



## APPLICATION SHEET - Ortho Clinical Diagnostics VITROS 4600/5600

MyCare™ Psychiatry Clozapine Assay

Reagent ID: CLZ-RGT

### Clozapine

OPTIONS --> CONFIGURE ASSAYS --> USER DEFINED ASSAYS --> "OK" --> SELECT ASSAY (1 - 20) --> NEW

Full assay name:

e.g., Clozapine

Short assay name:

e.g., CLZ

Fluid type:

Serum

Assay model type:

2 Point Rate

Template:

2PT R1-S-R2

Cal model type:

Logit/Log4

Calibrator Bottles:

6

Replicates per Cal:

2

### REVIEW / EDIT ASSAY --> DILUTION PARAMETERS

Diluent:

None

Standard Dilution Factor:

1.0

Reflex Dilution:

Off

Reflex Dilution Factor:

1.0

Reduction Factor

1.0

### REVIEW / EDIT ASSAY --> RESULT PARAMETERS

Units:

ng/mL

Significant Digits

4

Precision Digits:

0

User Adjusted Slope:

1.0

User Adjusted Intercept:

0.0

CuveTip Expiration Time:

25

Temperature Sensitive:

Disabled / No

Reference Range:

\_\_\_\_\_ to \_\_\_\_\_

Supplementary Range:

\_\_\_\_\_ to \_\_\_\_\_

Measuring (Reportable) Range:

68 to 1500

### REVIEW / EDIT ASSAY --> RESULT PARAMETERS --> MORE ASSAY PARAMETERS

Initial Absorbance Limits:

-0.200 to 3.500

Second Absorbance Limits:

-0.200 to 3.500

Antigen Excess Factor:

9.0



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**REVIEW / EDIT ASSAY --> PROTOCOL PARAMETERS**

	Protocol Step	Volume	Pack/Bottle Name	Seconds	Wavelength
1	Reagent (R1)	100.0	UDxx / A		
2	Incubation			0	
3	Sample	4.0			
4	Incubation			76	
5	Reagent (R2)	50.0	UDxx / B		
6	Incubation			38	
7	Read				600 nm
8	Incubation			256.5	
9	Read				600 nm

**REVIEW / EDIT ASSAY --> CALIBRATION PARAMETERS**

Bottle Number	Dilution Factor	Calibrator Replicate Response Range	Calibrator Value	Lot** Cal Kit Lot
1	1.0	0.2	0 ng/mL	
2	1.0	0.2	75 ng/mL	
3	1.0	0.2	121 ng/mL	
4	1.0	0.2	248 ng/mL	
5	1.0	0.2	539 ng/mL	
6	1.0	0.2	1423 ng/mL	

**REVIEW / EDIT ASSAY --> CALIBRATION PARAMETERS --> MORE CAL PARAMETERS**

Monotonicity: Decrease	Max. Response High: 3.0	Max. Response Low: -3.0
Cal. Fit Goodness Limit: 0.990	Min. Response High: 3.0	Min. Response Low: -3.0
Calibration Interval: 26		



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#### REVIEW / EDIT ASSAY --> REAGENT LOT

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On Board Stability

29

Reagent Lot Number:

Kit lot number

Shelf Expiration Date:

Kit Exp Date

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#### REVIEW / EDIT ASSAY --> TRIPLE READ PARAMETERS

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	Reportable Concentration	Triple Read Limit
Reportable Min:	68 ng/mL	42
Critical Concentration:	350 ng/mL	12 %
Reportable Max:	1500 ng/mL	12 %

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#### FILLING AND LOADING REAGENT PACKS

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IMPORTANT: Mix the reagents before pouring them into any analyser-specific (secondary) reagent carrier. Once reagents have been transferred into the analyzer-specific reagent carrier, immediately place the reagents on board the analyzer.

1. Inspect the packaging for any signs of damage. Remove the reagent pack from the carton and ensure that the pack is not damaged. The label and cap should be securely attached.
2. Write any necessary information about the reagent on the label before you fill the pack.
3. Remove the cap from Bottle A. Keep the cap on Bottle B.
4. Ensure that there are no particulates in the reagent, then transfer the entire contents of the Reagent 1 bottle into Bottle A gently to prevent foaming or splashing.
5. Replace the cap on Bottle A. Tighten the cap until it is snug enough to protect the reagent and provide sufficient resistance for the MICROTIP PACK OPENER.
6. Remove the cap from Bottle B.
7. Repeat step 4 and step 5 for filling Bottle B with Reagent 2.
8. Load the reagent pack. IMPORTANT: do not loosen or remove the caps before you load the reagent pack.

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

\*\* Saladax Biomedical MyCare Psychiatry Calibrator Kit 2 Cat. No. MCP2-CAL  
For further information refer to the package insert or  
Contact Saladax Biomedical Customer Support at:

Telephone: +1 (610) 419-6731  
E-mail: techsupport@saladax.com