



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

Product Alert Notice

Introduction

E-Z Chek® 6.8 – 8.5 Dialysate 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 concentrate color blocks at 8.0 and 8.5 pH. There are two different models for testing dialysate pH (see #3 and #4 below). **This product alert note concerns bicarbonate/citrate based dialysate and the correct RPC test strip (K100-0117CT) for testing the pH of bicarbonate/citrate based dialysate.**

Important Notes

1. Bicarbonate/citrate based final dialysate has a starting pH which is greater than that of standard dialysate (bicarbonate/acetate dialysis fluid). Bicarbonate/citrate dialysate has a pH of approximately 7.5 vs. bicarbonate/acetate dialysate at an approximate pH of 7.3.
 - a. A starting pH of 7.5 puts the bicarbonate/citrate dialysate near the AAMI/CMS maximum allowable dialysate pH of 7.6.
2. Bicarbonate/citrate based dialysate, when allowed to sit in open air immediately after make-up, experiences a more rapid change (increase) in pH than standard bicarbonate/acetate dialysate.
 - a. Compared with standard dialysate, a more rapid change (increase) in pH for the citrate dialysate **makes it critical to read the test strip at exactly 10 seconds and under bright light.**
3. RPC part number **K100-0117CT** is for use in testing the pH of **bicarbonate/citrate dialysate**.
4. RPC part number **K100-0117** is for use in testing the pH of **bicarbonate/acetate dialysate**.

Important Tips for use of E-Z Chek® K100-0117CT Dialysate & 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 (K100-0117CT), 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).

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