



APPLICATION SHEET – Ortho Clinical Diagnostics VITROS® 4600/5600/XT 7600
 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: <input type="text" value="Clozapine"/> Short Assay Name: <input type="text" value="CLZ"/> Fluid type: <input type="text" value="Serum"/> Assay Model Type: <input type="text" value="2 Point Rate"/> Template: <input type="text" value="2PT R1-S-R2"/>
4	5	6	
7	8	9	
10	11	12	
13	14	15	
16	17	18	
19	20		
			Cal Model Type: <input type="text" value="Logit/Log4"/> Calibrator Bottles: <input type="text" value="6"/> Reagent Reps per Cal: <input type="text" value="2"/>

Review / Edit → Reagent Lot

Reagent Lot Information

Enter the Reagent Lot Information.

On Board Stability: (days)

Reagent Lot Number:

Shelf Expiration Date:

Review / Edit → Dilution Params

Edit Dilution Parameters

Edit the Dilution Parameters.

Diluent: Standard Dilution Factor:

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

RANGES

Units:
 Significant Digits: Precision Digits:

Reference: -
 Supplementary: -
 Reportable: -

USER ADJUSTED PARAMETERS

Slope: Intercept:

CuveTip Expiration Time:

Temperature Sensitive: (Unchecked)

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 (ng/mL)

 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:

 Calibrator***
 Value

0 ng/mL
75 ng/mL
121 ng/mL
248 ng/mL
539 ng/mL
1423 ng/mL

Expiration Date

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

Edit the Additional Cal Parameters.

Monotonicity:	<input type="text" value="Decrease"/>
Max Response High:	<input type="text" value="3.000"/>
Max Response Low:	<input type="text" value="-3.000"/>
Cal Fit Goodness Limit:	<input type="text" value="0.990"/>

Min Response High:	<input type="text" value="3.000"/>
Min Response Low:	<input type="text" value="-3.000"/>
Calibration Interval:	<input type="text" value="26"/> days

Review / Edit → Triple Read Params
Edit Triple Read Parameters

	Reportable Concentration	Triple Read Limit	
Reportable Min:	<input type="text" value="68 ng/mL"/>	<input type="text" value="42"/>	
Critical Concentration:	<input type="text" value="350 ng/mL"/>	<input type="text" value="26"/>	%
Reportable Max:	<input type="text" value="1500 ng/mL"/>	<input type="text" value="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.