



## APPLICATION SHEET - Siemens Atellica

MyCare™ Psychiatry Clozapine Assay

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
R2 Reagent	
Component 1 Volume	39
Component 2 Volume	0
Diluent Volume	0
Mix	Moderate
Test Count	100
Life (hours)	1992
Onboard Life (hours)	24
Use Well 2	disabled



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### Clozapine

#### 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
<input checked="" type="checkbox"/> Automatically Order Calibrations	Yes
<input type="checkbox"/> Lot Calibration Expiration (Days)	No
<input type="checkbox"/> Pack Calibration Expiration (Hours)	No
<input checked="" type="checkbox"/> New Lot	Yes
<input type="checkbox"/> IFU Changed	
<input checked="" type="checkbox"/> Perform QC with Calibration	Yes
Calibrator Onboard Stability (Hours) Refrigerated	24
Number of Calibrators <sup>1</sup>	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 <sup>2</sup> Level (1)	152 (ng/mL)
Control <sup>2</sup> Level (2)	461 (ng/mL)
Control <sup>2</sup> Level (3)	907 (ng/mL)
+/- Range (1)	126 - 178 (ng/mL)
+/- Range (2)	341 - 581 (ng/mL)
+/- Range (3)	671 - 1143 (ng/mL)

<sup>1</sup>Saladax Biomedical MyCare Psychiatry Calibrator Kit 2 Cat. No. MCP2-CAL

<sup>2</sup>Saladax 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](mailto:techsupport@saladax.com)



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### 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
R2 Reagent	
Component 1 Volume	39
Component 2 Volume	0
Diluent Volume	0
Mix	Moderate
Test Count	100
Life (hours)	1992
Onboard Life (hours)	24
Use Well 2	disabled



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Analysis Method	End Point (EPA)
Primary Wavelength	596
Blank Wavelength	None
Main Start Time	357
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Absorbance Offset	None
Decreasing Reaction Absorbance	disabled
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#### Configuring Open Channel Assay Calibration

Specimen Type	Serum / Plasma
Standard Curve	Logit3
Lot Calibration Interval (Days)	20
Pack Calibration Interval (Days)	20
<input checked="" type="checkbox"/> Automatically Order Calibrations	Yes
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Number of Calibrators<sup>1</sup> 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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#### Configuring Open Channel Assay QC Definitions

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

<sup>1</sup>Saladax Biomedical MyCare Psychiatry Calibrator Kit 2 Cat. No. MCP2-CAL

<sup>2</sup>Saladax Biomedical MyCare Psychiatry Control Kit 2 Cat. No. MCP2-CON

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