



APPLICATION SHEET – Ortho Clinical Diagnostics VITROS® 4600/5600/XT 7600 – SI Units
MyCare™ Psychiatry Clozapine Assay
Reagent ID: CLZ-RGT

** User Defined Parameters

OPTIONS → CONFIGURE ASSAYS → USER DEFINED ASSAYS → “OK” → SELECT ASSAY (1-20) → NEW			
OPTIONS & CONFIGURATION – User Defined Assays			
1	2	3	Full Assay Name: Clozapine Short Assay Name: CLZ Fluid type: Serum Assay Model Type: 2 Point Rate Template: 2PT R1-S-R2
4	5	6	
7	8	9	
10	11	12	
13	14	15	
16	17	18	
19	20		Cal Model Type: Logit/Log4 Calibrator Bottles: 6 Reagent Reps per Cal: 2

Review / Edit → Reagent Lot	
Reagent Lot Information	
Enter the Reagent Lot Information.	
On Board Stability: 29 (days)	
Reagent Lot Number: **Kit Lot Shelf Expiration Date: **Kit Expiration	

Review / Edit → Dilution Params	
Edit Dilution Parameters	
Edit the Dilution Parameters.	
Diluent: None	Standard Dilution Factor: 1.0
REFLEX DILUTION	
Reflex Dilution: Off Dilution Factor: 1.0 Reduction Factor: 1.0	

Review / Edit → Result Params
OPTIONS & CONFIGURATION – Edit Result Parameters

CLZ – Serum

 Reporting Type:
RESULT PARAMETERS

 Units:
 Significant Digits: Precision Digits:
USER ADJUSTED PARAMETERS

 Slope: Intercept:

 CuveTip Expiration Time:

 Temperature Sensitive: ☐ (Unchecked)

RANGES

 Reference: -

 Supplementary: -

 Reportable: -
Review / Edit → Result Params → More Assay Params
Edit 2 Point Rate Additional Parameters

Initial Absorbance Limits

 -

 Antigen Excess Factor:

Second Absorbance Limits

 -
Review / Edit → Protocol Params
OPTIONS & CONFIGURATION – Edit Protocol Parameters

CLZ – Serum

#	Protocol Step	Volume	Pack/Bottle	Seconds	Wavelength
1	Reagent (R1)	100.0	**UDxx/A		
2	Incubation			0.00	
3	Sample	4.0			
4	Incubation			76.00	
5	Reagent (R2)	50.0	**UDxx/B		
6	Incubation			38.00	
7	Read				600 nm
8	Incubation			256.50	
9	Read				600 nm

Review / Edit → Calibration Parameters
OPTIONS & CONFIGURATION – Enter / Edit Calibration Parameters

CLZ – Serum (nmol/L)

 Bottle
Number

 1
2
3
4
5
6

 Dilution
Factor

 1.0
1.0
1.0
1.0
1.0
1.0

 Calibrator Replicate
Response Range

 0.20000
0.20000
0.20000
0.20000
0.20000
0.20000

 Lot: ****Lot**

Calibrator***

Value

 0 nmol/L
230 nmol/L
370 nmol/L
759 nmol/L
1649 nmol/L
4354 nmol/L

Expiration Date

****Calibrator Exp**
Review / Edit → Calibrator Parameters → More Cal Params
Edit Linear or Logit / Log Additional Parameters

Edit the Additional Cal Parameters.

Monotonicity:	Decrease
Max Response High:	3.000
Max Response Low:	-3.000
Cal Fit Goodness Limit:	0.990

Min Response High:	3.000
Min Response Low:	-3.000
Calibration Interval:	26 days

Review / Edit → Triple Read Params
Edit Triple Read Parameters

	Reportable Concentration	Triple Read Limit	
Reportable Min:	208 nmol/L	129	
Critical Concentration:	1071 nmol/L	26	%
Reportable Max:	4590 nmol/L	26	%

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

For further information refer to the package insert of contact Saladax Biomedical Customer Support at:

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

FILLING AND LOADING REAGENT PACKS

IMPORTANT: Before pouring the reagents (R1 and R2) into the Ortho User Defined Assay Pack, mix the reagents (R1 and R2) by gently inverting them five times. Once reagents have been transferred into the pack, immediately place the reagents on board the analyzer.

1. Inspect the Ortho User Defined Assay reagent pack 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. 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 steps 4 and step 5 to fill Bottle B with Reagent 2.
8. Load the reagent pack. **IMPORTANT:** do not loosen or remove the caps before you load the reagent pack.