



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

CONTROL LYOPHIL. IN PLASMA FOR ANTIMYCOTICS – LEVELS 1, 2 and 3
**(5-Flucytosine, Anidulafungin, Caspofungin, Fluconazole, Ketoconazole, OH-Itraconazole,
Isovuconazole, Itraconazole, Micafungin, Posaconazole, Voriconazole)**

**Code LC82019
TO USE WITH KIT CODE LC82010**

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 ranges. 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 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 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	W	E
005	Apr 2023	Apr 2026

PACKAGING AVAILABLE:

- LC82019 CONTROL IN PLASMA FOR ANTIMYCOTICS – LEVELS 1,2 and 3 *3 x 5 x 1 ml*

Release N° 002	September 2019
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CONCENTRATIONS
CODE LC82019

LOT	MW	EX
005	Apr 2023	Apr 2026

ANALYTE	MEASUREMENT UNIT	MEDIUM VALUE L1	RANGE L1	MEDIUM VALUE L2	RANGE L2	MEDIUM VALUE L3	RANGE L3
5-FLUCYTOSINE	mg/l	7,15	5,01 – 9,30	19,10	13,38 – 24,85	58,04	40,60 – 75,50
ANIDULAFUNGIN	mg/l	0,63	0,44 – 0,82	3,47	2,43 – 4,51	6,68	4,67 – 8,68
CASPOFUNGIN	mg/l	1,27	0,90 – 1,60	3,47	2,43 – 4,51	10,30	7,20 – 13,30
FLUCONAZOLE	mg/l	0,98	0,69 – 1,28	3,11	2,20 – 4,00	8,64	6,00 – 11,20
KETOCONAZOLE	mg/l	1,04	0,70 – 1,40	3,59	2,51 – 4,66	8,28	5,80 – 10,80
OH-ITRACONAZOLE	mg/l	0,44	0,30 – 0,57	1,50	1,05 – 1,95	4,00	2,80 – 5,20
ISAVUCONAZOLE	mg/l	1,02	0,71 – 1,32	3,64	2,55 – 4,73	9,85	6,90 – 12,81
ITRACONAZOLE	mg/l	0,36	0,25 – 0,46	1,49	1,04 – 1,93	3,90	2,73 – 5,07
MICAFUNGIN	mg/l	0,55	0,38 – 0,71	1,65	1,15 – 2,14	5,95	4,17 – 7,74
POSACONAZOLE	mg/l	0,13	0,09 – 0,17	0,39	0,28 – 0,51	1,00	0,70 – 1,31
VORICONAZOLE	mg/l	0,44	0,31 – 0,57	1,40	0,96 – 1,78	3,76	2,60 – 4,90

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

produced by



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

Release N° 002

September 2019