



APPLICATION SHEET - Siemens Atellica CH / CI Analyzers

MyCare™ Psychiatry Clozapine Assay Kit

Reagent ID: CLZ-RGT

Clozapine

Configuring Definition for Open Channel Assays

Assay Name	XCLZ
ID	Set by software
Units	ng/mL
Test Version	1.0
Display Name	XCLZ
Sample Type	Serum / Plasma
Assay Range	68 - 1500

Sample

Predilution

Sample Volume	50
Dilution factor	1

Below Measuring Interval Configuration

Sample Volume	0
Dilution factor	blank

Above Measuring Interval Configuration

Sample Volume	0
Dilution factor	blank

Configuring Sample/Reagent for Open Channel Assays

R1 Reagent

Component 1 Volume	78
Component 2 Volume	0
Diluent Volume	0
Mix	Gentle

Sample

Component 1 Volume	3
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R2 Reagent

Component 1 Volume	39
Component 2 Volume	0
Diluent Volume	0
Mix	Moderate

Test Count 100

Life (hours) 1992

Onboard Life (hours) 1992

Use Well 2 disabled



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Configuring Open Channel Assay Calculation

Analysis Method	End Point (EPA)
Primary Wavelength	596
Blank Wavelength	None
Main Start Time	357
Main End Time	516
Absorbance Offset	None
Decreasing Reaction Absorbance	disabled
Start-Point Estimation	disabled

Configuring Open Channel Assay Calibration

Specimen Type	Serum / Plasma
Standard Curve	Logit3
Lot Calibration Interval (Days)	20
Pack Calibration Interval (Days)	20
☒ Automatically Order Calibrations	Yes
☐ Lot Calibration Expiration (Days)	No
☐ Pack Calibration Expiration (Hours)	No
☒ New Lot	Yes
☐ IFU Changed	
☒ Perform QC with Calibration	Yes
Calibrator Onboard Stability (Hours)	
Refrigerated	24
Number of Calibrators ¹	6

Level	Weight	Replicates	Dilution Factor	Sample	Volume
1	1	2	1	1	50 µL
2	1	2	1	2	50 µL
3	1	2	1	3	50 µL
4	1	2	1	4	50 µL
5	1	2	1	5	50 µL
6	1	2	1	6	50 µL

Calibrator Concentrations (ng/mL) 0, 75, 121, 248, 539, 1423



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Configuring Open Channel Assay QC Definitions

Control ² Level (1)	152 (ng/mL)
Control ² Level (2)	461 (ng/mL)
Control ² Level (3)	907 (ng/mL)
+/- Range (1)	126 - 178 (ng/mL)
+/- Range (2)	341 - 581 (ng/mL)
+/- Range (3)	671 - 1143 (ng/mL)

¹Saladax Biomedical MyCare Psychiatry Calibrator Kit 2 Cat. No. MCP2-CAL

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

For further information refer to the package insert or

Telephone: +1 610 419-6731

Contact Saladax Biomedical Customer Support at:

E-mail: techsupport@saladax.com



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MyCare™ Psychiatry Clozapine Assay Kit

Reagent ID: CLZ-RGT

Clozapine

Configuring Definition for Open Channel Assays

Assay Name	XCLZ
ID	Set by software
Units	nmol/L
Test Version	1.0
Display Name	XCLZ
Sample Type	Serum / Plasma
Assay Range	208 - 4590

Sample

Predilution

Sample Volume	50
Dilution factor	1

Below Measuring Interval Configuration

Sample Volume	0
Dilution factor	blank

Above Measuring Interval Configuration

Sample Volume	0
Dilution factor	blank

Configuring Sample/Reagent for Open Channel Assays

R1 Reagent

Component 1 Volume	78
Component 2 Volume	0
Diluent Volume	0
Mix	Gentle

Sample

Component 1 Volume	3
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R2 Reagent

Component 1 Volume	39
Component 2 Volume	0
Diluent Volume	0
Mix	Moderate

Test Count 100

Life (hours) 1992

Onboard Life (hours) 1992

Use Well 2 disabled



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Blank Wavelength	None
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Configuring Open Channel Assay Calibration

Specimen Type	Serum / Plasma
Standard Curve	Logit3
Lot Calibration Interval (Days)	20
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☒ Automatically Order Calibrations	Yes
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☐ Pack Calibration Expiration (Hours)	No
☒ New Lot	Yes
☐ IFU Changed	No
☒ Perform QC with Calibration	Yes
Calibrator Onboard Stability (Hours)	
Refrigerated	24

Number of Calibrators¹ 6

Level	Weight	Replicates	Dilution Factor	Sample	Volume
1	1	2	1	1	50 µL
2	1	2	1	2	50 µL
3	1	2	1	3	50 µL
4	1	2	1	4	50 µL
5	1	2	1	5	50 µL
6	1	2	1	6	50 µL

Calibrator Concentrations (nmol/L) 0, 230, 370, 759, 1649, 4354



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MyCare™ Psychiatry Clozapine Assay

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Clozapine

Configuring Open Channel Assay QC Definitions

Control ² Level (1)	465 (nmol/L)
Control ² Level (2)	1411 (nmol/L)
Control ² Level (3)	2775 (nmol/L)
+/- Range (1)	386 - 545 (nmol/L)
+/- Range (2)	1043 - 1778 (nmol/L)
+/- Range (3)	2053 - 3498 (nmol/L)

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