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

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

(3,4-MDMA, 3,4-MDA, 3,4-MDE, Amphetamine, Methamphetamine, Ketamine, MBDB, Ephedrine, Pseudoephedrine, Norpseudoephedrine, Beg, Cocaethylene, Methadone)

Code CC43019

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 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 controls are stable for 36 months from the date of preparation if stored at 2-8 ° C. After reconstitution are stable 7 days at 2-8 ° C and 1 month at -20 ° 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		
019	March 2024	March 2027

PACKAGING AVAILABLE:

- CC43019 CONTROL IN URINE FOR DRUGS OF ABUSE - LEVELS 1 and 2 ***2 x 6 x 5 ml***

Release N° 005	**July 2019**

CONCENTRATIONS
CODE CC43019

LOT		
019	March 2024	March 2027

ANALYTE	*MEASUREMENT UNIT*	*L1*	*RANGE L1*	*L2*	*RANGE L2*
3,4 – MDMA	**ng/ml**	**120,0**	**96,0 – 144,0**	**660,0**	**561,0 – 759,0**
3,4 – MDA	**ng/ml**	**130,0**	**104,0 – 156,0**	**580,0**	**493,0 – 667,0**
3,4 – MDE	**ng/ml**	**120,0**	**96,0 – 144,0**	**500,0**	**425,0 – 575,0**
AMPHETAMINE	**ng/ml**	**140,0**	**112,0 – 168,0**	**600,0**	**510,0 – 690,0**
METHAMPHETAMINE	**ng/ml**	**140,0**	**112,0 – 168,0**	**500,0**	**425,0 – 575,0**
BEG	**ng/ml**	**40,0**	**32,0 – 48,0**	**240,0**	**204,0 – 276,0**
COCAETHYLENE	**ng/ml**	**50,0**	**40,0 – 60,0**	**340,0**	**289,0 – 391,0**
METHADONE	**ng/ml**	**100,0**	**80,0 – 120,0**	**520,0**	**442,0 – 598,0**
MBDB	**ng/ml**	**140,0**	**112,0 – 168,0**	**700,0**	**595,0 – 805,0**
KETAMINE	**ng/ml**	**100,0**	**80,0 – 120,0**	**650,0**	**552,5 – 747,5**
EPHEDRINE	**ng/ml**	**100,0**	**80,0 – 120,0**	**680,0**	**578,0 – 782,0**
PSEUDOEPHEDRINE	**ng/ml**	**140,0**	**112,0 – 168,0**	**800,0**	**680,0 – 920,0**
NORPSEUDOEPHEDRINE	**ng/ml**	**140,0**	**112,0 – 168,0**	**600,0**	**510,0 – 690,0**

* 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 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

produced by

COMPANY WITH
MANAGEMENT SYSTEM
CERTIFIED BY DNV
= ISO 9001 =
= ISO 13485 =

eureka Lab Division

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