

Serim®

GUARDIAN™

HiSENSE ULTRA 0.1™

Test for Total Chlorine
(chloramines/free chlorine)
in feed or rinse water

DESCRIPTION

SERIM® GUARDIAN™ HiSENSE ULTRA 0.1™ Test Strips (Product Code 5167) provide a quick and convenient means for indicating low levels of total chlorine (chloramines/free chlorine) in feed water used to prepare dialysate. HiSENSE ULTRA 0.1 also provides a convenient means for indicating the concentration of residual chlorine (chlorine bleach) remaining in the water used to rinse dialysate lines following disinfection of hemodialysis equipment.

AAMI/ISO 23500:2011 has established a maximum allowable level for total chlorine of 0.1 mg/L. Removal of chloramine to a maximum level of 0.1 mg/l and removal of free chlorine to a maximum level of 0.5 mg/l are necessary to protect hemodialysis patients from red blood cell hemolysis. To permit a single test to be used, a maximum allowable level for total chlorine was set at the maximum allowable level for chloramine (0.1 mg/l).¹

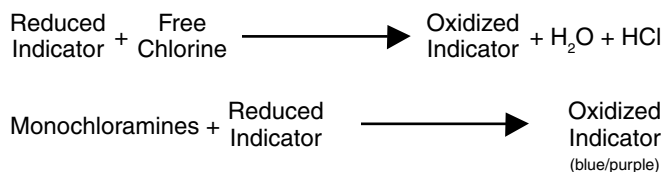
Using a 30-second semi-quantitative procedure, the strips will detect total chlorine concentrations between 0 and 3.0 ppm. The HiSENSE ULTRA 0.1 Test has color blocks at 0, 0.1, 0.5 and 3.0 ppm. In feed water, a result of 0.1 ppm total chlorine or above indicates that the water should not be used to prepare dialysate because of chloramine/free chlorine breakthrough or exhaustion of the carbon adsorption media in the water purification system.

For rinse water following disinfection of hemodialysis equipment, a 5-second qualitative procedure will detect 0.5 ppm free chlorine or above indicating further rinsing is needed.¹

The Association for the Advancement of Medical Instrumentation (AAMI) and National Association of Nephrology Technicians/Technologists (NANT) recommend that feed water samples be obtained after the first carbon tank to monitor chlorine/chloramine levels.^{2,3,4} It is also very important that the water system be in full operation for *at least 15 to 20 minutes* before the water is tested.⁴

CHEMICAL PRINCIPLES OF THE TEST

SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips semi-quantitatively measure both free chlorine and chloramines. The indicator pad contains two indicators. Free chlorine oxidizes one of the indicators (a colorless compound) to form pink/purple oxidation products. Monochloramines oxidize the second indicator to form a blue/purple complex.^{5,6,7}



WARNINGS AND PRECAUTIONS

- Do not use SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips to determine chlorine concentrations greater than 3 ppm.
- Keep all unused test strips in the original bottle.
- Replace cap immediately and tightly after removing a strip.
- Do not use a test strip (from an opened or unopened bottle) after the expiration date printed on the bottom 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.
- This is a **single use device**. After use discard the test strip according to federal, state and local regulations.

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

STORAGE

- All SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips must be kept 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).
- Lot number and expiration date are printed on the bottom of the bottle.

DIRECTIONS

Qualitative Procedure for Residual Chlorine in Rinse Water

When using the qualitative method, do not refer to the color blocks on the bottle label. If any pink/purple/gray color develops on the indicator pad, the residual chlorine concentration in the rinse water is ≥ 0.5 ppm.

1. Hold the indicator pad of the test strip in the rinse stream for 5 seconds.
2. Remove from stream and immediately examine the indicator pad for any pink/purple/gray color.
3. Record the results, then discard the test strip according to federal, state and local regulations.

Results:

PASS- If no color is immediately apparent, the residual chlorine concentration is below the AAMI standard of 0.5 ppm.

FAIL- Any pink, purple or gray color indicates that a residual chlorine concentration of 0.5 ppm or greater is present and additional rinsing is required.

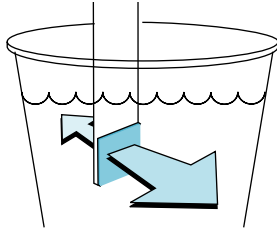
Semi-Quantitative Procedure for Total Chlorine in Feed or Rinse Water (chloramines or free chlorine)

An estimate of the total chlorine concentration between 0 and 3.0 ppm is obtained by comparing the color of the indicator pad to the color blocks on the bottle label.

