



REF K100-0117CT



E-Z Chek® 6.8 to 8.5 pH Test Strips

Instructions for Use

Indications for Use

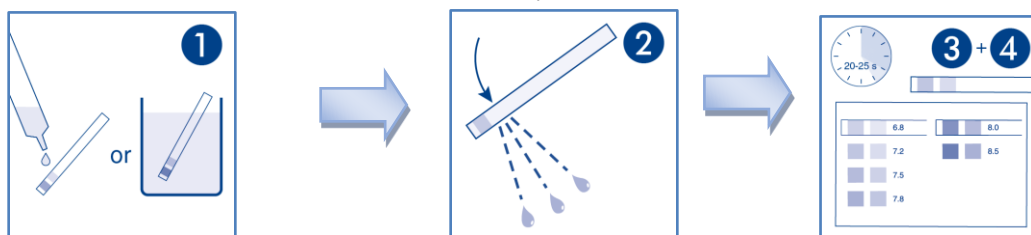
K100-0117CT E-Z Chek® 6.8 - 8.5 pH Test Strips are indicated for use in testing the pH of bicarbonate/ **citrate** dialysate and bicarbonate concentrate. These Test Strips provide an accurate means for validating the pH of dialysate to ensure it is within the current dialysis fluid standards and guidelines (AAMI/ ANSI/ ISO/ CMS). The color scale also includes two bicarbonate and water concentrate color blocks at 8.0 and 8.5 pH.

Test Procedure

Directions for Bicarbonate/Citrate Dialysate or Bicarbonate Concentrate:

* **Performing this test under bright lighting will produce the most accurate results.**

1. Dip in or wet test strip pads.
NOTE: When using the wet method, the fluid must flow over the pad for one second. When using this method, be sure to apply the solution above the pads and not directly on the pads.
2. Briskly shake off excess liquid.
3. Compare test results to color scale on bottle between 20 and 25 seconds. (Retest if the results are not read within the 25 second time frame.)
4. Determine pH value for the closest color match. (Match the strip as closely as possible to the color scales on the bottle. Colors that are between two scales indicate a pH that is between the two values for those scales.)



Warnings and Cautions

- **Do not** use this test strip to measure bicarbonate/**acetate** dialysate. **(Use K100-0117)**
- Allow dialysis machine to run until final dialysate conductivity and temperature have stabilized before testing.
- Do not touch the indicator pads.
- Expiration date and lot number are printed on the container label.
- Verify that the test strips are within their expiration date before use, and do not use them after the expiration date.
- Remove only as many test strips as are required. Close the container immediately after removing a strip.
- Keep all unused test strips in the original bottle.
- Do not allow the test strip to come in contact with liquids or with work surfaces that may contaminate the strip.
- Do not leave test strips in areas exposed to vapors of any type.
- Failure to follow instructions for use for the **K100-0117CT E-Z Chek® 6.8 – 8.5 pH Test Strips** may result in inaccurate test results.
- Proper test sample exposure time and wait time are critical for test strip accuracy.
- Proper test sample exposure time and wait time are critical for test strip accuracy.
- Measurement levels outside of the minimum and maximum allowable dialysate pH levels may cause severe injury or death to dialysis patients.
- When used as a medical device, Federal Law restricts this device to sale by or on order of a physician.

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Interferences

No interferences are known.

Chemical Properties of the Test

OSHA classifies test strips as an article not requiring a Safety Data Sheet (SDS).

Quality Control

RPC performs an independent quality control test on each lot number of test strips (Certi-Chek™ Field Verification Program). RPC includes a certificate of conformance with each shipment per lot and specifies the IFU revision applicable. The certificate Certificates of conformance are also available upon request and/or can be downloaded at www.rpc-rabrenco.com.

Storage and Handling

Temperature Limit	Keep Dry	Keep Away from Sunlight	Test strip per bottle	Recyclable	Immediately close after opening
39°F (4°C)  86°F (30°C)			 100	 RECYCLE	