



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-105009 **EXPIRATION DATE:** 2020-08-31

E-Z CHEK FIELD VERIFICATION TESTING**				
Control	Acceptance Rate* <small>(# pass/total tested x100)</small>	Pass/Fail	Initials	Date
I-1	100%	Pass	SS	8/31/17
I-2	100%	Pass	SS	8/31/17

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	Titrisol	Rockwell Medical	
Part Number	1.09887.0001	CB-25	
Lot Number	HC600824	29297-0717171	
Expiration Date	2021-08-31	2019-01-17	

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,

Dave Cox
 Director of Quality Assurance and Regulatory Affairs