

Certificate of Analysis

	Product Name		
	Psychiatry Olanzapine Reagent Kit		
Catalog Number		Lot Number	
C82915		5109-A	
Manufacture Date	Release Date	Expiration Date	
2025-07-08	2025-07-08	2026-12-01	

Document Reference	Version	Parameter Tested	Specification	Result
WI070 17		Low Control Recovery	≤ ± 15%	Pass
		Medium Control Recovery	≤ ± 15%	Pass
	High Control Recovery	≤ ± 15%	Pass	
		Precision (%CV)	≤ 10%	Pass
		Fill Volume	≥ 100 Tests	Pass

This certifies that the Saladax Biomedical, Inc. manufactured item listed above has been produced, controlled, and has met all applicable specifications for release at the Bethlehem, PA facility in accordance with the procedures and requirements of the Saladax Quality Management System. Products are manufactured/assembled and tested in compliance to ISO 13485:2016 requirements.

	Saladax Biomedical, Inc.	
Manufacturer Name and Address:	116 Research Dr.	
	Bethlehem, PA 18015 USA	

Released By (Quality Management):	Date:
2	10 Jul 2025

Distributed by: Beckman Coulter, Inc. 250 S. Kraemer Blvd. Brea, CA 92821

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