

## **Certificate of Analysis**

	Product Name		
Psy	ychiatry Total Risperidone Reagent	Kit	
Catalog Number		Lot Number 4169-B	
C82918			
Manufacture Date	Release Date	Expiration Date	
2025-11-20	2025-11-21	2026-09-01	

Document Reference	Version	Parameter Tested	Specification	Result
WI070 17		Low Control Recovery	≤ ± 15%	Pass
		Medium Control Recovery	≤ ± 15%	Pass
	17	High Control Recovery	≤ ± 15%	Pass
	Precision (%CV)	≤ 5%	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:
21 Nov 2025

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

BPR-GEN-RGTK-BEC.F5 Rev. 01