

Certificate of Conformance for Quality Assurance

• Quality Control Chart •

This document represents certification of conformance with all manufacturing, quality assurance, and test procedures required for the production and final assembly of the test strip indicated. RPC complies with all storage and handling requirements and performs quality control testing (on a lot number basis). This product was manufactured in compliance with the requirements of the Food & Drug Administration (FDA) Quality Systems Regulation (QSR). With the exception of test strip QC procedures, end users of this test strip must comply with all instructions for use and storage/handling requirements.

K100-0111 E-Z CHEK® OZONE TEST STRIPS

E-Z CHEK FIELD VERIFICATION TESTING**					
Control	Acceptance Rate* (# pass/total tested x100)	Pass/Fail	Initials	Date	
I	100%	PASS	D.C.	9/6/17	
II	100%	PASS	D.C.	9/6/17	

PASS INDICATED BY ACCEPTANCE RATE OF 100% FOR EACH CONTROL TESTED

CONTROL INFORMATION					
	Control I (Pos)	Control II (Neg) N/A			
Manufacturer	Sigma-Aldrich	RPC			
Part Number	402869-100G	Deionized water			
Lot Number	STBG4403V	N/A			
Expiration Date	2/14/2018	N/A			

NOTES: *Sample size determined per ACC-004, RPC Sampling Plan

** Certi-ChekTM Field Verification Testing performed according to ACC-006, K100-0111 E-Z Chek[®] Ozone Test Procedure

Sincerely,

Dave Cox

Director of Quality Assurance and Regulatory Affairs