1. Fill the enclosed sample cup with the water to be tested. Discard the contents and refill with ~20 ml of water.

2. Start the timer and immerse the indicator pad into the water sample. **Vigorously** swish test strip back and forth for a full 30 seconds. The indicator pad must be perpendicular to the direction of strip movement (Fig. 1).

Figure 1:



3. Remove the test strip and shake off excess water sample. Immediately compare color of the indicator pad to the color chart on the bottle label.
4. Record the results, then discard the test strip according to federal, state and local regulations.

Results:

Color blocks are designated at 0 ppm, 0.1 ppm, 0.5 ppm, and 3.0 ppm total chlorine. If the color of the indicator pad falls between two color blocks, concentrations may be determined by estimation.

If the total chlorine concentration is above the AAMI standard of 0.1 ppm, the water should not be used to prepare dialysate because of chloramine/free chlorine breakthrough or exhaustion of the carbon adsorption media in the water purification system.

Note:

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

QUALITY CONTROL

Implementing routine Quality Control procedures using positive and negative control solutions will increase user proficiency, minimize procedural errors and protect against inadvertent use of outdated product or product that has deteriorated due to improper storage or handling. Each facility should determine its own Quality Control program.

Serim Chlorine Control Pack (Product Code 5100QC) can be used to prepare a Positive Control Solution for the Serim HiSENSE ULTRA 0.1 (Product Code 5167).

PERFORMANCE CHARACTERISTICS

The performance characteristics of the SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips are based on analytical studies using samples yielding a range of chlorine/chloramine levels. Amperometric titration was used as the reference method for measuring these levels.⁸

Qualitative Procedure:

In blind studies based on 90 samples using 18 readers, concentrations of 0 and 0.5 ppm free chlorine gave 100% NEGATIVE and 100% POSITIVE results respectively.

Semi-Quantitative Procedure:

For free chlorine, in blind studies based on 150 samples using 30 readers, a concentration of 0 matched the 0 ppm color block 100 percent of the time and 0.5 ppm free chlorine matched the 0.5 ppm color block or greater 90 percent of the time.

For Chloramines, in blind studies based on 150 samples using 30 readers, concentrations of 0 and 0.1 ppm matched the 0

and 0.1 ppm color blocks respectively 100 percent of the time. Additional blind studies based on 95 samples using 19 readers, a concentration of 0.5 ppm chloramines matched the 0.5 ppm color block 100 percent of the time.

The sensitivity and accuracy of the test 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.

LIMITATIONS

SERIM GUARDIAN HiSENSE ULTRA 0.1 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, chloramines, iodine, and bromine.

Water samples containing ~0.7 ppm manganese will yield false positive results with SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips. At manganese concentrations of 0.05 ppm, an atypical faint pink color develops that does not match any of the color blocks.

SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips are not suitable for testing chlorine in bicarbonate concentrates or dialysate.

SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips may yield lower readings for monochloramines in feed water with total alkalinity concentrations above 250 ppm.

SERIM GUARDIAN HiSENSE ULTRA 0.1 Test Strips should not be used to test water with a pH ≥ 10 as falsely low results will be obtained.

REFERENCES

- ¹ Association for the Advancement of Medical Instrumentation, 2012 Dialysis Edition, ANSI/AAMI/ISO 23500:2011 (Revision of ANSI/AAMI RD52:2004/(R)2010 and related amendments A1 through A4), Annex B, page 38; published by the Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- ² Association for the Advancement of Medical Instrumentation, 2008 Dialysis Edition (ANSI/AAMI RD62: 2006) Section 4.2.9; published by the Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- ³ Dialysis Technology — A manual for dialysis technicians, Second Edition, page 109. National Association of Nephrology Technicians/Technologists (NANT), Dayton, OH, 2000.
- ⁴ *Monitoring Your Dialysis Water Treatment System*, pages 7-8, June 2005, Northwest Renal Network - CMS Contract #500-03-NW16
- ⁵ C. Sorber, W. Cooper and E Meier, "Selection for a Field Method for Free Available Chlorine in Disinfection," *Water and Wastewater*, J.D. Johnson, Ed. (Ann Arbor Publishers, Ann Arbor, MI, 1975), pp. 91–112.
- ⁶ R. Bauer, B.F. Phillips and C.O. Rupe, "A Simple Test for Estimating Free Chlorine," *Journal AWWA* (November 1972), pp. 787–789.
- ⁷ J. Lieberman, 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), pp. 1395–1400.
- ⁸ "Amperometric Titration Method," *Standard Methods for the Examination of Water and Wastewater*, 19th Edition (American Public Health Association, Washington D.C., 1995), pp. 4–41 to 4–43.



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