



# APPLICATION SHEET - Abbott Alinity c/ci-series

MyCare™ Psychiatry Clozapine Assay

Reagent ID: CLZ-RGT

## Clozapine

### Configure assay parameters - General

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH
Assay: <b>CLZ</b>		Type: <b>Photometric</b>		
Number: _____		Units: <b>ng/mL</b>		
Assay availability: <b>Enabled</b>		Run controls for onboard reagents by: <b>Lot</b>		
<b>Reaction Definition</b>		Primary	Secondary	Read Times
Reaction Mode: <b>END UP</b>		Wavelength: <b>604 / None</b>		Main: <b>36 - 37</b>
Absorbance Range: _____ - _____		Last Required Read: <b>37</b>		Flex: <b>NA - NA</b>
Sample Blank: <b>Self/Automatic</b>		Blank: <b>20 - 21</b>		Color Correction: <b>NA - NA</b>
<b>Reagent</b>		<b>Validity Checks</b>		<b>Calculation Limits:</b>
Reagent: <b>CLZ</b>		Reaction Verification: <b>None</b>		_____ - _____
Diluent: <b>NONE</b>		Reading Time A: _____ - _____		Minimum:
Diluent dispense mode:		Reading Time B: _____ - _____		Maximum Abs Variation:
		<b>Sample</b>		
	R1	R2	Diluted Sample	Dilution factor
Reagent Volume:	<b>80</b>	<b>40</b>		<b>= 1:1.00</b>
Water Volume:				<input checked="" type="radio"/>
Dispense mode:	<b>Type 2</b>	<b>Type 2</b>		<input type="radio"/>

### Configure assay parameters – General – Configure Reagent

Reagent name:	<b>CLZ</b>
Reagent type:	<b>R1 and R2</b>
Reagent low alert:	_____
Number of tests:	<b>80</b>
Onboard stability:	<b>816</b>
Run Calibrations for Reagent by:	<input checked="" type="radio"/> <b>Lot</b> <input type="radio"/> <b>Cartridge</b>

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#### Configure assay parameters - Calibration

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH
<b>Calibration</b>				
Calibration Method: <b>Logit 4</b>		Calibration Interval Complete: <b>480</b> (hours)		
Factor: <b>NA</b>		Default Request Type: <b>NA</b>		
Use Cal Factor: <b>NA</b>		Adjustment Type: <b>None</b>		
Calibration Expiration Warning: _____ (hours)		Adjustment Interval: _____ (hours)		Adjust level: _____
<b>Calibrators</b>			<b>Validity Checks</b>	
Calibrator set: <b>MCP2*</b>		Replicates: <b>2</b> Diluted		
Calibrator Level:	Sample	Sample	Diluent	Water
Blank:	<b>MCP2 - 1</b>	<b>3.2</b>		
Cal. 1:	<b>MCP2 - 2</b>	<b>3.2</b>		
Cal. 2:	<b>MCP2 - 3</b>	<b>3.2</b>		
Cal. 3:	<b>MCP2 - 4</b>	<b>3.2</b>		
Cal. 4:	<b>MCP2 - 5</b>	<b>3.2</b>		
Cal. 5:	<b>MCP2 - 6</b>	<b>3.2</b>		
Cal. 6:				
		Blank absorbance range: <b>NA - NA</b>		
		Span: <b>NA - NA</b>		
		Span absorbance range: <b>NA - NA</b>		
		Expected cal. factor: _____		
		Expected cal factor tolerance (%): _____		
		Maximum curve adjustment: <b>NA</b>		
<b>Configure assay parameters – Calibration – New Calibrator Set</b>				
Calibrator: <b>MCP2*</b>				
Calibrator Level:		Concentration (ng/mL):		
Blank:		<b>MCP2 - 1</b> <b>0</b>		
Cal. 1:		<b>MCP2 - 2</b> <b>75</b>		
Cal. 2:		<b>MCP2 - 3</b> <b>121</b>		
Cal. 3:		<b>MCP2 - 4</b> <b>248</b>		
Cal. 4:		<b>MCP2 - 5</b> <b>539</b>		
Cal. 5:		<b>MCP2 - 6</b> <b>1423</b>		
Cal. 6:				

\*Saladax Biomedical MyCare Psychiatry Calibrator Kit 2 Cat. No. MCP2-CAL

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#### Configure assay parameters - Results

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH
<b>Units of Results</b>				
Units: <b>ng/mL</b>		Decimals: <b>0</b>	UCUM Units: <b>ng/mL</b>	
Correlation factor: <b>1</b>		Intersection: _____		
<b>Results</b>				
Low-Linearity Limit <b>68 (ng/mL)</b>		High-Linearity Limit <b>1500 (ng/mL)</b>		
Gender	Age (unit)	Age Interval	Normal Interval	Extreme Interval
_____	_____	_____ - _____	_____ - _____	_____ - _____
<b>Interpretation</b>				
	Name	Interval	Revision required	
	_____	< _____	<input type="radio"/>	
	_____	≥ _____	<input type="radio"/>	
	_____	≥ _____	<input type="radio"/>	
	_____	≥ _____	<input type="radio"/>	
	_____	≥ _____	<input type="radio"/>	

#### Configure assay parameters - Reanalysis Rules

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH			
<b>Assay Reanalysis Rules</b>							
<div style="border: 1px solid black; width: 150px; height: 100px; margin-bottom: 10px;"></div> Reanalysis rules: Result criterion: <input checked="" type="radio"/> Interval results <input type="radio"/> Interpretation <input type="radio"/> Exception From: _____ Until: _____  Original dilution: <b>Standard</b>							
<table border="1" style="width: 100%;"> <tr> <td style="width: 33%;">Selected reanalysis assays</td> <td style="width: 33%;">Dilution reanalysis</td> <td style="width: 33%;">Replicated</td> </tr> </table>					Selected reanalysis assays	Dilution reanalysis	Replicated
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#### Configure assay parameters - SmartWash

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH
<b>SmartWash Information</b>				
Component	Reagent/Assay	Wash Solution	Volume	Replicates
_____	_____	_____	_____	_____

Control Configuration				
Control:	<b>MCP2*</b>	Lot Number: _____	Expiration Date: _____	
Level: <b>Level 1</b>	Level Name: <b>Low</b>	Automated: <b>No</b>	Onboard Stability: <b>0</b>	In-use Stability: <b>0</b>
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	<b>152 (ng/mL)</b>	<b>13 (ng/mL)</b>	<b>126 - 178 (ng/mL)</b>	
Level: <b>Level 2</b>	Level Name: <b>Medium</b>	Automated: <b>No</b>	Onboard Stability: <b>0</b>	In-use Stability: <b>0</b>
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	<b>461 (ng/mL)</b>	<b>60 (ng/mL)</b>	<b>341 - 581 (ng/mL)</b>	
Level: <b>Level 3</b>	Level Name: <b>High</b>	Automated: <b>No</b>	Onboard Stability: <b>0</b>	In-use Stability: <b>0</b>
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	<b>907 (ng/mL)</b>	<b>118 (ng/mL)</b>	<b>671 - 1143 (ng/mL)</b>	

\*Saladax Biomedical MyCare Psychiatry Control Kit 2 Cat. No. MCP2-CON

\*\* The Expected Mean and 1 SD Values are calculated by entering in the control range and selecting "Calculate mean/SD"

\_\_\_\_\_ = User Defined Parameter

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

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