



RPC Policy on Customer QC Testing of Test Strips Purchased from RPC

**** Certi-Chek™ Field Verification Program ****

RPC is the leading manufacturer and distributor of test strips for use in testing dialysis solutions. RPC performs routine QC testing (on a lot number basis) for all test strips manufactured by RPC and for test strips distributed by RPC. This unique service is called the Certi-Chek™ Field Verification Program.

Certi-Chek™ testing is performed by RPC using industry accepted standard reference methods. 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. “Certificates of Analysis” available from manufacturers are simply QC documents that support the “in-factory” production of test strips. These Certificates of Analysis DO NOT take the place of the Certi-Chek™ Field Verification Program.

Customers purchasing test strips from RPC are required to adhere to all test strip instructions for use, including storage and handling requirements, but ***are not required to perform the test strip QC tests outlined in the individual test strip instructions for use*** as these tests are performed for the customer by RPC. Other manufacturers make some of the test strips distributed by RPC. These manufacturers are aware of, and endorse, the RPC policy of performing their test strip field QC tests for RPC customers.

A certificate of conformance (with test results) for QC validation is available for each test strip type, by lot number. This certificate should be kept on file as proof for surveyors/inspectors – that test strip quality assurance is performed by RPC – when the dialysis center personnel have documentation proving that the strips were purchased from RPC. The certificate of conformance can be faxed to you, or you can download it from the RPC Web site at www.rpc-rabrenco.com . You will need to know the RPC part number and lot number of the test strips for which you desire a certificate of conformance.

Any questions on this policy or the associated QC procedures should be addressed to the RPC Director of Quality Assurance at 800-647-3873.