

APPLICATION SHEET - Roche cobas® pro c 503 – SI Units

MyCare™ Psychiatry Clozapine Assay Kit

Reagent ID: CLZ-RGT

Clozapine

Configure analytical parameters					
Short Name	CLZ		Unit 1	nmol/L	
Long Name	SBI Clozapine		Unit 2	None	
Rerun Setting			Conversion Factor	1	
Below	OFF				
Above	OFF				
Technical Limit	208	-	4590		
Assay					
Assay	2 Point End		Primary	600	
Time	10		Secondary	NA	
Points	1	20	2	34	
	3	0	4	0	
Cassette Configuration					
	Reagent Volume	Dilution Volume	Dummy Reagents	Mode	Mix
R1	70	0	0	Without	4
R2	0	0	0	Without	4
R3	35	0	0	Without	4
Sample Volume					
	Sample Volume	Diluted Sample Vol.	Diluent Volume	Mix	
Normal	2.8	0	0	4	
Decreased	2.8	0	0	4	
Increased	2.8	0	0	4	
Diluent	Type	Water			
	ACN	None			
	Dilution	0			
Cell Wash					
Wash Cells With	Basic and Acid				
Higher Uncertainty	85				
QC Interval					
QC Interval Timeout	Disabled				



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Configure R.P. settings			
c pack	***		
No. of Tests	105		
Position	Reagent Type	Filling Volume	
B	R1	12	
C	R3	6.6	
*** Select from drop down; reagent packs CDC01–CDC10 are dedicated to development channel			
<button>Calculate Volume</button>			

Configure Ranges			
Linearity Limit			
4-8 Point	0		
9 Point	0		
Min. Total Rate	0		
Min. Diff. Rate	0		
Reaction Limit			
Check	Off		
Abs. Limit	0		
Application Correction Factor		Method	Decrease
		Sample Index Limits	
A	1.0	L	0
B	0.00	H	0
		I	0



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Configure calibration parameters						
Changeover Settings						
Lot Changeover	Full					
Reagent Pack Changeover	Cancel					
Calibration Trigger						
QC Violation	Method Cancel					
Timeout	Method Full			Stability 21		
Limit Values						
SD Limit	0					
Duplicate Limit	99 %					
	3.3 Abs.					
Sensitivity Start	0					
Sensitivity End	0					
Sensitivity Limit	-9.9999			9.9999		
S1 Abs. Limit	-3.3000			3.3000		
Calibration Method						
Curve Type	RCM1	Point	6	Weighting	0	
Configuring calibrators						
	S1	S2	S3	S4	S5	S6
Calibrator Code	*	*	*	*	*	*
Calibrator Volume	2.8	2.8	2.8	2.8	2.8	2.8
Diluted C. Volume	0	0	0	0	0	0
Diluent Volume	0	0	0	0	0	0
Calibrator Diluent						
Type	Water					
Code	None					
Dilution Factor	0					
*Calibrator Codes for development channels are 29001 - 29050						

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Configure assay parameters – Calibration / Install / Chemistry							
Define the following values by choosing EDIT for EACH MCP2 ¹ calibrator A through F.							
Edit Calibrator							
Name:	CLZ	Code:	**	Lot No.:	Cal Kit Lot		
Test	Std (1)	Std (2)	Std (3)	Std (4)	Std (5)	Std (6)	
CLZ	0	230	370	759	1649	4354	
						Std Concentration ²	
						Std (1)	0
						Std (2)	230
						Std (3)	370
						Std (4)	759
						Std (5)	1649
						Std (6)	4354
Unit of Measure nmol/L							
¹ Saladax Biomedical MyCare Psychiatry Calibrator Kit Cat. No. MCP2-CAL. ² MCP2 calibrator values are not lot-specific.							

Configure assay parameters – QC / Install							
Define the following values by choosing EDIT for EACH QC level Low through High							
Edit QC							
Name:	MCP2 – Low ¹	Code:	**	Lot No.:	Con Kit Lot	Expiration:	#
	Individual ²		Cumulative		Confidence		
CLZ	Mean	T.SD	Mean	T.SD	Low	High	
	465	40	465	40	386	545	
Name:	MCP2 - Med ¹	Code:	**	Lot No.:	Con Kit Lot	Expiration:	#
	Individual ²		Cumulative		Confidence		
CLZ	Mean	T.SD	Mean	T.SD	Low	High	
	1411	184	1411	184	1043	1778	
Name:	MCP2 – High ¹	Code:	**	Lot No.:	Con Kit Lot	Expiration:	#
	Individual ²		Cumulative		Confidence		
CLZ	Mean	T.SD	Mean	T.SD	Low	High	
	2775	361	2775	361	2053	3498	
¹ Saladax Biomedical MyCare Psychiatry Control Kit 2 Cat. No. MCP2-CON ² MCP2 control values are not lot-specific.							

** Calibrator and Control Codes for development channels are 29001 - 29050



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For further information refer to the package insert or

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