



## **K100-0117 and Kit Number 5116A (5 each K100-0117) E-Z Chek® 6.8 – 8.5 pH Test Strips**

**Versus**

## **K100-0117CT E-Z Chek® 6.8 – 8.5 pH Test strips**

### **Important Application Note**

#### Introduction

E-Z Chek® 6.8 – 8.5 pH Test Strips are an accurate means for validating the pH of dialysate against the AAMI (RD52) specified range of 6.9 to 7.6. On the bottle color scales, a red line square surrounds the 6.8 and 7.8 pH values to indicate “no go” values outside the AAMI RD52/CMS recommended range for dialysate. The color scale also includes two bicarbonate and water concentrate color blocks at 8.0 and 8.5 pH. There are two test strip models/versions. One version is for use with bicarbonate/acetate dialysate (K100-0117) and the other is for use with bicarbonate/citrate dialysate (K100-0117CT).

#### **WARNING**

Measurement levels outside of the minimum and maximum allowable dialysate pH levels may cause severe injury or death to dialysis patients. For the United States, at the release date of this application note, the Centers for Medicare and Medicaid Services (CMS) uses AAMI/ANSI RD52 to define the acceptable dialysate pH range (6.9 to 7.6). In the future, the acceptable dialysate pH range may change should CMS decide to adopt the newer ISO/AAMI harmonized standards.

Failure to follow instructions for use for the K100-0117 and K100-0117CT E-Z Chek® 6.8 – 8.5 pH Test Strips may result in inaccurate test results.

Use the correct pH test strip with the correct dialysate type. **K100-0117 is for use with standard bicarbonate/acetate dialysate and K100-0117CT is for use with bicarbonate/citrate dialysate.**

Both versions have a separate two color block scale for testing bicarbonate concentrate mixed with water.

#### Important Tips for Using the E-Z Chek® K100-0117 and K100-0117CT 6.8 – 8.5 pH dialysate and bicarbonate concentrate test strips

- 1) **Read carefully, the entire instructions for use (IFUs)** for the model number test strip you are using. Be sure to follow the correct IFUs for the test you are using. Procedures vary between test models.
- 2) **For every test, use a stop watch or second hand of a clock/watch** to make sure the dip/swish time and wait time called for in the IFUs is correct. Proper test sample exposure time and wait time are critical for test strip accuracy.
- 3) **Be aware that the color of an unused test strip** (K100-0117 or K100-0117CT), directly out of the bottle, **is not supposed to match any color** block on the bottle label. The color of the test strip will change to match the appropriate color block when exposed to dialysate or bicarbonate concentrate (per the IFUs).
- 4) **Be aware that**, RPC verifies accuracy of test strips by lot number. No additional testing is required by users unless specifically detailed in instructions for use (see RPC Certi-Chek® program).
- 5) **Be aware that ESRD surveyors may ask** the following question: “**How do you know** that this test is suitable for, or works properly in, this application?”. The best answer is: “By the use of documented process control”. **Documented process control** includes, compliance with instructions for use, training, and adherence to policies and procedures (including passing a color blindness test).