

E-Z CHEK® SENSITIVE TOTAL CHLORINE & CHLORAMINES TEST STRIPS P/N K100-0106

⚠ IMPORTANT

DESCRIPTION

E-Z Chek® Sensitive Total Chlorine & Chloramines Test Strips (K100-0106) provide a quick, and convenient means for indicating low levels of total chlorine (chloramine/free chlorine) in feed water used to prepare dialysate. These test strips also provide a convenient means for indicating the concentration of residual chlorine (chlorine bleach) detected in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.

Using a 40-second (total time) semi-quantitative procedure, the strips will detect total chlorine levels between 0 and 4.0 ppm. The E-Z Chek® Sensitive Total Chlorine & Chloramines Test Strips have color blocks at 0, 0.1, 0.5, and 4.0 ppm; 0.1 ppm is the AAMI (Association for the Advancement of Medical Instrumentation) maximum allowable concentration of chloramines in feed water¹.

In feed water, a result above 0.1 ppm chloramines indicates that the water should not be used to prepare dialysate because of breakthrough, due to the exhaustion of the carbon adsorption media in the water purification system. NANT (National Association of Nephrology Technicians/Technologists) / FDA recommends that feed water samples should be obtained after the first carbon tank to monitor chlorine / chloramine levels².

For rinse water following disinfection of hemodialysis equipment, a result of 0.5 ppm free chlorine or above indicates that further rinsing is needed¹.

⚠ WARNINGS & PRECAUTIONS

- Do not use these strips to determine chlorine potency.
- Keep all unused test strips in the original bottle.
- Do not remove desiccant pack.
- Replace cap immediately/tightly after removing a strip.
- Do not use test strips from an opened or unopened bottle after expiration date printed on top of the bottle.
- Do not touch the indicator pad.
- Do not allow the test strip to come in contact with liquids or with work surfaces that may be contaminated with potentially interfering substances.
- Do not leave test strips in areas exposed to chlorine vapors or other oxidizing vapors.
- *Caution:* When used as a medical device, Federal Law restricts this device to sale by or on order of a physician.

STORAGE:

Keep these strips in the original bottle with the lid tightly closed. Do not remove the desiccant pack. Store at temperatures between 15°-30°C (59°-86°F). Do not use a test strip (from an opened or unopened bottle) after the expiration date. Lot number and expiration date are printed on the top of the bottle.

Quantitative (Semi) Procedure for Feed Water and Rinse Water Total Chlorine Testing

An estimate of the concentration of chlorine in water is obtained by comparing the color of the indicator pad with the color blocks on the bottle label.

1. Using sample cup provided, fill with approximately 20 ml of water. Discard contents and re-fill before testing.
2. Immerse indicator pad in sample solution and move test strip back and forth vigorously for 10 seconds. The indicator pad must be perpendicular to the direction of strip movement (Fig. 1)

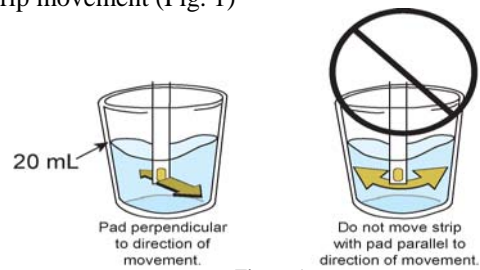


Figure 1

3. Remove strip from solution, do not shake. Wait a full 30 seconds. While waiting, fold the white plastic handle of the test strip under the aperture (as in Figure 2 below) so that it provides a consistent viewing background.
4. After the 30 second wait period, immediately compare the

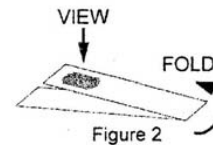


Figure 2

strip color to the K100-0106 color chart to determine the Total Chlorine level in the sample.

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This is a go/no go test at the 0.1ppm level. Any green coloration in the aperture viewing window should be considered a failed test, i.e. 0.1 ppm total chlorine may be present.

For increased low end resolution, the K100-0118 Ultra-Low™ Total Chlorine Test Strips can be used to test the water.

Color blocks are designated at 0 ppm, 0.1 ppm, 0.5 ppm, and 4.0 ppm (0 mg/L, 0.1 mg/L, 0.5 mg/L, and 4.0 mg/L) total chlorine. If the color of the indicator pad falls between two color blocks, concentrations may be determined by estimation.

Note:

- Since chlorine at low levels is not stable during prolonged storage, begin the test procedure immediately after collecting the sample.
- Chlorine is consumed during the reaction. To re-test a sample, always empty the container, obtain a fresh sample and repeat the procedure.

E-Z CHEK® SENSITIVE TOTAL CHLORINE & CHLORAMINES TEST STRIPS P/N K100-0106**PERFORMANCE CHARACTERISTICS**

The performance characteristics of the E-Z Chek® Sensitive Total Chlorine & Chloramines Test Strips (K100-0106) are based on analytical studies using samples yielding a range of chlorine/chloramine levels. Standards were verified using the ITS eXact™ Micro 7+ DPD-4 method. This method is comparable to American Water Works Association (AWWA) method 4500 Cl-G⁴.

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 anywhere between those values. Results will generally be within less than one color block of the reference value.

CHEMICAL PROPERTIES OF THE TEST

E-Z Chek® Sensitive Total Chlorine & Chloramines Test Strips semi-quantitatively measure both free chlorine and chloramines. The indicator pad contains an indicator and enhancer. Free chlorine oxidizes the indicator to form green/blue oxidation products. Monochloramines oxidize the enhancer which reacts with the indicator to form the green/blue complex.

QUALITY CONTROL

RPC performs an independent Quality Control Test on each lot number of test strips (Certi-Chek™ Field Verification Program). The test procedure and/or a letter from RPC certifying the test results are available upon request and/or can be downloaded from the RPC Web site at www.rpc-rabrenco.com. Proper use procedures, including storage and handling, must be documented to ensure accurate test results.

LIMITATION

K100-0106 E-Z Chek® Sensitive Total Chlorine & Chloramines Test Strips will give a positive result with any substance which will oxidize the indicators in the strip directly or indirectly under neutral pH conditions. These substances, which should not be present in carbon-treated water, include, among others, hypochlorite, chlorine, monochloramine, nitrogen trichloride, iodine, and bromine. K100-0106 Test Strips are not suitable for testing chlorine in bicarbonate concentrates or dialysate.

AVAILABILITY

Product Code K100-0106 E-Z Chek® Sensitive Total Chlorine & Chloramines Test Strips is one bottle of 100 test strips and instructions for use (this package insert).

E-Z Chek® Residual Chlorine Test Strips are also available from RPC: **K100-0101B E-Z Chek® Residual Chlorine Test Strips (0.5 ppm)**.

REFERENCES

¹ Association for the Advancement of Medical Instrumentation, 2005 Dialysis Edition (ANSI / AAMI RD62: 2001)

Section 4.22, Table 1; published by the Association for the Advancement of Medical Instrumentation, Arlington, Virginia

² Dialysis Technology – A manual for dialysis technicians, Second Edition, page 109. National Association of Nephrology Technicians/technologists NANT), Dayton, OH, 2000.

⁴ “4500 -Cl G. DPD Colorimetric Method,” Standard Methods for the Examination of Water and Wastewater, 19th Edition (American Water Works Association, American Public Health Association, Water Environment Federation, Washington D.C., 1995), pp. 4-45 to 4-46.

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