

Certificate of Analysis

	Product Name		
	Psychiatry Clozapine Reagent Kit		
Catalog Number	Lot Number		
C82914		4243-A	
Manufacture Date	Release Date	Expiration Date	
2024-10-17	2024-10-17	2026-09-01	

Document Reference	Version	Parameter Tested	Specification	Result
	Low Control Recovery	≤ ± 15%	Pass	
		Medium Control Recovery	≤ ± 15%	Pass
WI070 17	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

Date:	
17 Oct 2024	

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

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