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

(Norbuprenorphine, Buprenorphine)

Code CC44016

TO USE WITH THE KITS CODE GC44010, 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_2O 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.

		

PACKAGING AVAILABLE:

- CC44016 CALIBRATOR IN URINE FOR DRUGS OF ABUSE ***2 x 5 x 6 ml***

CONCENTRATIONS **CODE CC44016**

LOT		

ANALYTE	*MEASUREMENT UNIT*	*C1*	*C2*	*C3*	*C4*	*C5*
NORBUPRENORPHINE	**ng/ml**					
BUPRENORPHINE	**ng/ml**					

* The procedures for production and validation / quality control of the individual lot 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 techincal requirements for registration of pharmaceuticals for human use (ICH-Q2-R1-Nov 2005). The mean value and standard deviation were obtained in 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.

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FOR *IN VITRO* DIAGNOSTIC USE ONLY

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