


## Certificate of Analysis

Product Name		
Psychiatry Calibrator Kit 2		
Catalog Number		Lot Number
C82911		25-155-A
Manufacture Date	Release Date	Expiration Date
2025-08-29	2025-08-29	2027-08-31

Document Reference	Version	Parameter Tested		Specification	Result
WI070	17.0	Low Control Recovery		$\leq \pm 15\%$	Pass
		Medium Control Recovery		$\leq \pm 15\%$	Pass
		High Control Recovery		$\leq \pm 15\%$	Pass
		Precision (%CV)	Aripiprazole	$\leq 10\%$	Pass
			Clozapine	$\leq 10\%$	Pass
			Olanzapine	$\leq 10\%$	Pass
			Quetiapine	$\leq 10\%$	Pass
			Risperidone	$\leq 5\%$	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.

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

<b>Released By (Quality Management):</b>	<b>Date:</b>
	29 Aug 2025

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