



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: ng/mL		
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		Validity Checks		Calculation Limits:
Reagent: CLZ		Reaction Verification: None		_____ - _____
Diluent: NONE		Reading Time A: _____ - _____		Minimum:
Diluent dispense mode:		Reading Time B: _____ - _____		Maximum Abs Variation:
		Sample		
	R1	R2	Diluted Sample	Dilution factor
Reagent Volume:	80	40		= 1:1.00
Water Volume:				<input checked="" type="radio"/>
Dispense mode:	Type 2	Type 2		<input type="radio"/>

Configure assay parameters – General – Configure Reagent

Reagent name:	CLZ
Reagent type:	R1 and R2
Reagent low alert:	_____
Number of tests:	100
Onboard stability:	816
Run Calibrations for Reagent by:	<input checked="" type="radio"/> Lot <input type="radio"/> 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 (ng/mL):		
Blank:		MCP2 - 1 0		
Cal. 1:		MCP2 - 2 75		
Cal. 2:		MCP2 - 3 121		
Cal. 3:		MCP2 - 4 248		
Cal. 4:		MCP2 - 5 539		
Cal. 5:		MCP2 - 6 1423		
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: ng/mL		Decimals: 0	UCUM Units: ng/mL	
Correlation factor: 1		Intersection: _____		
Results				
Low-Linearity Limit 68 (ng/mL)		High-Linearity Limit 1500 (ng/mL)		
Gender	Age (unit)	Age Interval	Normal Interval	Extreme Interval
_____	_____	_____ - _____	_____ - _____	_____ - _____
Interpretation				
	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			
Assay Reanalysis Rules							
<div style="border: 1px solid black; width: 150px; height: 150px; display: inline-block; vertical-align: top; margin-right: 20px;"></div> Reanalysis rules: Result criterion: <input checked="" type="radio"/> Interval results <input type="radio"/> Interpretation <input type="radio"/> Exception From: _____ Until: _____ Original dilution: Standard							
<table border="1" style="width: 100%; border-collapse: collapse;"> <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
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	152 (ng/mL)	13 (ng/mL)	126 - 178 (ng/mL)	
Level: Level 2	Level Name: Medium	Automated: No	Onboard Stability: 0	In-use Stability: 0
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	461 (ng/mL)	60 (ng/mL)	341 - 581 (ng/mL)	
Level: Level 3	Level Name: High	Automated: No	Onboard Stability: 0	In-use Stability: 0
	Expected Mean**	Expected 1 SD**	Control Range	
CLZ	907 (ng/mL)	118 (ng/mL)	671 - 1143 (ng/mL)	

*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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