



Psychotropic Medication 2

Value Data Sheet 4072 CON P PS2

Controls for LC-MS/MS Assay

REF 4072 CON P PS2

LOT 09B24/C

 2026/01

IVD For in vitro diagnostic use

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Intended use:

The intended use of this product is verifying the PS2 assay. These lyophilized PS2 controls are prepared from human serum. Stabilizers are added to stabilize the analytes for accurate verification of the PS2 procedure.

After reconstitution these lyophilized controls should be treated as a patient sample.

Reconstitution:

Add exactly 500 µl of deionized water to the vial and let stand for 15 minutes.

Swirl the vial carefully and mix thoroughly. Let the vial stand for another 15 minutes and swirl one last time. Use the solution as a patient sample when all material is dissolved.

Storage and Stability

This product will be stable until the expiration date when stored unopened at 2 - 8 °C.

After reconstitution the stability of Olanzapine, Risperidone and 9-OH-risperidone is:

5 days at 4 °C

1 month at -20 °C

Aripiprazole, Quetiapine, Clozapine and Haloperidol cannot be stored after reconstitution.

The stated stabilities are only valid in case of no bacterial contamination. Avoid repeated freezing and thawing.

Caution:

The serum used for manufacturing the controls has been tested and found free from infectious and contagious diseases. Nevertheless, the controls should be considered as potentially infectious and treated with appropriate care.

Pack size:


PS2 Control Set

3 x 3 x 500 µl, Control I - III

Notes:

The concentrations of the analytes are chosen in ranges where valid results can be obtained.
The variation of the filling volume (CV) is < 1 %.

Concentrations:

4072 CON P PS2	<div><div>LOT</div><div></div></div>	09B24/07 2026/01		09B24/08 2026/01		09B24/09 2026/01	
		Control I 4081 P PS2		Control II 4082 P PS2		Control III 4083 P PS2	
Analyte	Mean (µg/l)	Range (µg/l)	Mean (µg/l)	Range (µg/l)	Mean (µg/l)	Range (µg/l)	
Aripiprazole	38.3	28.7 - 47.9	286	214 - 358	479	359 - 599	
Clozapine	105	78.7 - 131.3	380	285 - 475	900	675 - 1125	
Haloperidol	5.22	3.91 - 6.53	8.78	6.58 - 10.98	29.2	21.9 - 36.5	
Olanzapine	10.2	7.65 - 12.75	57.2	42.9 - 71.5	140	105 - 175	
Quetiapine	45.4	34.0 - 56.8	316	237 - 395	530	397 - 663	
Risperidone	5.74	4.30 - 7.18	13.8	10.3 - 17.3	65.3	49.0 - 81.6	
9-OH-risperidone	9.83	7.37 - 12.29	32.4	24.3 - 40.5	113	84.7 - 141.3	