



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-105019 **EXPIRATION DATE:** 2021-05-31

E-Z CHEK FIELD VERIFICATION TESTING**				
Control	Acceptance Rate* <small>(# pass/total tested x100)</small>	Pass/Fail	Initials	Date
I-1	100%	PASS	KEB	05/17/2018
I-2	100%	PASS	KEB	05/17/2018

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	ROCKWELL MEDICAL	EMD MILLIPORE CORP	
Part Number	CB-25	1.09887-0001	
Lot Number	29297-0717171	HC600824	
Expiration Date	01/17/2019	2021.08.31	

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,

Kathryn E. Brown
 Quality Engineer