

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.

K100-0114 E-Z CHEK[®] BLOOD LEAK TEST STRIPS

LOT#: L-46126 **EXPIRATION DATE:** 2018-12-31

E-Z CHEK FIELD VERIFICATION TESTING**					
Control	Acceptance Rate* (# pass/total tested x100)	Pass/Fail	Initials	Date	
I	100%	Pass	AV	12/27/2016	
II	100%	Pass	AV	12/27/2016	

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

CONTROL INFORMATION					
	Control I (Pos)	Control II (Neg) N/A			
Manufacturer	Quantimetrix Corporation	evoqua			
Part Number	1442-61	Deionized water			
Lot Number	44062A	N/A			
Expiration Date	08/2017	N/A			

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

** Certi-Chek™ Field Verification Testing performed according to ACC-009, K100-0114 E-Z Chek® Blood Leak Test Procedure

Sincerely,

Andrea Villalobos

RPC Quality Assurance Technician