



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.

K100-0117
E-Z CHEK® (6.8 - 8.5 pH)
TEST STRIPS

LOT#: L-18066 **EXPIRATION DATE:** 06/2019

E-Z CHEK FIELD VERIFICATION TESTING**				
Control	Acceptance Rate* <small>(# pass/total tested x100)</small>	Pass/Fail	Initials	Date
I	100%	Pass	AV	06/29/2016
II	N/A	N/A	N/A	N/A

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

CONTROL INFORMATION			
	Control I-1 (Pos)	Control I-2 (Pos)	Control II (Neg) <input checked="" type="checkbox"/> N/A
Manufacturer	EMD Millipore	Rockwell Medical	
Part Number	1.09887.0001	CB-25	
Lot Number	HCS65541	L-2605460-104161	
Expiration Date	07/20/2016	04/07/2017	

NOTES: *Sample size determined per ACC-004, RPC Sampling Plan
 ** Certi-Chek™ Field Verification Testing performed according to ACC-005, K100-0117 E-ZChek® (6.8-8.5 pH) Test Procedure

Sincerely,

Carrie Plummer
 Director of Quality Assurance and Regulatory Affairs