

E-Z CHEK® RESIDUAL CHLORINE TEST STRIPS P/N K100-0101B & KIT 5100A (6 each, K100-0101B)

DESCRIPTION

E-Z Chek® Residual Chlorine Test Strips provide a convenient, 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 method will detect levels above 0.5 ppm (mg/l) and a 30-second quantitative method allows estimation of concentrations between 0 and 5 ppm.

The qualitative rapid screening method can be used to determine that chlorine has been adequately rinsed from the machine. The quantitative method may be useful where 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.

The E-Z Chek® Residual Chlorine Test Strips are supplied in a ready-to-use form. When placed in contact with the rinse water, according to directions, the test area changes color relative to the amount of chlorine remaining in the rinse. Results of 0.5 ppm or above indicate that further rinsing is necessary.

WARNING

- **Improper strip activation and color interpretation may result in patient injury.**
- **Keep all unused strips in the original bottle. Do not remove desiccant pack. Replace cap immediately and tightly after removing a strip; the strips must be protected from heat and humidity.**
- **Do not touch the reagent pad area. Do not allow the pad to come into contact with liquids or with work surfaces, as these may be contaminated with potentially interfering substances.**

RPC performs an independent Quality Control Test on each lot number of test strips. The test procedure and/or a letter from RPC certifying the test results are available upon request. Proper use procedures, including storage and handling, must be documented to ensure accurate test results.

STORAGE:

The E-Z Chek® Residual Chlorine Test Strips must be kept in the original bottle with the lid tightly closed to obtain the best results. Do not remove the desiccant pack. Store at temperatures between 60° - 90°F (16° - 32°C). Do not use the test strips (from an opened or unopened bottle) after the expiration date.

IMPORTANT

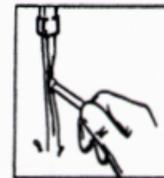
Always compare test results to color chart on the E-Z Chek® bottle for proper interpretation.

To Retest a Sample: Chlorine is consumed during the reaction. To retest a sample, empty the cup and repeat the entire procedure with a fresh sample.

Determination of Residual Iodine Levels: The E-Z Chek® Residual Chlorine Reagent Strips can be used to measure iodine in the absence of chlorine. For iodine concentration, follow the quantitative procedure and multiply the concentration level associated with the appropriate color block by 3.6.

Directions For Qualitative Results

1. Hold the reagent area in the rinse stream for 5 seconds.



2. If no color is apparent immediately upon removal, the chlorine level is less than 0.5 ppm and no further rinsing is indicated. Any pink/purple color indicates concentration of 0.5 ppm or greater.

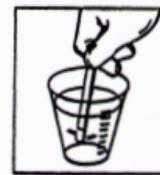


Directions For Quantitative Results

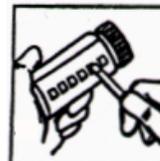
1. Fill standard sample cup with solution. Discard solution and re-fill.

Note: Since chlorine at low levels is not stable during prolonged storage, particularly in the presence of light, begin the test procedure immediately after collection.

2. Immerse reagent area of test strip in solution and move strip back and forth vigorously for 30 seconds.



3. Remove strip and compare to color chart within 10 seconds.



PN K100-0101B & KIT NUMBER 5100A (6 each, K100-0101B) TEST STRIPS**PERFORMANCE CHARACTERISTICS**

The performance characteristics of the E-Z Chek® Residual Chlorine Test Strips 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.

The sensitivity and accuracy of the strip test depends on several factors including variability of color perception, the variation in lighting condition and the possible presence of interfering substances. The lowest reliably detectable level of chlorine is about 0.25 ppm. Samples with reference chlorine concentrations falling between two color block values will give results ranging anywhere between those values. Results will generally be within one color block of the reference value. In blind studies, concentrations of 0.25 ppm have been read as less than 0.5 ppm, and concentrations of 1.0 ppm as greater than 0.5 ppm in all cases.

CAUTION

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

RESULTS

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= milligrams per liter or 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® Residual Chlorine Test Strips react with both free chlorine and combined chlorine (monochloramines). Chlorine oxidizes syringaldazine (a colorless compound) 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.

Reduced syringaldazine HOCl (colorless)



oxidized syringaldazine + H₂O + HCl (pink/purple)

Note: OSHA classifies tests strips as an article not requiring a Material Safety Data Sheet (MSDS).

LIMITATIONS

The test will give a positive result with any substance which will oxidize syringaldazine 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. E-Z Chek® Residual Chlorine Reagent Strips are not suitable for testing for 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.

AVAILABILITY

Product Code K100-0101B E-Z Chek® Residual Chlorine Test Strips is one bottle of 100 test strips and instructions for use (package insert). E-Z Chek® **Sensitive** Total Chlorine & Chloramines Test Strips **are also available from RPC:**

K100-0106 **Sensitive** 0.1 ppm Total Chlorine & Chloramines Test Strips

REFERENCES

- 1993 Association for the Advancement of Medical Instrumentation (ANSI/AAMI; RD5-1992) 5.
- 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.
- R. Bauer, B. F. Phillips and C.O. Rupe, "A Simple Test for Estimating Free Chlorine", Journal AWWA (November, 1972), pp. 787-789
- 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
- "Amperometric Titration Method", Standard Methods for the Examination of Water and Wastewater, 18th Edition (American Public Health Assn, Washington, D.C. 1991) 4-41 to 4-43.

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