS OF ABUSE (Cocaine)

Code CC46116
TO USE WITH THE KITS CODE GC46010, 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 H₂O 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:

- CC46116 CALIBRATOR IN URINE FOR DRUGS OF ABUSE -Cocaine- 5 x 2 x 5 ml

CONCENTRATIONS
CODE CC46116

LOT		

ANALYTE	UNITS OF MEASUREMENT	C1	MEDIUM VALUE OBTAINED $C1 \pm DS^*$	C2	MEDIUM VALUE OBTAINED $C2 \pm DS^*$	C3	MEDIUM VALUE OBTAINED $C3 \pm DS^*$	C4	MEDIUM VALUE OBTAINED $C4 \pm DS^*$	C5	MEDIUM VALUE OBTAINED $C5 \pm DS^*$
COCAINE	ng/ml	0	0	50,0	40,6 ± 2,7	100,0	91,2 ± 0,62	200,0	183,6 ± 12,7	500,0	453,6 ± 58,9

* 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.



FOR IN VITRO DIAGNOSTIC USE ONLY



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