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 Instructions for Use of test strips. This 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). 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#: 101111 **Expiration Date:** 2028-10-31 **IFU Rev:** E

CERTI-CHEK™ FIELD VERFIFICATION TESTING						
Control	Acceptance Rate (# pass/total tested x100)	Test Result	Number of Replicates	Pass/Fail	Initials	Date
I (Positive)	100%	Positive	13	PASS	EA	10/26/2026

Sincerely,

Elissa Arvizu

Elissa Arvizu
Quality Lab Tech I