



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-51017

EXPIRATION DATE: 2019-01-31

E-Z CHEK FIELD VERIFICATION TESTING**				
Control	Acceptance Rate* <small>(# pass/total tested x100)</small>	Pass/Fail	Initials	Date
I	100%	Pass	DC	1/30/17
II	100%	Pass	DC	1/30/17

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

CONTROL INFORMATION		
	Control I (Pos)	Control II (Neg) <input type="checkbox"/> N/A
Manufacturer	Quantimetrix Corporation	RPC
Part Number	1442-61	DI Water
Lot Number	44062	N/A
Expiration Date	2017-07	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,

Dave Cox
 Director of Quality Assurance and Regulatory Affairs