



APPLICATION SHEET- Roche cobas® 6000/c501 and cobas® 8000/c502

MyCare™ Psychiatry Clozapine Assay
 Reagent ID: CLZ-RGT

Clozapine

This Application requires the installation of a Development Channel

Configure assay parameters - Utility/Application/Analyze									
Assay/Time/Point	2 Point End		10	40	70	0	0		
Wavelength (2nd/Pri.)	Cancel	600							
Sample volume				Cassette Configuration					
Norm.	4.0	0.0	0	Code 0777773					
Dec.	4.0	0.0	0	Expiration Days		99			
Inc.	4.0	0.0	0	Reagent Volume					
Dilution				R1	100	0	Inactive		
• Water				R2	0	0	Bottle Setting		
o Diluent	0	1		R3	50	0			
Linearity Limit	0%	0%	0	0					
Prozone Limit	0	0	0	0	0	0	Inside	0	0
Abs. Limit	0	Decrease		Version No. 00-01					
Cell Detergent	Detergent 1+2		Stirring Level		8				
Stirring Setting	M1		M2	M3					
UP	Stirring	LOW	Stirring	No Stir	Stirring				

Configure assay parameters - Utility/Application/Analyze/Bottle Setting			
Bottle			
a	Cancel	0	0.0
b	R1	86	11.6
c	R3	86	7.0

Configure assay parameters - Utility/Application/Calib.			
Calibration Type	RCM		
Point	6		
Span	6		
Weight	0		
Update Type	Difference	1	4
SD Limit	999		
Duplicate Limit	99%	32000	Abs.
Sensitivity Limit	-99999	99999	
S1 Abs. Limit	-32000	32000	
Auto Masking			
Auto Calibration	Timeout ●		
Cassette	Full		
	28 Day		
Changeover	Cassette Full		
QC Violation	Method Blank		
	Rule 1s		
	Control 1 None		
	Control 2 None		
	Control 3 None		



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Configure assay parameters - Utility/Application/Range					
Application Code	#				
Unit	ng/mL		Expected Values		
Report Name	CLZ		Male		
Data Mode	Active		<input type="text" value="99"/> Year		<input type="text" value="-99999"/> <input type="text" value="999999"/>
<input type="checkbox"/> Automatic Rerun			<input type="text" value="100"/> Year		<input type="text" value="-99999"/> <input type="text" value="999999"/>
Technical Limit	<input type="text" value="68"/>	<input type="text" value="1500"/>			
Repeat Limit	<input type="text" value="-99999"/>	<input type="text" value="999999"/>			
<input type="checkbox"/> Control Interval Time			<input type="text" value="99"/> Year		<input type="text" value="-99999"/> <input type="text" value="999999"/>
<input type="checkbox"/> Automatic QC On Board Stability 1			<input type="text" value="100"/> Year		<input type="text" value="-99999"/> <input type="text" value="999999"/>
<input type="checkbox"/> Qualitative			<input type="text" value="-99999"/> <input type="text" value="999999"/>		
	L	<input type="text" value="0"/>	Default		
	H	<input type="text" value="0"/>	Sex		
	I	<input type="text" value="0"/>	<input checked="" type="radio"/> Male <input type="checkbox"/> Female		
			Range		
			<input checked="" type="radio"/> Range 1 <input type="checkbox"/> Range 2 <input type="checkbox"/> Range 3		

#--User Defined Parameter

Configure assay parameters - Utility/Application/Other						
	(1)	(2)	(3)	(4)	(5)	(6)
Calibrator Code*	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
Concentration						
Rack No. -Pos.						
Sample Volume	<input type="text" value="4.0"/>	<input type="text" value="4.0"/>	<input type="text" value="4.0"/>	<input type="text" value="4.0"/>	<input type="text" value="4.0"/>	<input type="text" value="4.0"/>
Diluted S Volume	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>
Diluent Volume	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>

* Calibrator Codes for development channels are usually between 801 and 899.

#--User Defined Parameter

Configure assay parameters - Calibration/Install/Chemistry			
No.	Calibrator	Code	Lot No.
	MCP2 A	#	#
	MCP2 B	#	#
	MCP2 C	#	#
	MCP2 D	#	#
	MCP2 E	#	#
	MCP2 F	#	#

#--User Defined Parameter



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Clozapine

Configure assay parameters - Calibration/Install/Chemistry																			
Define the following values by choosing EDIT for EACH calibrator MCP2 A through MCP2 F.*																			
Edit Calibrator																			
Name: MCP2#	Code: #			Lot No.: #															
Test	Std (1)	Std (2)	Std (3)	Std (4)	Std (5)	Std (6)	Std Concentration*												
CLZ	0	75	121	248	539	1423	<table border="1"> <tr><td>Std (1)</td><td>0</td></tr> <tr><td>Std (2)</td><td>75</td></tr> <tr><td>Std (3)</td><td>121</td></tr> <tr><td>Std (4)</td><td>248</td></tr> <tr><td>Std (5)</td><td>539</td></tr> <tr><td>Std (6)</td><td>1423</td></tr> </table>	Std (1)	0	Std (2)	75	Std (3)	121	Std (4)	248	Std (5)	539	Std (6)	1423
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Std (2)	75																		
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Std (4)	248																		
Std (5)	539																		
Std (6)	1423																		
							Unit of Measure ng/mL												

*Saladax Biomedical MyCare Psychiatry Calibrator Kit 2 Cat. No. MCP2-CAL
 #--User Defined Parameter

Configure assay parameters - QC/Install							
Define the following values by choosing EDIT for EACH QC level Low through High.**							
Edit QC							
Name: MCP2 - Low	Code:*** #			Lot No.: #			Expiration: #
CLZ	Individual		Cumulative		Confidence		
	Mean	T.SD	Mean	T.SD	Low	High	
	152	26	152	26	126	178	
Name: MCP2 - Med	Code:*** #			Lot No.: #			Expiration: #
CLZ	Individual		Cumulative		Confidence		
	Mean	T.SD	Mean	T.SD	Low	High	
	456	120	461	120	341	581	
Name: MCP2 - High	Code:*** #			Lot No.: #			Expiration: #
CLZ	Individual		Cumulative		Confidence		
	Mean	T.SD	Mean	T.SD	Low	High	
	907	236	907	236	671	1143	

**Saladax Biomedical MyCare Psychiatry Control Kit 2 Cat. No. MCP2-CON
 ***QC Codes are usually between 801 and 899.
 #--User Defined Parameter

For further information refer to the package insert or
 contact Saladax Biomedical Customer Support at:

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 E-mail: techsupport@saladax.com