

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

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

(Amiodarone, Desethylamiodarone, Flecainide, Propafenone, Sotalol, Quinidine)

Code LC99119

OBJECTIVE

These plasma controls are used for internal quality control and serve to control the accuracy and precision of analytical procedures dedicated to the quantitative determination of the analytes they contain. These freeze-dried controls are in human matrix and are available in two different concentration ranges. They must be handled as if they were a real patient sample.

RECONSTITUTION

Remove the metal seal and rubber cap from the vial. Add exactly 1 ml of HPLC grade water to the vial. Replace the rubber cap, shake and leave to stand for 5 - 10 minutes. Before use shake the vial by inversion to dissolve the material until a clear and homogeneous solution is obtained.

STORAGE AND STABILITY

The calibrators are stable for 36 months from the date of preparation if stored at 2-8 $^{\circ}$ C. After reconstitution are stable 7 days at 2-8 $^{\circ}$ C and 1 month at -20 $^{\circ}$ C. Do not use after the expiry date.

PRECAUTIONS

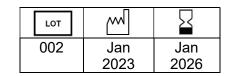
These controls in human matrix should be treated with care and treated as potentially infectious.

LOT	M	
002	Jan	Jan
	2023	2026

AVAILABLE PACKAGINGS:

- LC99119 CONTROL IN PLASMA FOR ANTIARRHYTHMICS - LEVELS 1, 2 and 3 3 x 5 x 1 ml

Release N° 001	February 2010
----------------	---------------



ANALYTE	MEASUREMENT UNIT	MEDIUM VALUE L1	RANGE L1	MEDIUM VALUE L2	RANGE L2	MEDIUM VALUE L3	RANGE L3
AMIODARONE	mg/l	0,3	0,2 - 0,4	0,8	0,6 – 1,0	2,3	1,6 – 3,0
DESETHYLAMIODARONE	mg/l	0,3	0,2 - 0,4	0,7	0,5 - 0,9	1,7	1,2 - 2,2
FLECAINIDE	mg/l	0,3	0,2 - 0,4	0,8	0,6 - 1,0	1,1	0,8 - 1,5
PROPAFENONE	mg/l	0,3	0,2 - 0,4	0,8	0,6 - 1,0	2,0	1,4 - 2,7
SOTALOL	mg/l	0,5	0,4 - 0,7	1,7	1,2 - 2,2	3,2	2,2 - 4,1
QUINIDINE	mg/l	1,5	1,1 – 2,0	3,6	2,5 - 4,6	6,2	4,3 – 8,1

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.

 $(\epsilon$

FOR IN VITRO DIAGNOSTIC USE ONLY

produced by

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



USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

EUREKA srl – LAB DIVISION , Via Enrico Fermi 25, 60033 Chiaravalle (AN) ITALY Tel. + 39 071 74 50 790 Fax. + 39 071 74 96 579 info@eurekaone.com www.eurekakit.com



Release N° 001 February 2010