Certi-Chek™ Field Verification Program

• Certificate of Conformance •

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. In addition to these quality assurance procedures, Certi-Chek™ testing is performed by RPC by using industry accepted standard reference methods at the dialysis specific maximum allowable level for the indicated substance under test. Certi-Chek™ testing replaces the required test strip field validation called for in most test strip Instructions for Use. It is in addition to the immediate post-production QC testing that is required to confirm proper manufacturing of the test strips. 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.

K100-0104
E-Z CHEK® 0-14 pH
TEST STRIPS

LOT#: L-104025 **EXPIRATION DATE:** 2025-07-31

CERTI-CHEK™ FIELD VERFIFICATION TESTING						
Control	**Acceptance Rate (# pass/total tested x100)**	**Test Value**	**Number of Replicates**	**Pass/Fail**	**Initials**	**Date**
I (Positive)	**100%**	**4 pH**	**13**	**PASS**	**DC**	**8/4/2021**
II (Positive)	**100%**	**7 pH**	**13**	**PASS**	**DC**	**8/4/2021**
III (Positive)	**100%**	**10 pH**	**13**	**PASS**	**DC**	**8/4/2021**

Sincerely,

Dave Cox
Director of Quality Assurance and Regulatory Affairs

Reprocessing Products Corp (RPC) • Tucson, AZ • Minneapolis, MN • USA • (520) 888-5551 • Fax (520) 888-5557
Product Quality at Discount Pricing℠