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Psychtropic Medication 1

Value Data Sheet 4052 CON P PS1

Controls for LC-MS/MS Assay

REF 4052 CON P PS1

LOT 25F22/C

2025/04

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Replaces:

Date of release: 20-05-2022

Intended use:

The intended use of this product is verifying the PS1 assay. These lyophilized PS1 controls are prepared from humane 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, the controls should be considered as potentially infectious and treated with appropriate care.

Pack size:

P\$1 Control Set 3 x 3 x 500 µl, Control I - III

Important Notes:

This is a preliminary Value Data Sheet not intended for use on actual patient material. No rights or claims can be arrived from the contents of this document.

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 P\$1	LOT 25F22/08 2 2025/04		LOT 25F22/09		25F22/10 2025/04	
	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	21	16 - 26	87	65 - 109	255	191 - 319
Imipramine	34	26 - 42	141	106 - 176	271	203 - 339
Norclozapine	77	58 - 96	146	110 - 182	276	207 - 345
Clozapine	103	77 - 129	332	249 - 415	688	516 - 860
Nortriptyline	24	18 - 30	61	46 - 76	194	146 - 242
Norclomipramine	32	24 - 40	75	57 - 94	304	228 - 380
Clomipramine	26	20 - 32	69	52 - 86	269	202 - 336
Desipramine	47	35 - 59	154	115 - 193	301	226 - 376
Zuclopenthixol	10	7.4 - 12.4	25	19 - 31	35	26 - 44
E-10-OH-Nortriptyline	38	29 - 47	70	52 - 88	192	144 - 240
Z-10-OH-Nortriptyline	17	13 - 21	38	28 - 47	68	51 - 85