



REF K100-0101B

## E-Z Chek<sup>®</sup> Residual Chlorine Test Strips

### Instructions for Use

#### Indications for Use

K100-0101B E-Z Chek<sup>®</sup> Residual Chlorine Test Strips provide a convenient and accurate means of measuring the concentration of chlorine bleach remaining in water being used to rinse out dialysate lines following disinfection of hemodialysis equipment. A rapid screening (qualitative) method will detect levels above 0.5ppm (mg/L) and a 30 second quantitative method allows estimation of concentration between 0 and 5ppm. The qualitative method can be used to determine that chlorine has been adequately rinsed from the machine. The quantitative method may be useful when corrective measures are undertaken on machines dispensing unacceptable levels of chlorine for extended periods and for testing containers, i.e. bicarb jugs, disinfected with bleach.



#### IMPORTANT

Always compare test strips to color chart on K100-0101B E-Z Chek<sup>®</sup> bottle for proper interpretation.

#### Test Procedure

##### Qualitative Test

1. Verify the test strips have not expired.
2. Remove a test strip from container and close container immediately. Do not touch test pad at the end of the strip.
3. Hold the reagent area of the test strip in the rinse stream for 5 seconds. (Figure 1)
4. Appearance of any pink/purple color indicates a level of 0.5ppm (mg/L) or more. If no color is apparent immediately upon removal, the chlorine level is less than 0.5ppm and no further rinsing is indicated. Results of 0.5ppm or above indicate further rinsing is necessary.<sup>1</sup>
5. Compare test results to color chart on the K100-0101B E-Z Chek<sup>®</sup> bottle for proper interpretation. (Figure 3)

##### Quantitative Test

1. Verify the test strips have not expired.
2. Remove a test strip from container and close container immediately. Do not touch test pad at the end of the strip.
3. Fill standard sample cup with test solution. Discard solution and re-fill. (Figure 2)
4. Immerse reagent area of test strip in solution and move test strip back and forth vigorously for 30 seconds.
5. Remove strip and compare to color chart within 10 seconds. (Figure 3)

**Note:** Chlorine is consumed during the reaction. To retest a sample, empty the sample cup, obtain a fresh sample and repeat the procedure.



Figure 1



Figure 2



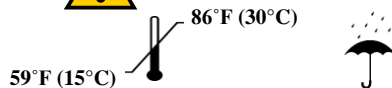
Figure 3

**Note:** Chlorine at low levels is not stable during storage, particularly in the presence of light. Begin the test procedure immediately after collecting sample.



#### WARNINGS AND PRECAUTIONS

#### Storage and Handling



- Improper strip activation and color interpretation may result in patient injury.
- Store away from heat and humidity at temperatures between 59°F - 86°F (15°C - 30°C).
- Keep all unused test strips in the original bottle with lid tightly closed. Replace cap immediately.

#### Storage and Handling (continued)

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- Do not remove the desiccant pack from the bottle/container.
- Do not use test strips (from an opened or unopened bottle), after the expiration date. The expiration date is the last day of the month printed on bottle/container. (year/month/day). The lot number is printed on the bottle/container.
- Do not allow the test strips to contact work surfaces that may be contaminated with interfering substances.
- Do not leave the test strips in areas exposed to chlorine vapors or other oxidizing vapors.



When used as a medical device, Federal law restricts this device to sale by or on order of a physician.

### Limitations

The test will give a positive result with any substance which will oxidize syringaldazine (a specific indicator and colorless compound for free available chlorine), directly or which will oxidize iodide to iodine under neutral pH conditions. These substances include, among others, hypochlorite, chlorine, monochloramine, nitrogen trichloride, ozone, iodine, bromine and peroxide. K100-0101B test strips are not suitable for testing chlorine in bicarbonate concentrates. Syringaldazine does not react with many of the substances found in non-purified water such as sulfate nitrate, chloride, copper, calcium and magnesium. Manganese (IV) and iron (III) give false positive results, while the presence of nitrate will yield a false negative. However, since rinsing of hemodialysis systems is usually done with highly purified water, it is unlikely that these potentially interfering substances will appear in the rinse water.

### Performance Characteristics

The performance characteristics of the E-Z Chek<sup>®</sup> Residual Chlorine Test Strips (K100-0101B) are based on analytical studies using samples to which sodium hypochlorite was added to give a range of chlorine levels. Amperometric titration was used as the reference method for measuring chlorine levels.<sup>5</sup>

The sensitivity and accuracy of the test strip depends on several factors including variability in the user's color perception, the variation in lighting conditions, and the possible presence of interfering substances. Samples with reference chlorine concentrations falling between two color block values will give results ranging between those values. Results will generally be within one color block of reference value. The concentration of chlorine in rinse water is obtained by comparing the color of the reagent pad with color blocks on the label. The color blocks are calibrated in terms of chlorine concentration in parts per million (ppm, mg/L). Color blocks are designated as 0, 0.5, 1, 2, and 5 ppm (mg/L) chlorine. Concentrations (color development) that fall between color block values should be estimated.

### Chemical Properties of the Test

E-Z Chek<sup>®</sup> Residual Chlorine Test Strips (K100-0101B) react with both free chlorine and combined chlorine (monochloramines). Chlorine oxidizes syringaldazine to form a red-purple oxidation product. The reagent pad on the strip is buffered to pH 6.8 and contains potassium iodide. Combined chlorine in the form of monochloramines oxidizes the potassium iodide to iodine which in turn oxidizes syringaldazine to the colored form.<sup>2, 3, 4</sup>

### Quality Control

RPC performs an independent quality control test on each lot number of test strips (Certi-Chek<sup>™</sup> Field Verification Program). RPC includes a certificate of conformance with each shipment. Certificates of conformance are also available upon request and/or can be downloaded at [www.rpc-rabrenco.com](http://www.rpc-rabrenco.com).

### References

1. 1993 Association for the Advancement of Medical Instrumentation (ANSI/AAMI; RD5-1992).
2. C. Sorber, W. Cooper, and E Meier, "Selection of a Field Method for Free Available Chlorine," Disinfection-Water and Wastewater, L D. Johnson, Ed. (Ann Arbor Publishers, Ann Arbor, MI, 1975), 91-112
3. R. Bauer, B. F. Phillips and C.O. Rupe, "A Simple Test for Estimating Free Chlorine", Journal AWWA (November, 1972), pp. 787-789
4. J. Liebermann, N.M. Roscher, E.P. Meier, and W.J. Cooper, "Development of the FACTS Procedure for Combined Forms of Chlorine and Ozone in Aqueous Solutions", Environ Sci Technol 14 (1980) 1395-1400
5. "Amperometric Titration Method", Standard Methods for the Examination of Water and Wastewater, 18<sup>th</sup> Edition (American Public Health Assn, Washington, D.C. 1991) 4-41 to 4-43.