



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

CONTROL LYOPHIL. MULTIPARAMETRIC IN URINE FOR DRUGS OF ABUSE – LEVELS 1 and 2

(6-MAM, Amphetamine, Beg, Buprenorphine, Cocaine, Codeine, delta-9-THC-COOH, Dihydrocodeine, EDDP, Ephedrine, Ketamine, MBDB, MDA, MDE, MDMA, Methamphetamine, Methadone, Morphine, Norbuprenorphine, Norpseudoephedrine, Pseudoephedrine)

Code LC74019

OBJECTIVE

These controls in urine 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 two different concentration range.

RECONSTITUTION

Remove the metal seal and rubber stopper from the vial. Add exactly 1 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 controls are stable for 12 months from the date of preparation if stored at -25/-15 °C. After reconstitution are stable 3 months at -25/-15 °C. Do not use after the expiry date.

PRECAUTIONS

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

LOT		

AVAILABLE PACKAGING:

- LC74019 CONTROL IN URINE FOR DRUGS OF ABUSE - LEVELS 1 and 2

2 x 5 x 1 ml

N° 005

06/2024

CONCENTRATIONS
CODE LC74019

LOT		

<i>ANALYTE</i>	<i>MEASUREMENT UNIT</i>	<i>L1</i>	<i>RANGE L1</i>	<i>L2</i>	<i>RANGE L2</i>
6-MAM	ng/ml				
AMPHETAMINE	ng/ml				
BEG	ng/ml				
BUPRENORPHINE	ng/ml				
COCAINE	ng/ml				
CODEINE	ng/ml				
DELTA-9-THC-COOH	ng/ml				
DIHYDROCODEINE	ng/ml				
EDDP	ng/ml				
EPHEDRINE	ng/ml				
KETAMINE	ng/ml				

CONCENTRATIONS
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<i>ANALYTE</i>	<i>MEASUREMENT UNIT</i>	<i>L1</i>	<i>RANGE L1</i>	<i>L2</i>	<i>RANGE L2</i>
MBDB	ng/ml				
MDA	ng/ml				
MDE	ng/ml				
MDMA	ng/ml				
METHADONE	ng/ml				
METHAMPHETAMINE	ng/ml				
MORPHINE	ng/ml				
NORBUPRENORPHINE	ng/ml				
NORPSEUDOEPHEDRINE	ng/ml				
PSEUDOEPHEDRINE	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 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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