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

CALIBRATOR LYOPHIL. IN URINE FOR DRUGS OF ABUSE

(Beg, Cocaethylene)

Code CC46016

TO USE WITH THE KITS CODE GC46010, LC74010

OBJECTIVE

The calibrators in urine 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 calibration curve of five points. The calibrators are freeze-dried human matrix and should be handled as if they were a real patient sample.

RECOVERY

Remove the metal seal and rubber stopper from the vial. Add exactly 5 ml of HPLC-grade water through the tube. Replace the rubber stopper, allow to stand for at least 5 to 10 minutes. Before use, mix by inverting the vial to dissolve the material until a homogeneous 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 for 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:

- CC46016 CALIBRATOR IN URINE FOR o -Beg and Cocaethylene- ***5 x 2 x 5 ml***

N° 006	**06/2024**

CONCENTRATIONS
CODE CC46016

ANALYTE	*MEASUREMENT UNIT*	*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**
BEG	**ng/ml**										
COCAETHYLENE	**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.**

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FOR *IN VITRO* DIAGNOSTIC USE ONLY

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