

E-Z Chek[®] Sensitive Total Chlorine & Chloramines Test Strips



Instructions for Use

Indications for Use

E-Z Chek[®] Sensitive Total Chlorine & Chloramines Test Strips provide a quick, and convenient means for indicating low levels of total chlorine (chloramines/free chlorine) in feed water used to prepare dialysate. The test strips are also indicated for use in the determination of the concentration of residual chlorine (sodium hypochlorite commonly called chlorine bleach) detected in the water used to rinse dialysate lines following disinfection of hemodialysis equipment.

Test Procedure

Semi-Quantitative Procedure for Feed Water and Rinse Water Total Chlorine Testing

1. Verify the test strips have not expired.
2. Rinse standard sample cup provided with water to be tested. Re-fill with approximately 20ml of test water.
3. Remove a test strip from container and close container immediately after removing a strip. Do not touch test pad at the end of the strip.
4. Immerse indicator pad of test strip in sample water and vigorously move back and forth for 10 seconds. See Figure 1. (Approximately 30-35 back and forth strokes in 10 seconds.) The indicator pad must be perpendicular to the direction of the strip movement.
5. Remove strip from water, 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.

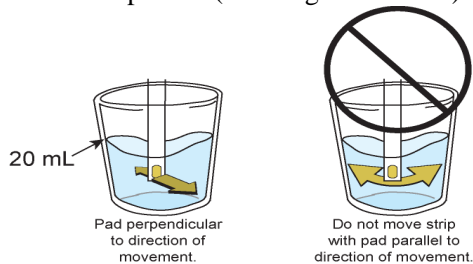


Figure 1

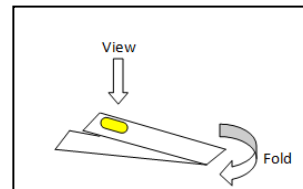


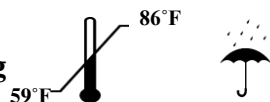
Figure 2

6. After the 30 second wait period, immediately compare the strip to the K100-0106 color chart to determine the Total Chlorine level in the sample.

IMPORTANT

This is a go/no-go test at the 0.1ppm level. Any green coloration in the aperture viewing window should be considered to be a failed test, i.e. greater than 0.1ppm total chlorine may be present. If the color of the indicator pad falls between two color blocks, the concentration may be determined by interpolation or estimation. For increased low end resolution (less than 0.1ppm), the K100-0118 Ultra-Low[™] Total Chlorine Test Strips may be used.

Storage and Handling



- Store at temperatures between 59°F - 86°F (15°C - 30°C).
- Do not use a test strip (from an opened or unopened bottle) after the expiration date.
- The lot number and expiration date are printed on the top of the cap.
- Do not allow the test strip to come in contact with liquids or work surfaces that may be contaminated with potentially interfering substances.
- Do not leave the test strips in areas exposed to chlorine vapors or other oxidizing vapors.
- Keep all unused test strips in the original bottle.
- Do not remove the desiccant pack.



REF

K100-0106

Warnings and Precautions

- Do not use these test strips to determine chlorine potency.
- Since chlorine at low levels is not stable during prolonged storage, begin the test procedure immediately after collecting sample.
- Chlorine is consumed during the reaction, always empty sample cup, obtain a fresh sample to repeat the procedure.

Limitations

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, bromine, chlorine, iodine, monochloramine, and nitrogen trichloride. The K100-0106 test strips are not suitable for testing chlorine in bicarbonate concentrates or dialysate.

Other Information

The AAMI (Association for the Advancement of Medical Instrumentation), lists the maximum allowable concentration of chloramines in feed water as 0.1ppm.⁽ⁱ⁾ In feed water, a result above 0.1ppm chloramines indicates that the water should not be used to prepare dialysate because of breakthrough, due to 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 levels⁽ⁱⁱ⁾.

For rinse water following disinfection of hemodialysis equipment, a maximum allowable result of 0.5ppm free chlorine or above indicates that further rinsing is needed.⁽ⁱ⁾ K100-0101B E-Z Chek® Residual Chlorine Test Strips (0.5ppm) are suitable for testing for the absence of chlorine in rinse water.

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/chloramines levels. Standards were verified using the ITS eXact™ Micro 7+ DPD-4 method. This method is comparable to the American Water Works Association (AWWA) method 4500 Cl-G.⁽ⁱⁱⁱ⁾

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.

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.

References

- ⁽ⁱ⁾ 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.
- ⁽ⁱⁱ⁾ Dialysis Technology – A manual for dialysis technicians, Second Edition, page 109. National Association of Nephrology Technicians/technologists NANT), Dayton, OH, 2000.
- ⁽ⁱⁱⁱ⁾ “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.



Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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