

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: CLZ		Type: Photometric																														
Number: _____		Units: nmol/L																														
Assay availability: Enabled		Run controls for onboard reagents by: Lot																														
Reaction Definition Primary Secondary Read Times																																
Reaction Mode: END UP		Wavelength: 604 / None		Main: 36 - 37																												
Absorbance Range: _____ - _____		Last Required Read: 37		Flex: NA - NA																												
Sample Blank: Self/Automatic		Blank: 20 - 21		Color Correction: NA - NA																												
Reagent Reagent: CLZ Diluent: NONE Diluent dispense mode:		Validity Checks Calculation Limits: Reaction Verification: None Reading Time A: _____ - _____ Reading Time B: _____ - _____ Minimum: Maximum Abs Variation:																														
R1 R2 Reagent Volume: 80 40 Water Volume: Dispense mode: Type 2 Type 2		Sample <table border="1"> <thead> <tr> <th>Dilution name</th> <th>Sample</th> <th>Diluted Sample</th> <th>Diluent</th> <th>Water</th> <th>Dilution factor</th> <th>Default dilution</th> </tr> </thead> <tbody> <tr> <td>Standard</td> <td>3.2</td> <td>_____</td> <td>_____</td> <td>_____</td> <td>= 1:1.00</td> <td>●</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>○</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>○</td> </tr> </tbody> </table>			Dilution name	Sample	Diluted Sample	Diluent	Water	Dilution factor	Default dilution	Standard	3.2	_____	_____	_____	= 1:1.00	●							○							○
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Standard	3.2	_____	_____	_____	= 1:1.00	●																										
						○																										
						○																										

Configure assay parameters – General – Configure Reagent

Reagent name:	CLZ
Reagent type:	R1 and R2
Reagent low alert:	_____
Number of tests:	80
Onboard stability:	816
Run Calibrations for Reagent by:	☒ Lot ☐ Cartridge

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Configure assay parameters - Calibration

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH
Calibration				
Calibration Method: Logit 4		Calibration Interval Complete: 480 (hours)		
Factor: NA		Default Request Type: NA		
Use Cal Factor: NA		Adjustment Type: None		
Calibration Expiration Warning: _____ (hours)		Adjustment Interval: _____ (hours)		Adjust level: _____
Calibrators			Validity Checks	
Calibrator set: MCP2*			Replicates: 2	
Diluted				
Calibrator Level:	Sample	Sample	Diluent	Water
Blank: MCP2 - 1	3.2			
Cal. 1: MCP2 - 2	3.2			
Cal. 2: MCP2 - 3	3.2			
Cal. 3: MCP2 - 4	3.2			
Cal. 4: MCP2 - 5	3.2			
Cal. 5: MCP2 - 6	3.2			
Cal. 6:				
			Blank absorbance range: NA - NA	
			Span: NA - NA	
			Span absorbance range: NA - NA	
			Expected cal. factor: _____	
			Expected cal factor tolerance (%): _____	
			Maximum curve adjustment: NA	
Configure assay parameters – Calibration – New Calibrator Set				
Calibrator: MCP2*				
Calibrator Level:		Concentration (nmol/L):		
Blank: MCP2 - 1		0		
Cal. 1: MCP2 - 2		230		
Cal. 2: MCP2 - 3		370		
Cal. 3: MCP2 - 4		759		
Cal. 4: MCP2 - 5		1649		
Cal. 5: MCP2 - 6		4354		
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
Units of Results Units: nmol/L Decimals: 0 UCUM Units: nmol/L Correlation factor: 1 Intersection: _____				
Results Low-Linearity Limit 208 (nmol/L) High-Linearity Limit 4590 (nmol/L)				
Gender	Age (unit)	Age Interval	Normal Interval	Extreme Interval
_____	_____	_____ - _____	_____ - _____	_____ - _____
Interpretation				
Name		Interval	Revision required	
_____		< _____	☐	
_____		≥ _____	☐	
_____		≥ _____	☐	
_____		≥ _____	☐	
_____		≥ _____	☐	

Configure assay parameters - Reanalysis Rules

GENERAL	CALIBRATION	RESULTS	REANALYSIS RULES	SMARTWASH			
Assay Reanalysis Rules							
Reanalysis rules: Result criterion: ☒ Interval results ☐ Interpretation ☐ Exception From: _____ Until: _____ Original dilution: Standard							
<table border="1"> <tr> <td>Selected reanalysis assays</td> <td>Dilution reanalysis</td> <td>Replicated</td> </tr> </table>					Selected reanalysis assays	Dilution reanalysis	Replicated
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Configure assay parameters - SmartWash

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

Control Configuration				
Control:	MCP2*	Lot Number:	_____	Expiration Date: _____
Level: Level 1	Level Name: Low	Automated: No	Onboard Stability: 0	In-use Stability: 0
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	465 (nmol/L)	40 (nmol/L)	386 - 545 (nmol/L)	
Level: Level 2	Level Name: Medium	Automated: No	Onboard Stability: 0	In-use Stability: 0
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	1411 (nmol/L)	184 (nmol/L)	1043 - 1778 (nmol/L)	
Level: Level 3	Level Name: High	Automated: No	Onboard Stability: 0	In-use Stability: 0
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	2775 (nmol/L)	361 (nmol/L)	2053 - 3498 (nmol/L)	

*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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E-mail: techsupport@saladax.com