



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

CONTROL LYOPHIL. IN WHOLE BLOOD FOR DRUGS OF ABUSE - LEVELS 1, 2 and 3
(3,4-MDMA, 3,4-MDA, 3,4-MDE, Amphetamine, Methamphetamine, Ketamine, Morphine, Codeine, 6-Monoacetylmorphine, Beg, Cocaethylene, Methadone, Cocaine, EDDP, Norbuprenorphine, Buprenorphine, MBDB, Ecgonine Methyl Ester, Fentanyl, Delta-9-THC, Delta-9-THC-COOH, 11-OH-THC)

Code LC89019

OBJECTIVE

These controls in whole blood are used for internal quality control and serve to keep under control the accuracy and precision of the analytical procedures dedicated to the quantitative determination of the analytes contained therein. These controls are lyophilized in human matrix and are available in three different concentration range.

RECOVERY

Remove the metal seal and rubber stopper from the vial. Add exactly 1 ml of HPLC-grade water through the tube. Replace the rubber stopper, allow to stand for at least 30 to 40 minutes. Before use, mix by inverting the vial to dissolve the material until a homogeneous solution.

STORAGE AND STABILITY

The controls are stable for 36 months from the date of preparation if stored at -20 ° C. After reconstitution are stable for 1 week at 2-8 °C **except for Cocaine and Cocaethylene that must be reconstituted and analysed in the same day**. Do not use after the expiry date.

PRECAUTIONS

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



LOT		

PACKAGING AVAILABLE:

- LC89019 CONTROL IN WHOLE BLOOD FOR DRUGS OF ABUSE - LEVELS 1, 2 and 3 3 x 5 x 1 ml



N° 005	06/2024
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CONCENTRATIONS
CODE LC89019

LOT		

<i>ANALYTE</i>	<i>MEASUREMENT UNIT</i>	<i>L1</i>	<i>RANGE L1</i>	<i>L2</i>	<i>RANGE L2</i>	<i>L3</i>	<i>RANGE L3</i>
MORPHINE	ng/ml						
CODEINE	ng/ml						
6-MAM	ng/ml						
METHADONE	ng/ml						
EDDP	ng/ml						
ECGONINE METHYL ESTER	ng/ml						
COCAINE	ng/ml						
COCAETHYLENE	ng/ml						
BEG	ng/ml						
AMPHETAMINE	ng/ml						
METHAMPHETAMINE	ng/ml						
KETAMINE	ng/ml						

**CONCENTRATIONS
CODE LC89019**

LOT		

<i>ANALYTE</i>	<i>MEASUREMENT UNIT</i>	<i>L1</i>	<i>RANGE L1</i>	<i>L2</i>	<i>RANGE L2</i>	<i>L3</i>	<i>RANGE L3</i>
3,4 – MDMA	ng/ml						
3,4 – MDA	ng/ml						
3,4 – MDE	ng/ml						
MBDB	ng/ml						
BUPRENORPHINE	ng/ml						
NORBUPRENORPHINE	ng/ml						
FENTANYL	ng/ml						
DELTA-9-THC-COOH	ng/ml						
DELTA-9-THC	ng/ml						
11-OH-THC	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 technical 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 fulfills 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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