



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

CONTROL LYOPHIL. IN PLASMA FOR ANTIPSYCHOTICS - LEVELS 1, 2 and 3
(Clozapine, Norclozapine, Olanzapine, Risperidone, Quetiapina, Ziprasidone, Haloperidol, Aripiprazole,
Fluphenazine, Paliperidone)

Code LC83019

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 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

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|  |  |  |
| 004 | Oct 2023 | Oct 2026 |




AVAILABLE PACKAGINGS:

- LC83019 CONTROL IN PLASMA FOR ANTIPSYCHOTICS - LEVELS 1, 2 and 3 3 x 5 x 1 ml

Release N° 001

February 2010

CONCENTRATIONS
CODE LC83019

| | | |
|---|---|---|
|  LOT |  |  |
| 004 | Oct 2023 | Oct 2026 |

| <i>ANALYTE</i> | <i>MEASUREMENT UNIT</i> | <i>MEDIUM VALUE L1</i> | <i>RANGE L1</i> | <i>MEDIUM VALUE L2</i> | <i>RANGE L2</i> | <i>MEDIUM VALUE L3</i> | <i>RANGE L3</i> |
|----------------|-------------------------|------------------------|-----------------|------------------------|-----------------|------------------------|-----------------|
| CLOZAPINE | ng/ml | 56,7 | 39,7 – 73,8 | 326,8 | 228,7 – 424,8 | 1.037,6 | 726,3 – 1.348,9 |
| NORCLOZAPINE | ng/ml | 35,9 | 25,1 – 46,7 | 329,7 | 230,8 – 428,7 | 1.029,1 | 720,3 – 1.337,8 |
| OLANZAPINE | ng/ml | 8,2 | 5,7 – 10,6 | 34,4 | 24,1 – 44,8 | 113,9 | 79,8 – 148,1 |
| RISPERIDONE | ng/ml | * | * | * | * | * | * |
| QUETIAPINE | ng/ml | 55,5 | 38,8 – 72,1 | 320,8 | 224,5 – 417,0 | 1.079,0 | 755,3 – 1.402,7 |
| ZIPRASIDONE | ng/ml | 29,3 | 20,5 – 38,1 | 132,2 | 92,5 – 171,8 | 424,0 | 296,8 – 551,3 |
| HALOPERIDOL | ng/ml | 2,3 | 1,6 – 3,0 | 4,8 | 3,3 – 6,2 | 14,5 | 10,2 – 18,9 |
| ARIPIRAZOLE | ng/ml | 63,8 | 44,7 – 83,0 | 293,3 | 205,3 – 381,3 | 920,3 | 644,2 – 1.196,4 |
| FLUPHENAZINE | ng/ml | 1,2 | 0,8 – 1,5 | 8,2 | 5,7 – 10,6 | 26,7 | 18,7 – 34,7 |
| PALIPERIDONE | ng/ml | 8,2 | 5,8 – 10,7 | 38,6 | 27,0 – 50,1 | 124,3 | 87,0 – 161,6 |

* value not disponible at printing time

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.



FOR IN VITRO DIAGNOSTIC USE ONLY

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= ISO 9001 =
= ISO 13485 =

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