


Certificate of Analysis

Product Name		
Psychiatry Clozapine Reagent Kit		
Catalog Number	Lot Number	
C82914	3093-C	
Manufacture Date	Release Date	Expiration Date
2023-09-21	2023-10-02	2025-08-01

Document Reference	Version	Parameter Tested	Specification	Result
WI070	03	Low Control Recovery	$\leq \pm 15\%$	Pass
		Medium Control Recovery	$\leq \pm 15\%$	Pass
		High Control Recovery	$\leq \pm 15\%$	Pass
		Precision (%CV)	$\leq 10\%$	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.

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

Released By (Quality Management):	Date:
	05 Oct 2023

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