



## Psychotropic Medication 1

Value Data Sheet 4052 CON P PS1

Controls for LC-MS/MS Assay

**REF** 4052 CON P PS1

**LOT** 07P23/C

 2025/11

**IVD** For in vitro diagnostic use

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### Intended use:

The intended use of this product is verifying the PS1 assay. These lyophilized PS1 controls are prepared from human serum. Stabilizers are added to stabilize the analytes for accurate verification of the PS1 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 the analytes is: 1 month at -20 °C

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, they should be considered as potentially infectious and treated with appropriate care.

### Pack size:

PS1 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:

4052 CON P PS1	<div><div>LOT</div><div></div></div> 07P23/07 2025/11	<div><div>LOT</div><div></div></div> 07P23/08 2025/11	<div><div>LOT</div><div></div></div> 07P23/09 2025/11			
	Control I 4061 P PS1	Control II 4062 P PS1	Control III 4063 P PS1			
Analyte	Mean (µg/l)	Range (µg/l)	Mean (µg/l)	Range (µg/l)	Mean (µg/l)	Range (µg/l)
Amitriptyline	20.5	15.4 - 25.6	74.1	55.6 - 92.6	216	162 - 270
Imipramine	32.6	24.4 - 40.8	115	86.2 - 143.8	227	170 - 284
Norclozapine	67.0	50.2 - 83.8	121	90.7 - 151.3	290	217 - 363
Clozapine	103	77.2 – 128.8	358	268 - 448	692	519 - 865
Nortriptyline	19.9	14.9 - 24.9	53.4	40.0 - 66.8	173	130 - 216
Norclomipramine	28.5	21.4 - 35.6	67.7	50.8 - 84.6	286	214 - 358
Clomipramine	22.3	16.7 - 27.9	53.6	40.2 - 67.0	207	155 - 259
Desipramine	44.2	33.1 - 55.3	142	106 - 178	280	210 - 350
E-10-OH-Nortriptyline	43.8	32.8 - 54.8	73.8	55.3 - 92.3	205	154 - 256
Z-10-OH-Nortriptyline	18.2	13.6 - 22.8	42.6	31.9 - 53.3	84.6	63.4 - 105.8
Zuclopentixol*	8.77	6.58 - 10.96	23.6	17.7 - 29.5	49.2	36.9 - 61.5

\* Measurement of zuclopentixol requires a high degree of sensitivity. For this reason Diagnostix used a Sciex Citrine system (comparable to a Sciex 6500) for this determination. Using a less sensitive system could result in less accurate results and therefore it is recommend to increase the sample volume within the 2-20 µl range. Refer to the Instructions for Use for more information.