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

CONTROL LYOPHIL. IN PLASMA FOR ANTIEPILEPTICS - LEVELS 1, 2 and 3

(Levetiracetam, Lamotrigine, Primidone, Oxacarbamazepine, Carbamazepine Epoxide, 10,11-Dihydro-10-Hydroxy-Carbamazepine, Carbamazepine, Phelbamate, Desmethylsuximide, Rufinamide, Phenytoin, Methsuximide, Topiramate, Phenobarbital, Valproic Acid, Ethosuximide, Lacosamide, Perampanel, Zonisamide, Sulthiame, Pregabalin, Brivaracetam, Gabapentin, Stiripentol, Vigabatrin, Tiagabine)

Code LC04919

PURPOSE

These plasma controls are used for internal quality assurance in clinical-chemical laboratories and are made to keep under control the care and precision of the analytical procedure in charge to the quantitative determination of in the analytes in them included. These lyophilised controls are based on human plasma and are available with mean values in the normal as well as in the pathological range. The controls have to be prepared like patient samples in one series of analyses.

RECONSTITUTION

Remove the metal seal and rubber stopper from the vial. Add exactly 1 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

These 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 -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		
016	Feb 2024	Feb 2027

PACKAGING AVAILABLE:

- LC04919 CONTROL IN PLASMA FOR ANTIEPILEPTICS - LEVELS 1, 2 and 3 ***3 x 5 x 1 ml***

Release N° 002	**September 2019**

CONCENTRATIONS
CODE LC04919

LOT		
016	Feb 2024	Feb 2027

ANALYTE	*MEASUREMENT UNIT*	*MEDIUM VALUE L1*	*RANGE L1*	*MEDIUM VALUE L2*	*RANGE L2*	*MEDIUM VALUE L3*	*RANGE L3*
LEVETIRACETAM	**µg/ml**	**11,3**	**9,0 – 13,6**	**30,6**	**24,5 – 36,7**	**40,6**	**32,5 – 48,8**
LAMOTRIGINE	**µg/ml**	**2,3**	**1,8 – 2,8**	**8,0**	**6,4 – 9,6**	**12,0**	**9,6 – 14,4**
PRIMIDONE	**µg/ml**	**5,7**	**4,5 – 6,8**	**16,3**	**13,0 – 19,5**	**26,0**	**20,8 – 31,2**
OXACARBAMAZEPINE	**µg/ml**	**1,4**	**1,1 – 1,7**	**4,0**	**3,2 – 4,7**	**6,0**	**4,8 – 7,1**
CARBAMAZEPINE EPOXIDE	**µg/ml**	**0,5**	**0,4 – 0,6**	**1,4**	**1,1 – 1,7**	**2,3**	**1,8 – 2,7**
10,11-DIHYDRO-10-HYDROXY-CARBAMAZEPINE	**µg/ml**	**6,8**	**5,5 – 8,2**	**25,4**	**20,3 – 30,5**	**35,1**	**28,1 – 42,1**
CARBAMAZEPINE	**µg/ml**	**3,5**	**2,8 – 4,6**	**9,8**	**7,9 – 11,8**	**14,8**	**11,8 – 17,8**
PHELBAMATE	**µg/ml**	**9,1**	**7,3 – 10,9**	**29,1**	**23,3 – 34,9**	**43,7**	**35,0 – 52,4**
RUFINAMIDE	**mg/l**	**7,2**	**5,8 – 8,6**	**21,9**	**17,5 – 26,3**	**35,6**	**28,5 – 42,7**
DESMETHYLSUXIMIDE	**mg/l**	**9,0**	**7,2 – 10,8**	**28,0**	**22,4 – 33,6**	**32,8**	**26,2 – 39,4**
PHENYTOIN	**mg/l**	**4,8**	**3,9 – 5,8**	**13,3**	**10,7 – 16,0**	**23,5**	**18,8 – 28,2**
METHSUXIMIDE	**mg/l**	**7,0**	**5,6 – 8,4**	**23,9**	**19,1 – 28,6**	**31,6**	**25,3 – 37,9**
TOPIRAMATE	**mg/l**	**4,3**	**3,5 – 5,2**	**13,2**	**10,6 – 15,9**	**19,2**	**15,4 – 23,1**
PHENOBARBITAL	**µg/ml**	**8,2**	**6,5 – 9,8**	**28,8**	**23,1 – 34,6**	**45,3**	**36,2 – 54,4**
VALPROIC ACID	**mg/l**	**17,0**	**13,6 – 20,5**	**61,2**	**49,0 – 73,5**	**90,7**	**72,5 – 108,8**
ETHOSUXIMIDE	**µg/ml**	**19,1**	**15,3 – 23,0**	**61,9**	**49,5 – 74,3**	**89,5**	**71,6 – 107,4**
LACOSAMIDE	**mg/l**	**2,6**	**2,1 – 3,1**	**10,2**	**8,1 – 12,2**	**14,8**	**11,8 – 17,7**
PERAMPANEL	**µg/ml**	**0,3**	**0,2 – 0,4**	**1,0**	**0,8 – 1,2**	**1,5**	**1,2 – 1,8**
ZONISAMIDE	**µg/ml**	**6,1**	**4,9 – 7,4**	**17,0**	**13,6 – 20,4**	**25,2**	**20,2 – 30,3**
SULTHIAME	**mg/l**	**3,3**	**2,6 – 3,9**	**9,6**	**7,6 – 11,5**	**17,1**	**13,7 – 20,5**
PREGABALIN	**mg/l**	**2,3**	**1,9 – 2,8**	**7,0**	**5,6 – 8,4**	**10,8**	**8,6 – 12,9**
BRIVARACETAM	**mg/l**	**1,9**	**1,5 – 2,3**	**7,4**	**6,0 – 8,9**	**10,3**	**8,2 – 12,3**
GABAPENTIN	**mg/l**	**5,7**	**4,6 – 6,9**	**17,8**	**14,2 – 21,3**	**25,5**	**20,4 – 30,7**
STIRIPENTOL	**mg/l**	**4,3**	**3,5 – 5,2**	**13,5**	**10,8 – 16,2**	**20,5**	**16,4 – 24,6**
VIGABATRIN	**mg/l**	**9,1**	**7,3 – 10,9**	**26,5**	**21,2 – 31,8**	**37,7**	**30,2 – 45,3**
TIAGABINE	**mg/l**	**0,07**	**0,06 – 0,08**	**0,2**	**0,1 – 0,3**	**0,3**	**0,2 – 0,4**

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

eureka Lab Division

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